Ivermectin Tablets

Ivermectin Tablets contain not less than 90.0 per cent and not more than 110.0 per cent of the stated amount of sum of ivermectin components H_2B_{1a} ($C_{48}H_{74}O_{14}$) and H_2B_{1b} ($C_{47}H_{72}O_{14}$). This may contain a suitable antioxidant.

Usual strengths. 3 mg; 6 mg; 12 mg.

Identification

In the Assay, the retention times of the H_2B_{1a} and H_2B_{1b} peaks in the chromatogram obtained with the test solution corresponds to the peaks in the chromatogram obtained with reference solution (a).

Tests

Dissolution (2.5.2)**.**
Apparatus No. 1,
Medium. 900 ml of buffer solution, prepared by dissolving 5 g of *sodium dodecyl sulphate* in 900 ml of *water*, add 10 ml of *1 M monobasic sodium phosphate monohydrate*, adjusted to pH 7.0 with *sodium hydroxide solution*, and dilute to 1000 ml with *water.*
Speed and time. 50 rpm and 45 minutes.

Withdraw a suitable volume of the medium and filter.

Determine by liquid chromatography (2.4.14).

Test solution. Use the filtrate and, if necessary, dilute with the dissolution medium.

Reference solution. Dissolve a weighed quantity of *ivermectn RS* with the dissolution medium to obtain a solution of similar concentration as that expected for the test solution.

Chromatographic system
- a stainless steel column 10 cm x 4.6 mm, packed with octadecylsilane bonded to porous silica (5 µm),
- mobile phase: a mixture of 53 volumes of *acetonitrile*, 35 volumes of *methanol* and 12 volumes *water*,
- flow rate: 1.2 ml per minute,
- spectrophotometer set at 245 nm,
- injection volume:100 µl.

The relative retention times with reference to H_2B_{1b} is about 0.81 and for H_2B_{1a} is about 1.0.

Inject the reference solution. The test is not valid unless the resolution between H_2B_{1a} and H_2B_{1b} peaks is not less than1.5, the capacity factor for the H_2B_{1a} peak is not less than 4.0, column efficiency determine from both H_2B_{1a} and H_2B_{1b} peaks is not less than 1500 theoretical plates, the tailing factor for the H_2B_{1a} is not more than 2.0 and the relative standard deviation for replicate injections for the H_2B_{1a} is not more than 2.0 per cent.

Inject the reference solution and the test solution.

Calculate the combined content of H_2B_{1a} and H_2B_{1b} in the medium.

D. Not less than 80 per cent of the stated amount of sum of $C_{48}H_{74}O_{14}$ (H_2B_{1a}) and $C_{47}H_{72}O_{14}$ (H_2B_{1b}) in the medium.

Uniformity of content. Complies with the test stated under Tablets.

Determine by liquid chromatography (2.4.14), as described under Assay with the following modification.

Test solution. Disperse one tablet in 5 ml of *water* with the aid of ultrasound for 10 minutes. Add 15 ml of *methanol*, sonicate for 5 minutes and mix. Allow the solution cool to room temperature and dilute to 25.0 ml with *methanol.*

Reference solution. Dissolve a weighed quantity of *ivermectn RS* with *methanol* to obtain a solution of similar concentration as that expected for the test solution.

Inject the reference solution and the test solution.

Calculate the content of sum of $C_{48}H_{74}O_{14}$ (H_2B_{1a}) and $C_{47}H_{72}O_{14}$ (H_2B_{1b}) in the tablets.

Limit of 8a-oxo- H_2B_{1a}. Not more than 2 per cent.

Determine by liquid chromatography (2.4.14), as described under Assay with the following modification.

- spectrophotometer set at 280 nm,

Reference solution. A 0.000096 per cent w/v solution of *3-tert-Butyl-4-hydroxyanisole (BHA) RS* in *methanol*.

The relative retention times are about 0.24 for BHA, 0.77 for 8a-oxo- H_2B_{1a} and 1.0 for $H_2B_{1a.}$

Inject the reference solution and the test solution.

Calculate the content of 8a-oxo- H_2B_{1a} in the tablets.

$$\text{Correction factor(CF)} = \frac{0.90\ (\text{molecular weight of H2B1a}) + 0.10\ (\text{molecular weight of H2B1b})}{\text{molecular weight of 8a} - \text{oxo} - \text{H2B1a}}$$

$$\text{CF} = \frac{873.10}{889.10} = 0.98$$

Other tests. Comply with the tests stated under Tablets.

Assay. Determine by liquid chromatography (2.4.14).

Test solution. Weigh and powder 20 tablets. Disperse a quantity of the powder containing 60 mg of Ivermectin in 25 ml of *water,* with the aid of ultrasound for 10 minutes and dilute to 250.0 ml with *methanol*.

Reference solution (a). A 0.025 per cent w/v solution of *ivermectin RS* in *methanol.*

Reference solution (b). Dilute 1.0 ml of reference solution (a) to 100.0 ml with *methanol*. Dilute 1.0 ml of the solution to 5.0 ml with *methanol*

Chromatographic system
- a stainless steel column 25 cm x 4.6 mm, packed with octadecylsilane bonded to porous silica (5 µm),
- mobile phase: a mixture of 53 volumes of *acetonitrile*, 35 volumes of *methanol* and 12 volumes *water*,
- flow rate: 1.2 ml per minute,
- spectrophotometer set at 245 nm,
- injection volume:10 µl.

The relative retention times are about 0.82 for H_2B_{1b} and 1.0 for H_2B_{1a}.

Inject reference solution (a) and (b). The test is not valid unless the column efficiency for H_2B_{1a} is not less than 1500 theoretical plates, the capacity factor for H_2B_{1b} is not less than 3.0, the tailing factor for H_2B_{1a} is not more than 2.0 and relative standard deviation for the area response of total ivermectin (H_2B_{1a} and H_2B_{1b}) for replicate injections is not more than 2.0 per cent in reference solution (a) and the signal-to-noise ratio of the principal peak is not less than 10.0 in reference solution (b).

Inject reference solution (a) and the test solution, measure sum of the peak areas for content H_2B_{1a} and H_2B_{1b}.

Calculate sum of the content of H_2B_{1a} ($C_{48}H_{74}O_{14}$) and H_2B_{1b} ($C_{47}H_{72}O_{14}$) in the tablets.

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