Perampanel Tablets

Perampanel Tablets contain not less than 95.0 per cent and not more than 105.0 per cent of the stated amount of perampanel, $C_{23}H_{15}N_3O$.

Usual strengths. 2 mg; 4 mg; 6 mg; 8 mg; 10 mg; 12 mg.

Identification

In the Assay, the principal peak in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with reference solution (b).

Tests

Dissolution (2.5.2).
Apparatus No. 2 (Paddle),
Medium. 900 ml of *0.1 M hydrochloric acid*,
Speed and time. 50 rpm and 30 minutes.

Withdraw a suitable volume of the medium and filter. Measure the absorbance of the filtrate, dilute suitably if necessary with the medium, at the maximum at about 320 nm and at about 600 nm (2.4.7). Calculate the content of $C_{23}H_{15}N_3O$ in the medium from the difference in absorbance at 320 nm and at 600 nm, obtained from a solution of known concentration of *perampanel IPRS*, prepared by dissolving 22 mg of *perampanel IPRS* in 0.1 per cent w/v of *ammonium acetate* in a mixture of equal volumes of *water* and *acetonitrile* and dilute to 100.0 ml with the same solvent. Dilute 1.0 ml of the solution to 100.0 ml with the dissolution medium.

Q. Not less than 85 per cent of the stated amount of $C_{23}H_{15}N_3O$.

Related substances. Determine by liquid chromatography (2.4.14).

Solvent mixture. 0.1 per cent w/v of *ammonium acetate* in a mixture of equal volumes of *water* and *acetonitrile*.

Test solution. Disperse a quantity of powdered tablets containing 10 mg of Perampanel in the solvent mixture, with the aid of ultrasound and dilute to 50.0 ml with the solvent mixture. Centrifuge and use the clear supernatant.

Reference solution (a). A 0.05 per cent w/v solution of *perampanel IPRS* in the solvent mixture.

Reference solution (b). Dilute 10.0 ml of reference solution (a) to 25.0 ml with the solvent mixture.

Reference solution (c). Dilute 5.0 ml of reference solution (b) to 200.0 ml with the solvent mixture.

Reference solution (d). A 0.005 per cent w/v solution of *perampanel impurity B IPRS* (3-Bromo-1-phenyl-5-pyridin-2-yl-2(*1H)*-pyridone) in the solvent mixture. Transfer 1.0 ml of the solution to a 50-ml volumetric flask, add 10.0 ml of reference solution (a) and dilute to volume with the solvent mixture.

Chromatographic system
- a stainless steel column 7.5 cm × 4.6 mm, packed with octadecylsilane bonded to porous silica (3.5 µm) (Such as YMC-Pack Pro C18),
- column temperature: 35º,
- sampler temperature: 25°,
- mobile phase: A. 0.1 per cent w/v solution of *ammonium acetate* in a mixture of 90 volumes of *water* and 10 volumes of *acetonitrile*,
  B. 0.1 per cent w/v solution of *ammonium acetate* in a mixture of 10 volumes of *water* and 90 volumes of *acetonitrile*,
- flow rate: 1 ml per minute,
- a gradient programme using the conditions given below,
- spectrophotometer set at 290 nm,
- injection volume: 10 µl.

Time	Mobile phase A	Mobile phase B

(in min.)	(per cent v/v)	(per cent v/v)
0	60	40
10	60	40
15	0	100
15.01	60	40
20	60	40

Inject reference solution (d). The test is not valid unless the resolution between the peaks due to perampanel impurity B and perampanel is not less than 7 and the tailing factor is not more than 2.0 for perampanel peak.

Inject reference solution (c) and the test solution. In the chromatogram obtained with the test solution, the area of any secondary peak is not more than 0.08 times the area of the principal peak in the chromatogram obtained with reference solution (c) (0.2 per cent) and the sum of the areas of all the secondary peaks is not more than 0.4 times the area of the principal peak in the chromatogram obtained with reference solution (c) (1.0 per cent). Ignore any peak with an area less than 0.02 times the area of the principal peak in the chromatogram obtained with reference solution (c) (0.05 per cent).

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 an intact tablet in the solvent mixture with the aid of ultrasound and dilute to 50.0 ml with the solvent mixture. Centrifuge and use the clear supernatant liquid. Dilute further with the solvent mixture, if necessary.

Reference solution. A 0.004 per cent w/v solution of *perampanel IPRS* in the solvent mixture.

Inject the reference solution. The test is not valid unless the relative standard deviation for replicate injections is not more than 1.0 per cent in the chromatogram obtained with the reference solution.

Inject the reference solution and the test solution.

Calculate the content of $C_{23}H_{15}N_3O$ in the tablet.

Other tests. Comply with the tests stated under Tablets.

Microbial contamination (2.2.9). Total aerobic microbial count is not more than 1000 CFU/g and total combined molds and yeasts is not more than 100 CFU/g. 1 g is free from, each of, *Staphylococcus aureus, Pseudomonas aeruginosa and Escherichia coli.*

Assay. Determine by liquid chromatography (2.4.14), as described under Related substances.

Inject reference solution (b). The test is not valid unless relative standard deviation for replicate injections is not more than 1.0 per cent.

Inject reference solution (b) and the test solution.

Calculate the content of $C_{23}H_{15}N_3O$ in the tablets.

Storage. Store at a temperature not exceeding 30°.