Government of Nepal
Ministry of Health and Population
Department of Drug Administration
National Medicines Laboratory
Quality and Method Validation Section

Analytical profile of Clobazam Mouth Dissolving Tablet

Analytical Profile No.: CLOB 075/076/AP041

Clobazam Mouth Dissolving Tablet contains not less than 90.0% and not more than 110.0% of the stated amount of Clobazam.

1. Identification:

In the assay, the principle peak in the chromatogram obtained with the sample solution should correspond to the peak in the chromatogram obtained with the reference solution.

2. Dissolution

2.1 Dissolution Parameters

Apparatus: Paddle

Medium: 900ml of 0.1M Hydrochloric Acid

Speed and Time: 75 rpm and 30 minutes

Withdraw a suitable volume of the medium and filter

2.2 Test Solution: Dilute 10 ml of the filtrate to 20ml with dissolution medium.

2.3 Standard Preparation: Weigh accurately about 55.5 mg of Clobazam WS into 100 ml volumetric flask. Add 45ml of Acetonitrile, sonicate to dissolve it then make up the volume with water. Dilute 1ml of resulting solution to 100ml with dissolution medium to obtain 0.00555mg/ml concentration solution.

2.4 Procedure: Use the chromatographic system as described in the Assay. Inject the reference solution and the test solution.

Calculate the percent release of Clobazam.

2.5 Limit: Not less than 80% (D) of the stated amount

3. Uniformity of Content

Determine by liquid chromatography, as described in the Assay, using the following test solution.

Test Solution: Weigh 10 tablets individually and place one tablet individually in 100 ml volumetric flask. Add 70 ml of mobile phase & sonicate for 15 minutes to dissolve, cool to room temperature & make up the volume with same solvent. Dilute 10 ml of resulting solution to 20ml with mobile phase to obtain 0.05mg/ml concentration solution.

4. Assay

4.1 Test Solution: Weigh individually 20 tablets & crush the tablet into fine powder. Weigh accurately the powder eq. to 5 mg of Clobazam into 100 ml volumetric flask, add 70 ml of mobile phase & sonicate for 15 minutes to dissolve, cool to room temperature & make up the volume with same solvent.

4.2 Reference Solution: Weigh accurately about 50 mg of Clobazam WS into 100 ml volumetric flask. Dissolve with 70ml of mobile phase and make up the volume up to the mark with same solvent. Dilute 2ml of resulting solution to 20ml with mobile phase to obtain 0.05mg/ml concentration solution.

4.3 Chromatographic Condition:

Column: C18 (15 cm X 4.6 mm), 5µm
Flow rate: 1.0 ml/min
Wavelength: UV 230 nm
Injection volume: 20 µl
Column Oven Temperature: 35˚ C
Mobile Phase: A mixture of 45 volume of Acetonitrile & 55 volume of Water

4.4 Procedure: Inject the reference solution five/six times and test 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 in not more than 2.0%. Measure the peak response. Calculate the content of Clobazam.

5. Other tests: As per pharmacopoeial requirements.