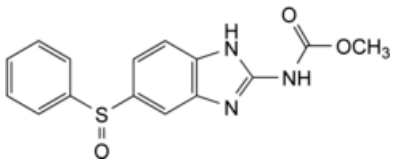
Edition: BP 2025 (Ph. Eur. 11.6 update)

Oxfendazole

General Notices

(Oxfendazole for Veterinary Use, Ph. Eur. monograph 1458)



$C_{15}H_{13}N_3O_3S$ 315.3 *53716-50-0*

Action and use

Antihelminthic.

Preparation

Oxfendazole Oral Suspension

Ph Eur

DEFINITION

Methyl [5-(phenylsulfinyl)-1*H*-benzimidazol-2-yl]carbamate.

Content

97.5 per cent to 100.5 per cent (dried substance).

CHARACTERS

Appearance

White or almost white powder.

Solubility

Practically insoluble in water, slightly soluble in ethanol (96 per cent) and in methylene chloride.

It shows polymorphism (*5.9*).

IDENTIFICATION

Infrared absorption spectrophotometry (2.2.24).

Comparison oxfendazole CRS.

If the spectra obtained in the solid state show differences, dissolve the substance to be examined and the reference substance separately in ethanol (96 per cent) R, evaporate to dryness and record new spectra using the residues.

TESTS

Related substances

Liquid chromatography (2.2.29).

Test solution Dissolve 25.0 mg of the substance to be examined in the mobile phase and dilute to 100.0 mL with the mobile phase.

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

Reference solution (b) In order to prepare impurity C *in situ*, add 0.25 mL of strong hydrogen peroxide solution R to 10 mL of the test solution, then dilute to 25 mL with the mobile phase.

Reference solution (c) Dissolve 5.0 mg of fenbendazole CRS (impurity A) in the mobile phase and dilute to 100.0 mL with the mobile phase. Dilute 1.0 mL of the solution to 20.0 mL with the mobile phase.

Reference solution (d) Dissolve 10.0 mg of oxfendazole impurity B CRS in the mobile phase and dilute to 100.0 mL with the mobile phase. Dilute 1.0 mL of the solution to 20.0 mL with the mobile phase.

Reference solution (e) Dissolve 5 mg of oxfendazole with impurity D CRS in the mobile phase and dilute to 20 mL with the mobile phase.

Column:

— *size*: *l* = 0.25 m, Ø = 4.6 mm;

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

Mobile phase Mix 36 volumes of acetonitrile R and 64 volumes of a 2 g/L solution of sodium pentanesulfonate R previously adjusted to pH 2.7 with a 2.8 per cent *V/V* solution of sulfuric acid R.

Flow rate 1 mL/min.

Detection Spectrophotometer at 254 nm.

Injection 20 µL.

Run time 6 times the retention time of oxfendazole.

Identification of impurities Use the chromatogram obtained with reference solution (c) to identify the peak due to impurity A; use the chromatogram obtained with reference solution (d) to identify the peak due to impurity B; use the chromatogram obtained with reference solution (b) to identify the peak due to impurity C; use the chromatogram supplied with oxfendazole with impurity D CRS and the chromatogram obtained with reference solution (e) to identify the peak due to impurity D.

Relative retention With reference to oxfendazole (retention time = about 7 min): impurity C = about 0.4; impurity B = about 1.9; impurity D = about 2.7; impurity A = about 5.4.

System suitability Reference solution (b):

— resolution: minimum 4.0 between the peaks due to impurity C and oxfendazole.

Limits:

— *impurity B*: not more than the area of the corresponding peak in the chromatogram obtained with reference solution (d) (2.0 per cent);

— *impurity A*: not more than the area of the corresponding peak in the chromatogram obtained with reference solution (c) (1.0 per cent);

— *impurities C, D*: for each impurity, not more than the area of the principal peak in the chromatogram obtained with reference solution (a) (1.0 per cent);

— *unspecified impurities*: not more than 0.2 times the area of the principal peak in the chromatogram obtained with reference solution (a) (0.20 per cent);

— *total*: maximum 3.0 per cent;

— *disregard limit*: 0.1 times the area of the principal peak in the chromatogram obtained with reference solution (a) (0.10 per cent).

Loss on drying (*2.2.32*)

Maximum 0.5 per cent, determined on 1.000 g by drying *in vacuo* at 105 °C for 2 h.

Sulfated ash (*2.4.14*)

Maximum 0.2 per cent, determined on 1.0 g.

ASSAY

Dissolve 0.250 g in 3 mL of *anhydrous formic acid R*. Add 40 mL of *anhydrous acetic acid R*. Titrate with *0.1 M perchloric acid*, determining the end-point potentiometrically (*2.2.20*).

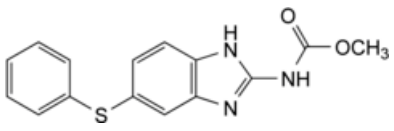
1 mL of *0.1 M perchloric acid* is equivalent to 31.53 mg of $C_{15}H_{13}N_3O_3S$.

STORAGE

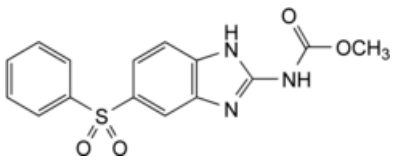
Protected from light.

IMPURITIES

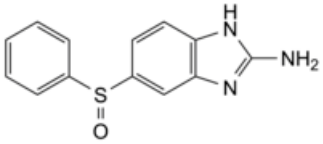
Specified impurities *A, B, C, D.*



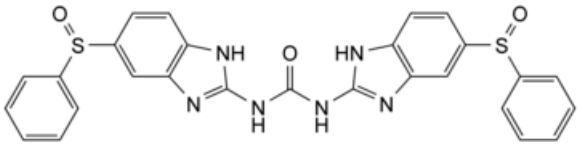
A. methyl [5-(phenylsulfanyl)-1*H*-benzimidazol-2-yl]carbamate (fenbendazole),



B. methyl [5-(phenylsulfonyl)-1*H*-benzimidazol-2-yl]carbamate,



C. 5-(phenylsulfinyl)-1*H*-benzimidazol-2-amine,



D. *N*,*N*′-bis[5-(phenylsulfinyl)-1*H*-benzimidazol-2-yl]urea.

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