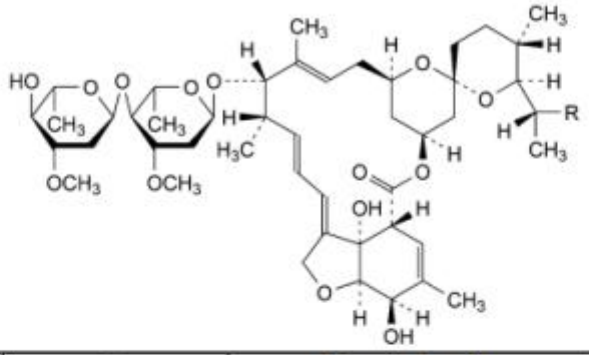
MSDS

IVERMECTIN

Ivermectinum



Component	R	Molecular formula	M_r
H_2B_{1a}	CH_2-CH_3	$C_{48}H_{74}O_{14}$	875
H_2B_{1b}	CH_3	$C_{47}H_{72}O_{14}$	861

Ivermectin B1a: [71827-03-7]
Ivermectin B1b: [70209-81-3]

DEFINITION

Mixture of (2aE,4E,5′S,6S,6′R,7S,8E,11R,13R,15S,17aR,20R,20aR,20bS)-7-[[2,6-dideoxy-4-O-(2,6-dideoxy-3-O-methyl-α-L-arabino-hexopyranosyl)-3-O-methyl-α-L-arabino-hexopyranosyl]oxy]-20,20b-dihydroxy-5′,6,8,19-tetramethyl-6′-[(1S)-1-methylpropyl]-3′,4′,5′,6,6′,7,10,11,14,15,17a,20,20a,20b-tetradecahydrospiro[11,15-methano-2H,13H,17H-furo[4,3,2-pq][2,6]benzodioxacyclooctadecene-13,2′-[2H]pyran]-17-one (or 5-O-demethyl-22,23-dihydroavermectin A_{1a}) (component H_2B_{1a}) and

(2aE,4E,5′S,6S,6′R,7S,8E,11R,13R,15S,17aR,20R,20aR,20bS)-7-[[2,6-dideoxy-4-O-(2,6-dideoxy-3-O-methyl-α-L-arabino-hexopyranosyl)-3-O-methyl-α-L-arabino-hexopyranosyl]oxy]-20,20b-dihydroxy-5′,6,8,19-tetramethyl-6′-(1-methylethyl)-3′,4′,5′,6,6′,7,10,11,14,15,17a,20,20a,20b-tetradecahydrospiro[11,15-methano-2H,13H,17H-furo[4,3,2-pq][2,6]benzodioxacyclooctadecene-13,2′-[2H]pyran]-17-one (or 5-O-demethyl-25-de(1-methylpropyl)-25-(1-methylethyl)-22,23-dihydroavermectin A_{1a}) (component H_2B_{1b}).

Semi-synthetic product derived from a fermentation product.

Content:

- ivermectin (H_2B_{1a} + H_2B_{1b}): 95.0 per cent to 102.0 per cent (anhydrous substance);
- ratio H_2B_{1a}/(H_2B_{1a} + H_2B_{1b}) (areas by liquid chromatography): minimum 90.0 per cent.

CHARACTERS

Appearance: white or yellowish-white, crystalline powder, slightly hygroscopic.

Solubility: practically insoluble in water, freely soluble in methylene chloride, soluble in ethanol (96 per cent).

IDENTIFICATION

A. Infrared absorption spectrophotometry (2.2.24).

Comparison: ivermectin CRS.

B. Examine the chromatograms obtained in the assay.

Results: the 2 principal peaks in the chromatogram obtained with the test solution are similar in retention time to the 2 principal peaks in the chromatogram obtained with reference solution (a).

TESTS

Appearance of solution. The solution is clear (2.2.1) and not more intensely coloured than reference solution BY_7 (2.2.2, Method II).

Dissolve 1.0 g in 50 mL of toluene R.

Specific optical rotation (2.2.7): − 20 to − 17 (anhydrous substance).

Dissolve 0.250 g in methanol R and dilute to 10.0 mL with the same solvent.

Related substances. Liquid chromatography (2.2.29).

Test solution. Dissolve 40.0 mg of the substance to be examined in methanol R and dilute to 50.0 mL with the same solvent.

Reference solution (a). Dissolve 40.0 mg of ivermectin CRS in methanol R and dilute to 50.0 mL with the same solvent.

Reference solution (b). Dilute 1.0 mL of reference solution (a) to 100.0 mL with methanol R.

Reference solution (c). Dilute 5.0 mL of reference solution (b) to 100.0 mL with methanol R.

Reference solution (d). Dilute 5.0 mL of reference solution (a) to 100.0 mL with methanol R.

Column:

- size: l = 0.25 m, Ø = 4.6 mm;
- stationary phase: octadecylsilyl silica gel for chromatography R (5 µm).

Mobile phase: water R, methanol R, acetonitrile R (15:34:51 V/V/V).

Flow rate: 1 mL/min.

Detection: spectrophotometer at 254 nm.

Injection: 20 µL.

System suitability:

- resolution: minimum 3.0 between the 1st peak (component H_2B_{1b}) and the 2nd peak (component H_2B_{1a}) in the chromatogram obtained with reference solution (a);
- signal-to-noise ratio: minimum 10 for the principal peak in the chromatogram obtained with reference solution (c);
- symmetry factor: maximum 2.5 for the principal peak in the chromatogram obtained with reference solution (a).

Limits:

- impurity with a relative retention of 1.3 to 1.5 with reference to the principal peak: not more than 2.5 times the area of the principal peak in the chromatogram obtained with reference solution (b) (2.5 per cent);
- any other impurity (apart from the 2 principal peaks): not more than the area of the principal peak in the chromatogram obtained with reference solution (b) (1 per cent);
- total: not more than 5 times the area of the principal peak in the chromatogram obtained