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

Deferiprone Oral Solution

General Notices

(Ph. Eur. monograph 2987)

Action and use

Chelating agent (iron).

Ph Eur

DEFINITION

Oral solution of *Deferiprone (2236)*, for human use.

It complies with the monograph Liquid preparations for oral use (0672) and the following additional requirements.

Content

95.0 per cent to 105.0 per cent of the content of deferiprone ($C_7H_9NO_2$) stated on the label.

IDENTIFICATION

A. Record the UV spectrum of the principal peak in the chromatograms obtained with the solutions used in the assay, with a diode array detector in the range 210-400 nm.

Results The UV spectrum of the principal peak in the chromatogram obtained with test solution (b) is similar to the UV spectrum of the principal peak in the chromatogram obtained with reference solution (c).

B. Examine the chromatograms obtained in the assay.

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

TESTS

Related substances

Liquid chromatography (*2.2.29*). *Use only colourless glassware. Protect the solutions from light.*

Buffer solution Dissolve 0.25 g of *sodium edetate R*, 4.3 g of *sodium octanesulfonate monohydrate R* and 13.8 g of *sodium dihydrogen phosphate monohydrate R* in *water for chromatography R*, and dilute to 1000 mL with the same solvent; adjust to pH 2.1 with *phosphoric acid R*.

Solvent mixture *methanol R*, buffer solution (20:80 *V/V*)

Test solution (a) To a volume of the preparation to be examined containing the equivalent of 100 mg of deferiprone, add the mobile phase and dilute to 100.0 mL with the mobile phase.

Test solution (b) Dilute 5.0 mL of test solution (a) to 50.0 mL with the solvent mixture.

Reference solution (a) Dilute 1.0 mL of test solution (b) to 100.0 mL with the mobile phase.

Reference solution (b) Dissolve 2 mg of *maltol R* (impurity B) in the mobile phase and dilute to 100 mL with the mobile phase. Mix 2.5 mL of the solution and 10 mL of test solution (a) and dilute to 100 mL with the mobile phase.

Reference solution (c) Dissolve 50.0 mg of *deferiprone CRS* in the solvent mixture and dilute to 100.0 mL with the solvent mixture. Dilute 10.0 mL of the solution to 50.0 mL with the solvent mixture.

Column:

— *size*: *l* = 0.15 m, Ø = 3.9 mm;

— *stationary phase*: *end-capped octadecylsilyl silica gel for chromatography R* (5 µm);

— *temperature*: 30 °C.

Mobile phase *methanol R*, buffer solution (13:87 *V/V*).

Flow rate 1.0 mL/min.

Detection Spectrophotometer at 280 nm.

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

Run time 4 times the retention time of deferiprone.

Identification of impurities Use the chromatogram obtained with reference solution (b) to identify the peak due to impurity B.

Relative retention With reference to deferiprone (retention time = about 11 min): impurity B = about 0.3.

System suitability Reference solution (b):

— *resolution*: minimum 5.0 between the peaks due to impurity B and deferiprone.

Calculation of percentage contents:

— for each impurity, use the concentration of deferiprone in reference solution (a).

Limits:

— *unspecified impurities*: for each impurity, maximum 0.10 per cent;

— *total*: maximum 0.3 per cent;

— *reporting threshold*: 0.05 per cent; disregard the peak due to impurity B.

ASSAY

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

Column:

— *size*: *l* = 0.15 m, Ø = 4.6 mm;

— *stationary phase*: *end-capped octadecylsilyl silica gel for chromatography R* (5 µm).

Mobile phase Solvent mixture.

Flow rate 1.1 mL/min.

Injection Test solution (b) and reference solution (c).

Run time 1.5 times the retention time of deferiprone.

Retention time Deferiprone = about 7 min.

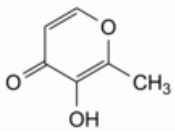
System suitability Reference solution (c):

— *repeatability*: maximum relative standard deviation of 1.5 per cent determined on 6 injections.

Calculate the percentage content of deferiprone ($C_7H_9NO_2$) taking into account the assigned content of *deferiprone CRS*.

IMPURITIES

Other detectable impurities (the following substances would, if present at a sufficient level, be detected by one or other of the tests in the monograph)*: B*.



B. 3-hydroxy-2-methyl-4*H*-pyran-4-one (maltol).

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