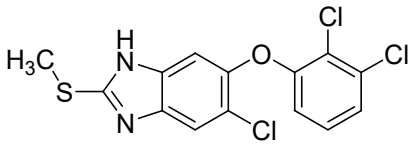
Triclabendazole



$C_{14}H_9Cl_3N_2OS$ Mol. Wt. 359.7

Triclabendazole is 5-Chloro-6-(2,3-dichlorophenoxy)-2-(methylsulfanyl)-1*H*-benzimidazole.

Triclabendazole contains not less than 99.0 per cent and not more than 101.0 per cent of $C_{14}H_9ClN_2OS$, calculated on the drided basis.

Category. Anthelmintic.

Description. A white or almost white, crystalline powder.

Identification

Determine by infrared absorption spectrophotometry (2.4.6). Compare the spectrum with that obtained with *triclabendazole IPRS* or with the reference spectrum of Triclabendazole.

Tests

Related substances. Determine by liquid chromatography (2.4.14).

Test solution. Dissolve 50 mg of the substance under examination in 10 ml of *acetonitrile* and dilute to 25.0 ml with the mobile phase.

Reference solution (a). A 0.0004 per cent w/v solution of *triclabendazole IPRS* in the mobile phase.

Reference solution (b). A solution containing 0.0003 per cent w/v each of, *triclabendazole impurty A IPRS*, *triclabendazole impurty B IPRS* and *triclabendazole impurty D IPRS*, in reference solution (a).

Chromatographic system
- a stainless steel column 25 cm × 4.6 mm, packed with base deactivated end-capped octadecylsilane bonded to porous silica (5 µm)
- mobile phase: a mixture of 40 volumes of a buffer solution prepared by dissolving 0.77 g of *ammonium acetate* in 800 ml of *water*, add 1 ml of *triethylamine*, adjusted to pH 4.5 with *glacial acetic acid* and dilute to 1000.0 ml with *water*, and 60 volumes of *acetonitrile*,
- flow rate: 1 ml per minute,
- spectrophotometer set at 305 nm,
- injection volume: 20 µl.

Name	Relative retention time	Correction factor
Triclabendazole impurty A1	0.6	1.9
Triclabendazole impurty B2	0.7	--
Triclabendazole (Retention time: about 10 minutes)	1.0	--
Triclabendazole impurty D3	1.9	2.7

[1]5-chloro-6-(2,3-dichlorophenoxy)-2-(methylsulfinyl)-1*H*-benzimidazole.
[2]5-chloro-6-(2,3-dichlorophenoxy)-1*H*-benzimidazole-2-thiol.
[3]4-chloro-5-(2,3-dichlorophenoxy)-2-nitroaniline.

Inject the reference solution (b) to identify the peakS due to triclabendazole impurty A, B and D.

Inject the reference solution (b). The test is not valid unless the resolution between the peaks due to triclabendazole impurty A and triclabendazole impurty B is not less than 2.5.

Inject reference solution (a) and the test solution. Run the chromatogram 2.5 times the retention time of the principal peak. In the chromatogram obtained with the test solution, the area of any peak corresponding to, triclabendazole impurty A and triclabendazole impurty D, each of, is not more than 1.5 times the area of the principal peak in the chromatogram obtained with reference solution (a) (0.3 per cent). The area of any other secondary peak is not more than the area of the principal peak in the chromatogram obtained with reference solution (a) (0.2 per cent) and the sum of the areas of all the secondary peaks is not more than 5 times the area of the principal peak in the chromatogram with reference solution (a) (1.0 per cent). Ignore any peak with an area less than 0.5 times the area of the principal peak in the chromatogram obtained with reference solution (a) (0.1 per cent).

Heavy metals (2.3.13). 1.0 g complies with limit test for heavy metals, Method B (20 ppm).

Sulphated ash (2.3.18). Not more than 0.1 per cent.

Loss on drying (2.4.19). Not more than 0.5 per cent, determined on 1.0 g by drying in an oven at 105° for 6 hours.

Assay. Dissolve 0.28 g of the substance under examination in 50 ml of *anhydrous acetic acid*. Allow to cool and titrate with *0.1 M perchloric acid*, determining the end-point potentiometrically (2.4.25). Carry out a blank titration.

1 ml of *0.1 M perchloric acid* is equivalent to 0.03597 g of $C_{14}H_9C_{l3}N_2OS$.

Storage. Store protected from light, at a temperature not exceeding 30°.

Solubility. Sparingly soluble in *ethanol (95 per cent),* soluble in *acetone,* practically insoluble in *water.*