Clobazam Mouth Dissolving Tablet

Analytical Profile No.: CLOB 075/076/AP041

Clobazam Mouth Dissolving Tablet contains not less than 90 % and not more than 110 % Clobazam of stated amount.

1. **Identification:** The retention time of the major peak in the chromatogram of test solution corresponds to that of the reference solution as obtained in assay.

Tests:

2. Dissolution: *Determine by Liquid chromatography.*

2.1 Dissolution Parameters:

Apparatus:	Paddle
Medium:	900 ml of 0.1 M HCl
Speed and Time:	75 rpm for 30 minutes
Temperature:	37 ± 0.5 ^{0}C

Withdraw a suitable volume of the medium and filter.

2.2 Test Solution: Dilute 10 ml of the filtrate to 20 ml with dissolution medium. Filter it through 0.2 micron membrane filter.

2.3 Reference Solution: Weigh accurately about 55.5 mg of Clobazam reference standard into 100 ml volumetric flask. Add 45 ml of Acetonitrile, sonicate to dissolve it then make up the volume with water. Dilute 1 ml of resulting solution to 100 ml with dissolution medium to obtain 0.00555 mg/ml concentration solution. Filter it through 0.2 micron membrane filter.

2.4 Chromatographic Condition and Procedure: Proceed as directed under assay, calculate the percent release of Clobazam in each tablet.

2.5 Limit: NLT 80 % (D) of the stated amount.

3. Uniformity of Content:

3.1 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. After sonication, dilute to 100 ml with same solvent. Dilute 10 ml of resulting solution to 20 ml with mobile phase to obtain 0.05 mg/ml concentration solution. Filter it through 0.2 micron membrane filter.

3.2 Reference Solution: Same as Assay

3.3 Chromatographic Condition and Procedure: Proceed as described in Assay.

Calculate the content of Clobazam in each tablet.

3.4 Limit: 85 – 115 % of stated amount

4. Assay: *Determine by liquid chromatography*

4.1 Test Solution: Weigh individually 20 tablets & crush them into fine powder. Weigh accurately the powder equivalent to 5 mg of Clobazam into 100 ml volumetric flask, add 70 ml of mobile phase & sonicate for 15 minutes to dissolve. After sonication, dilute to 100 ml with same solvent. Filter the solution through 0.2 µm membrane filter.

4.2 Reference Solution: Weigh accurately about 50 mg of Clobazam reference standard into 100 ml volumetric flask. Dissolve with 70 ml of mobile phase and make up the volume up to the mark with same solvent. Dilute 2 ml of resulting solution to 20 ml with mobile phase to obtain 0.05 mg/ml concentration solution. Filter it through 0.2 micron membrane filter.

4.3 Chromatographic Condition:

Column:	C18 (15 cm X 4.6 mm), 5µm
Flow rate:	1.0 ml/min

Injection volume:	20 µl
Wavelength:	230 nm
Detector:	UV
Column Temperature:	35˚ C
Mobile Phase:	Acetonitrile : Water (45:55)

4.4 Procedure: Inject the reference solution five times as per the above mentioned chromatographic condition. 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 %. Calculate the content of Clobazam per tablet.

5. Other tests: As per pharmacopoieal requirement.