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Albendazole Oral Suspension

General Notices

Action and use

Benzimidazole antihelminthic.

DEFINITION

Albendazole Oral Suspension is a suspension of Albendazole in a suitable vehicle.

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

Content of albendazole, $C_{12}H_{15}N_3O_2S$

90.0 to 110.0% of the stated amount.

IDENTIFICATION

A. To a volume of oral suspension containing 25 mg of Albendazole add 50 mL of 0.1M *sodium hydroxide* and shake with the aid of ultrasound for 10 minutes. Dilute to 100 mL with the same solvent, filter through a 0.45-µm filter and dilute 1 volume of this solution to 10 volumes with the same solvent. The *light absorption*, Appendix II B, in the range 240 to 340 nm of the resulting solution exhibits a maximum at 308 nm, a minimum at 281 nm and a shoulder at 269 nm.
B. To a volume of oral suspension containing 25 mg of Albendazole add 50 mL of 0.1M *hydrochloric acid* and shake with the aid of ultrasound for 10 minutes. Dilute to 100 mL with the same solvent, filter through a 0.45-µm filter and dilute 1 volume of this solution to 10 volumes with the same solvent. The *light absorption*, Appendix II B, in the range 240 to 340 nm of the resulting solution exhibits a maximum at 292 nm, a minimum at 273 nm and a shoulder at 261 nm.
C. In the Assay, the chromatogram obtained with solution (1) shows a peak with the same retention time as the principal peak in the chromatogram obtained with solution (2).

TESTS

Acidity

pH, 4.5 to 5.5, Appendix V L.

Related substances

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

Solvent A 30% of mobile phase A and 70% of mobile phase B.

(1) Dilute a quantity of the oral suspension with 1% v/v solution of *methanolic sulfuric acid* to give a solution containing 1.0% w/v of Albendazole and dilute 1 volume of the resulting solution to 2 volumes with solvent A.
(2) Dilute 1 volume of solution (1) to 100 volumes with solvent A.
(3) Dissolve 25.0 mg of *albendazole BPCRS* and 25.0 mg of *oxibendazole BPCRS* in 5 mL of 1% v/v solution of *methanolic sulfuric acid* and dilute to 50 mL with solvent A.

CHROMATOGRAPHIC CONDITIONS

(a) Use a stainless steel column (25 cm × 4.6 mm) packed with *end-capped octadecylsilyl silica gel for chromatography* (5 µm) (Waters Symmetry is suitable).
(b) Use gradient elution and the mobile phase described below.
(c) Use a flow rate of 0.7 mL per minute.
(d) Use an ambient column temperature.
(e) Use a detection wavelength of 292 nm.
(f) Inject 20 µL of each solution.

MOBILE PHASE

Mobile phase A *0.015M* *ammonium dihydrogen orthophosphate*.

Mobile phase B *methanol*.

Time (Minutes)	Mobile phase A (% v/v)	Mobile phase B (% v/v)	Comment
0-3	100	0	isocratic
3-5	100→30	0→70	linear gradient
5-70	30	70	isocratic
70-72	30→100	70→0	linear gradient
72-80	100	0	re-equilibration

SYSTEM SUITABILITY

The test is not valid unless, in the chromatogram obtained with solution (3), the *resolution factor* between the two principal peaks is at least 7.0.

LIMITS

In the chromatogram obtained with solution (1):

the area of any *secondary peak* is not greater than the area of the principal peak in the chromatogram obtained with solution (2) (1%);

the sum of the areas of any *secondary peaks* is not greater than twice the area of the principal peak in the chromatogram obtained with solution (2) (2%).

Disregard any peak with an area less than 0.05 times the area of the principal peak in the chromatogram obtained with solution (2) (0.05%).

ASSAY

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

(1) Add 70 mL of 1% v/v solution of *methanolic sulfuric acid* to a quantity of the oral suspension containing 0.10 g of Albendazole, stir for 15 minutes, mix with the aid of ultrasound for 10 minutes and add sufficient 1% v/v solution of *methanolic sulfuric acid* to produce 100 mL. Allow to stand and dilute 5 volumes of the clear supernatant to 25 volumes with 1% v/v solution of *methanolic sulfuric acid*.
(2) 0.020% w/v of *albendazole BPCRS* in 1% v/v solution of *methanolic sulfuric acid*.

CHROMATOGRAPHIC CONDITIONS

The chromatographic conditions described under Related substances may be used.

DETERMINATION OF CONTENT

Determine the *weight per mL* of the oral suspension, Appendix V G, and calculate the content of $C_{12}H_{15}N_3O_2S$, weight in volume, using the declared content of $C_{12}H_{15}N_3O_2S$ in *albendazole BPCRS*.