Brivaracetam Oral Solution

Brivaracetam Oral Solution is a solution of brivaracetam in a suitable aqueous vehicle.

Brivaracetam Oral Solution 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 strength.10mg per ml.

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

pH(2.4.24). 4.9 to 5.9.

Related substances.Determine by liquid chromatography (2.4.14).

Solution A. A 0.1 per cent v/v solution of *orthophosphoric acid* in *water*.

Test solution. Dissolve a quantity of the oral solution containing 24 mg of Brivaracetam in the mobile phase with the aid of ultrasound for 10 minutes with intermittent shaking and dilute to 100.0 ml with the mobile phase, filter.

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

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 C 18)
- column temperature: 35°,
- mobile phase: a mixture of 80 volumes ofsolution A, 18 volumes of *acetonitrile* and 2 volume of *methanol*,
- flow rate: 1.5ml 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 2,000 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 test solution. The area of any secondary peak is not more than 0.5 per cent and the sum of the areas of all the secondary peaks is not more than 2.0 per cent, calculated by area normalisation.

Other tests. Comply with the tests stated under Oral Liquids.

Microbial contamination (2.2.9).Total aerobic microbial count is not more than 100 CFU per mland total fungal count is not more than 10 CFU per g. 1 ml is free from *Escherichia coli.*

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

Inject the reference solution and the test solution.

Determine the weight per ml of the oral suspension (2.4.29) and calculate the content of $C_{11}H_{20}N_2O_2$ in the oral solution.

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