DEPARTMENT OF DRUG ADMINISTRATION
National Medicines Laboratory
ANALYTICAL METHOD VALIDATION COMMITTEE

Levetiracetam Dispersible Tablets

Analytical profile no.: Leveti 077/078/AP 091

Levetiracetam Dispersible Tablets contains not less than 95.0% and not more than 105.0% of the stated amount of Levetiracetam.

Usual Strength: Levetiracetam DT 250mg, 500mg

1. Identification:

In the Assay, the principle peak in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with the reference solution.

Tests:

2. Dissolution: *Deteremine by liquid chromatography*

2.1 Dissolution Parameters:

Apparatus: Paddle

Medium: 900ml of purified water

Speed and Time: 50 rpm and 30 minutes

Withdraw a suitable volume of the medium and filter.

Determine by liquid chromatography.

2.2 Test Solution: Dilute the filtrate, if necessary, with dissolution medium.

2.3 Reference Solution: Weigh accurately about 22.2 mg of Levetiracetam WS in 100 ml volumetric flask. Dissolve in 70ml of dissolution medium and make up the volume to 100 ml with dissolution medium. Further dilute 5 ml of this solution to 20 ml with dissolution medium.

2.4 Procedure: Use the chromatographic system as described in the Assay.

Inject the reference solution and the test solution.

2.5 Limit: Not less than 80 percent (D) of the stated amount of Levetiracetam.

3. Assay: *Determine by liquid chromatography*

3.1 Test Solution: Weigh individually 20 tablets & crush the tablet into fine powder. Weigh a quantity of powder equivalent to 300 mg of Levetiracetam in 250 ml volumetric flask, add about 200 ml of mobile phase and sonicate to dissolve, cool to room temperature and make up the volume

to 250 ml with same solvent. Centrifuge and dilute 4 ml of supernatant solution to 50 ml with mobile phase.

3.2 Reference Solution: Weigh accurately about 24 mg of Levetiracetam WS in 250ml volumetric flask, add about 200 ml of mobile phase and sonicate to dissolve. Cool and make up the volume to 250 ml with same solvent.

3.3 Chromatographic system:

- **Column:** C18 100 A°, 15 cm x 4.6 mm, 5µm particle size (Make: Phenomenex or equivalent)
- **Flow rate:** 2.0 ml/min
- **Wavelength:** 210 nm
- **Injection volume:** 20 µl
- **Detector:** UV/PDA
- **Column temperature:** 45 °C
- **Mobile Phase:** A mixture of 95 volumes of buffer solution pH 2.8 and 5 volumes of Acetonitrile
- **Buffer solution pH 2.8:** Dissolve 6.8 g of Monobasic Potassium phosphate and 0.85 g of Sodium 1-heptane sulfonate in 1000ml of water and mix. Adjust pH to 2.8 with dilute Orthophosphoric acid.

3.4 Procedure: Inject the reference solution five/six times and sample solutions. The test is not valid unless the column efficiency is not less than 2000 theoretical plates, tailing factor is not more than 2.0 and the relative standard deviation for replicate injections is not more than 2.0%. Measure the peak responses. Calculate the content of Levetiracetam in the tablet.

4. Other tests: As per pharmacopoeial requirement.