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

# Fenbendazole Oral Suspension

General Notices

**Action and use**

Antihelminthic.

## DEFINITION

Fenbendazole Oral Suspension is an aqueous suspension of Fenbendazole.

*The oral suspension complies with the requirements stated under Oral Liquids and with the following requirements.*

**Content of fenbendazole, $C_{15}H_{13}N_3O_2S$**

95.0 to 105.0% of the stated amount.

## IDENTIFICATION

In the Assay, the retention time of the principal peak in the chromatogram obtained with solution (1) is the same as that of the principal peak in the chromatogram obtained with solution (2).

## TESTS

**Related impurities A, B and 1**

Carry out the method for *liquid chromatography*, Appendix III D, using the following solutions.

(1) Mix with the aid of ultrasound, a quantity of the oral suspension containing 0.1 g of Fenbendazole with 50 mL of 0.1M *methanolic hydrochloric acid* for 30 minutes, cool, dilute to 100 mL with *methanol (65%)*, mix and filter through a glass-fibre filter (Whatman GF/C is suitable).
(2) Dilute 1 volume of a 0.001% w/v solution of *fenbendazole impurity A EPCRS* (methyl (1*H*-benzimidazol-2-yl)carbamate) in 0.1M *methanolic hydrochloric acid* to 2 volumes with *methanol (65%)*.
(3) Dilute 1 volume of a 0.001% w/v solution of *fenbendazole impurity B EPCRS* (methyl(5-chloro-1*H*-benzimidazol-2-yl)carbamate) in 0.1M *methanolic hydrochloric acid* to 2 volumes with *methanol (65%)*.
(4) Dilute 1 volume of a 0.001% w/v solution of *fenbendazole impurity 1 BPCRS* ((5-phenylthio)-2-aminobenzimidazole) in 0.1M *methanolic hydrochloric acid* to 2 volumes with *methanol (65%)*.
(5) Dilute 1 volume of a solution containing 0.002% w/v each of *fenbendazole impurity A EPCRS*, *fenbendazole impurity B EPCRS*, *fenbendazole impurity 1 BPCRS* and 0.20% w/v of *fenbendazole BPCRS* in 0.1M *methanolic hydrochloric acid* to 2 volumes with *methanol (65%)*.

CHROMATOGRAPHIC CONDITIONS

(a) Use a stainless steel column (25 cm × 4.6 mm) packed with *octadecylsilyl silica gel for chromatography* (5 µm) (Nucleosil C18 is suitable).
(b) Use isocratic elution and the mobile phase described below.

(c) Use a flow rate of 1 mL per minute.
(d) Use an ambient column temperature.
(e) Use a detection wavelength of 280 nm.
(f) Inject 20 µL of each solution.

MOBILE PHASE

350 volumes of a 0.5% w/v solution of *sodium dihydrogen orthophosphate* and 650 volumes of *methanol* containing 1.88 g of *sodium hexanesulfonate*, the pH of which has been adjusted to 3.5 with *orthophosphoric acid*.

SYSTEM SUITABILITY

The test is not valid unless the chromatogram obtained with solution (5) closely resembles the reference chromatogram supplied with *fenbendazole BPCRS*.

LIMITS

In the chromatogram obtained with solution (1):

the area of any peak corresponding to fenbendazole impurity A (methyl (1*H*-benzimidazol-2-yl)carbamate) is not greater than the area of the corresponding peak in the chromatogram obtained with solution (2), (0.5%);

the area of any peak corresponding to fenbendazole impurity B (methyl(5-chloro-1*H*-benzimidazol-2-yl)carbamate) is not greater than the area of the corresponding peak in the chromatogram obtained with solution (3) (0.5%);

the area of any peak corresponding to fenbendazole impurity 1 ((5-phenylthio)-2-aminobenzimidazole) is not greater than the area of the corresponding peak in the chromatogram obtained with solution (4) (0.5%).

## ASSAY

Carry out the method for *liquid chromatography*, Appendix III D, using the following solutions.

(1) Mix with the aid of ultrasound a quantity of the oral suspension containing 0.1 g of Fenbendazole with 50 mL of 0.1M *methanolic hydrochloric acid* for 30 minutes, cool, dilute to 100 mL with *methanol (65%)*, mix and filter through a glass-fibre filter (Whatman GF/C is suitable). Dilute 5 volumes of the resulting solution to 50 volumes with *0.1M hydrochloric acid* in *methanol (85%)*.
(2) 0.01% w/v of *fenbendazole BPCRS* in a mixture of 1 volume of *0.1M hydrochloric acid* and 1 volume of *methanol (85%)*.

CHROMATOGRAPHIC CONDITIONS

The chromatographic conditions described under Related substances may be used.

SYSTEM SUITABILITY

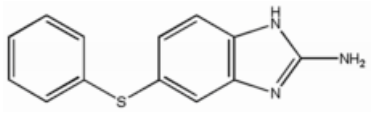
The test is not valid unless the chromatogram obtained with solution (5) closely resembles the reference chromatogram supplied with *fenbendazole BPCRS*.

DETERMINATION OF CONTENT

Calculate the content of $C_{15}H_{13}N_3O_2S$ in the oral suspension from the chromatogram obtained and using the declared content of $C_{15}H_{13}N_3O_2S$ in *fenbendazole BPCRS*.

## IMPURITIES

The impurities limited by the requirements of this monograph include impurities A and B listed under Fenbendazole and the following:




1. (5-phenylthio)-2-aminobenzimidazole.