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

Dienogest Tablets

Analytical Profile No.: Dieno 079/080/AP 128

Dienogest Tablets contains not less than 90.0% and not more than 110.0% of the stated amount of Dienogest.

Usual Strength: 2 mg

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.

2. Dissolution: *Deteremine by liquid chromatography*

2.1 Dissolution Parameters:

Apparatus: Paddle

Medium: 500ml of 0.3% Sodium Lauryl Sulphate

Speed and Time: 100 rpm and 30 minutes

Withdraw a suitable volume of the medium and filter.

2.2 Test Solution: Use the filtrate.

2.3 Reference Solution: Weigh accurately and transfer about 40 mg of Dienogest WS to a 100 ml volumetric flask, add about 70 ml of mobile phase, sonicate to dissolve, cool to room temperature and make up the volume with same solvent. Further dilute 1 ml of the solution to 100 ml with dissolution media.

2.4 Procedure: Use the chromatographic system as described in the Assay using 50 µl as injection volume. Inject the reference solution and the test solution.

Calculate the percent release of Dienogest.

2.5 Limit: Not less than 75 percent (D) of the stated amount of Dienogest.

3. Uniformity of Content

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

Test Solution: Disperse one tablet in 10 ml mobile phase.

4. Assay: *Determine by liquid chromatography*

4.1 Test solution: Weigh and powder 20 tablets. Weigh about 500 mg of the sample into 50 ml volumetric flask, add 25 ml of mobile phase, sonicate to dissolve. Cool to room temperature and make up volume with same solvent.

4.2 Reference solution: Transfer an accurately weighed quantity about 40 mg of Dienogest WS into a 100 ml volumetric flask. Add about 70 ml of mobile phase, sonicate to dissolve, cool to room temperature and make up volume with same solvent. Dilute 5 ml of resulting solution to 10 ml with same solvent and mix.

4.3 Chromatographic system:

Column: C18 (4.6mmX 150mm, 5µ)

Flow rate: 1.0 ml/min

Wavelength: 300 nm

Injection volume: 10µl

Column Temperature: 30ºC

Mobile Phase: A mixture of 40 volume of acetonitrile and 60 volume of water.

4.4 Procedure: Inject the reference solution five 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 Estradiol Valerate in Estradiol Valerate Tablets.

5. Other tests: As per pharmacopoeial requirements.