Brivaracetam Tablets

Brivaracetam Tablets contains not less than 90.0 per cent and not more than 110.0 per cent of the stated amount of brivaracetam, $C_{11}H_{20}N_2O_2$.

Usual Strengths. 25 mg; 50 mg; 75 mg; 100 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 the reference solution.

Tests

Dissolution (2.5.2).
Apparatus No. 2 (paddle),
Medium. 900 ml of buffer solution prepared by dissolving 6.8 g of *potassium dihydrogen orthophosphate* and 0.5 g of *sodium hydroxide* in 1000 ml of *water*, adjusted to pH 6.4 with *1 M sodium hydroxide*,
Speed and time. 50 rpm and 30 minutes.

Withdraw a suitable volume of the medium and centrifuge at 4000 rpm for 10 minutes.

Determine by liquid chromatography (2.4.14).

Solvent mixture. 80 volumes of 0.1 per cent v/v solution of *orthophosphoric acid* in *water*, 10 volumes of *methanol* and 10 volumes of *acetonitrile*.

Test solution. Use the clear supernatant liquid, dilute if necessary with the dissolution medium.

Reference solution. A 0.1 per cent w/v solution of *brivaracetam IPRS* in the solvent mixture. Diluted 3.0 ml of the solution to 100.0 ml with the dissolution medium.

Chromatographic system
- a stainless steel column 15 cm x 4.6 mm, packed with octadecylsilane bonded to porous silica (5 µm) (Such as X Bridge C18),
- column temperature 35°,
- mobile phase: a mixture of 80 volumes of 0.1 per cent v/v solution of *orthophosphoric acid* with *water* and 20 volumes of a mixture of 90 volumes of *acetonitrile* and 10 volumes of *methanol*,
- flow rate: 1.5 ml per minute,
- spectrophotometer set at 210 nm,
- injection volume: 20 µl.

Inject the reference solution. The test is not valid unless the column efficiency is not less than 2000 theoretical plates, the tailing factor is not more than 2.0 and the relative standard deviation for replicate injections is not more than 2.0 per cent.

Inject the reference solution and the test solution.

Calculate the content of $C_{11}H_{20}N_2O_2$ in the medium.

D. Not less than 80 per cent of the stated amount of $C_{11}H_{20}N_2O_2$.

Related substances. Determine by liquid chromatography (2.4.14), as described under Dissolution with the following modifications.

Test solution. Disperse sufficient quantity of intact tablets containing 0.3 g of Brivaracetam in the solvent mixture, with the aid of ultrasound with intermediate shaking and dilute to 200.0 ml with the solvent mixture. Centrifuge at 4000 rpm for 15 minutes. Dilute 4.0 ml of supernatant liquid to 25.0 ml with the solvent mixture.

Reference solution. A 0.024 per cent w/v solution of *brivaracetam IPRS* in the solvent mixture.

Inject the reference solution .The test is not valid unless the column efficiency is not less than 2000 theoretical plates, the tailing factor is not more than 2.0 and the relative standard deviation for replicate injection is not more than 2.0 per cent.

Inject the test solution. The area of any secondary peak is not more than 0.5 per cent and the sum of area of all the secondary peaks is not more than 2.0 per cent, calculated by area normalization.

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

Inject the reference solution and the test solution.

Calculate the content of $C_{11}H_{20}N_2O_2$ in the tablets.

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

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