Brivaracetam Oral Solution

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Manufacturers, regulatory authorities, health authorities, researchers, and other stakeholders are invited to provide their feedback and comments on this draft proposal. Manufacturers are also invited to submit samples of their products to the IPC to ensure that the proposed monograph adequately controls the quality of the product(s) they manufacture. Comments and samples received after the last date will not be considered by the IPC before finalizing the monograph.

Please send any comments you may have on this draft document to lab.ipc@gov.in, with a copy to Dr. Gaurav Pratap Singh (email: gpsingh.ipc@gov.in) before the last date for comments.

Document History and Schedule for the Adoption Process

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Further follow-up action as required.	

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.10 mg 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 25 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). A 0.025 per cent w/v solution of *brivaracetam IPRS* in the mobile phase.

Reference solution (b). Dilute 1.0 ml of reference solution (a) to 100.0 ml with 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 of solution A, 18 volumes of *acetonitrile* and 2 volumes of *methanol*,
- flow rate: 1.5 ml per minute,
- spectrophotometer set at 210 nm,
- injection volume: 20 µl.

Inject reference solution (b). 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 reference solution (b) and the test solution. The area of any secondary peak is not more than 0.5 times the area of the principal peak in the chromatogram obtained with reference solution (b) (0.5 per cent) and the sum of the areas of all the secondary peaks is not more than twice the area of the principal peak in the chromatogram obtained with reference solution (b) (2.0 per cent).

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

Microbial contamination (2.2.9). Total aerobic microbial count is not more than 10^2 CFU per ml and total fungal count is not more than 10^3 CFU per g. 1 ml is free from *Escherichia coli.*

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

Inject reference solution (a) and the test solution.

Determine the weight per ml of the oral solution (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.