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

Oxfendazole Oral Suspension

General Notices

Action and use

Antihelminthic.

DEFINITION

Oxfendazole Oral Suspension is an aqueous suspension of Oxfendazole.

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

Content of oxfendazole, $C_{15}H_{13}N_3O_3S$

90.0 to 110.0% of the stated amount.

IDENTIFICATION

Shake a quantity of the oral suspension containing 0.1 g of Oxfendazole with 50 mL of *methanol* for 15 minutes, centrifuge, evaporate the supernatant liquid to a volume of about 2 mL, cool and filter. Wash the residue with a little *water* and dry at 105° at a pressure not exceeding 2.7 kPa for 1 hour. The residue complies with the following tests.

A. The *infrared absorption spectrum*, Appendix II A, is concordant with the *reference spectrum* of oxfendazole *(RSV 32)*.
B. The *light absorption*, Appendix II B, in the range 220 to 350 nm of a 0.001% w/v solution in 1M *hydrochloric acid* exhibits three maxima, at 226, 284 and 291 nm.

TESTS

Acidity

pH, 4.3 to 5.3, Appendix V L.

Related substances

Carry out the method for *thin-layer chromatography*, Appendix III A, using *silica gel G* as the coating substance and a mixture of 5 volumes of *glacial acetic acid* and 95 volumes of *ethyl acetate* as the mobile phase. Apply separately to the plate 20 µL of each of the following solutions. For solution (1) shake a quantity of the oral suspension containing 0.1 g of Oxfendazole with 20 mL of a mixture of 4 volumes of *ethyl acetate* and 1 volume of *glacial acetic acid* and filter. For solution (2) dilute 1 volume of solution (1) to 50 volumes with the same solvent mixture. Solution (3) contains 0.005% w/v of *fenbendazole BPCRS*. After removal of the plate, allow it to dry in air and examine under *ultraviolet light (254 nm)*. Any spot in the chromatogram obtained with solution (1) corresponding to methyl 5-phenylthio-1*H*-benzimidazol-2-ylcarbamate is not more intense than the spot in the chromatogram obtained with solution (3) (1%) and any other *secondary spot* is not more intense than the spot in the chromatogram obtained with solution (2) (2%).

ASSAY

Disperse a quantity of the well-mixed oral suspension containing 0.1 g of Oxfendazole in 15 mL of *water*. Add 200 mL of *methanol* and mix with the aid of ultrasound for 15 minutes, cool, add sufficient *methanol* to produce 500 mL and filter. Dilute 4 mL of the filtrate to 100 mL with *methanol* and measure the *absorbance* of the resulting solution at the maximum at 296 nm, Appendix II B. Calculate the content of $C_{15}H_{13}N_3O_3S$ taking 550 as the value of A(1%, 1 cm) at the maximum at 296 nm.