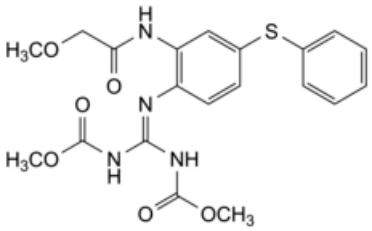
https://nhathuocngocanh.com/bp/

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

Febantel

General Notices

(Febantel for Veterinary Use, Ph. Eur. monograph 2176)



$C_{20}H_{22}N_4O_6S$ 446.5 *58306-30-2*

Action and use

Antihelminthic.

Ph Eur

DEFINITION

Dimethyl *N*,*N*′-[[[2-(methoxyacetamido)-4-(phenylsulfanyl)phenyl]imino]methylene]dicarbamate.

Content

97.5 per cent to 102.0 per cent (dried substance).

CHARACTERS

Appearance

White or almost white, crystalline powder.

Solubility

Practically insoluble in water, soluble in acetone, slightly soluble in anhydrous ethanol.

It shows polymorphism (5.9).

IDENTIFICATION

Infrared absorption spectrophotometry (2.2.24).

Comparison febantel CRS.

If the spectra obtained in the solid state show differences, dissolve the substance to be examined and the reference substance separately in acetone R, evaporate to dryness and record new spectra using the residues.

TESTS

Related substances

Liquid chromatography (2.2.29).

Solvent mixture acetonitrile R, tetrahydrofuran R (50:50 *V/V*).

Test solution (a) Dissolve 0.100 g of the substance to be examined in the solvent mixture and dilute to 10.0 mL with the solvent mixture.

Test solution (b) Dilute 5.0 mL of test solution (a) to 100.0 mL with the solvent mixture.

Reference solution (a) Dilute 1.0 mL of test solution (a) to 100.0 mL with the solvent mixture. Dilute 1.0 mL of this solution to 10.0 mL with the solvent mixture.

Reference solution (b) Dissolve 50.0 mg of febantel CRS in the solvent mixture and dilute to 10.0 mL with the solvent mixture. Dilute 5.0 mL of the solution to 50.0 mL with the solvent mixture.

Reference solution (c) Dissolve 5 mg of febantel for system suitability CRS (containing impurities A, B and C) in 1 mL of the solvent mixture.

Column:

— *size*: *l* = 0.15 m, Ø = 4.0 mm;

— *stationary phase*: spherical end-capped octadecylsilyl silica gel for chromatography R1 (5 µm).

Mobile phase Dissolve 6.8 g of potassium dihydrogen phosphate R in 1000 mL of water for chromatography R. Mix 350 mL of acetonitrile R with 650 mL of this solution.

Flow rate 1.0 mL/min.

Detection Spectrophotometer at 280 nm.

Injection 10 µL of test solution (a) and reference solutions (a) and (c).

Run time 1.5 times the retention time of febantel.

Identification of impurities Use the chromatogram supplied with febantel for system suitability CRS and the chromatogram obtained with reference solution (c) to identify the peaks due to impurities A, B and C.

Relative retention With reference to febantel (retention time = about 33 min): impurity A = about 0.16; impurity B = about 0.25; impurity C = about 0.34.

System suitability Reference solution (c):

— resolution: minimum 3.0 between the peaks due to impurities A and B; minimum 4.0 between the peaks due to impurities B and C.

Limits:

— *impurities A, B, C*: for each impurity, not more than the area of the principal peak in the chromatogram obtained with reference solution (a) (0.1 per cent);

— *unspecified impurities*: for each impurity, not more than twice the area of the principal peak in the chromatogram obtained with reference solution (a) (0.20 per cent);

— *total*: not more than 5 times the area of the principal peak in the chromatogram obtained with reference solution (a) (0.5 per cent);

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

Loss on drying (*2.2.32*)

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

Sulfated ash (*2.4.14*)

Maximum 0.1 per cent, determined on 1.0 g.

ASSAY

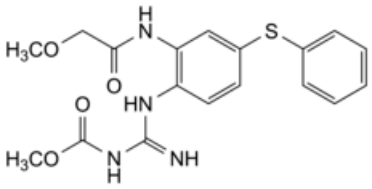
Liquid chromatography (*2.2.29*) as described in the test for related substances with the following modification.

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

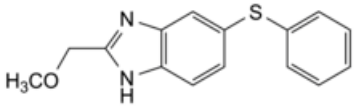
Calculate the percentage content of $C_{20}H_{22}N_4O_6S$ taking into account the assigned content of *febantel CRS*.

IMPURITIES

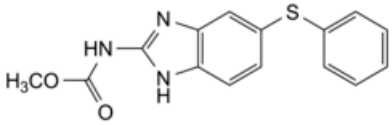
Specified impurities *A, B, C.*



A. methyl [*N*-[2-(methoxyacetamido)-4-(phenylsulfanyl)phenyl]carbamimidoyl]carbamate,



B. 2-(methoxymethyl)-5-(phenylsulfanyl)-1*H*-benzimidazole,



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