DEPARTMENT OF DRUG ADMINISTRATION
National Medicines Laboratory
ANALYTICAL METHOD VALIDATION COMMITTEE

Desvenlafaxine Extended Release Tablets

Analytical Profile No.: Desven 078/079/AP 108

Desvenlafaxine Extended Release Tablets contains not less than 90.0% and not more than 110.0% of the stated amount of Desvenlafaxine.

Usual Strength: 50 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.

Tests:

2. Dissolution:

2.1 Dissolution Parameters:

Apparatus: Basket

Medium: 900ml of 0.9% Sodium Chloride

Speed and Time: 100 rpm and 1, 6 &12 hours

[0.9% Sodium Chloride: Dissolve 54 g of sodium chloride in 6000 ml of water]

Withdraw a suitable volume of sample after 1 hr, 6 hrs & 16 hrs consecutively by replacing the volume after each withdrawal with the same dissolution medium maintained at same temperature and filter.

2.2 Test Solution: Use the filtrate.

2.3 Reference Solution: Weigh accurately about 40 mg of Desvenlafaxine Succinate WS in 100 ml volumetric flask and add about 70 ml dissolution medium and sonicate for about 10 min and make volume to 100 ml with dissolution medium. Dilute 5 ml of the solution to 25 ml with dissolution medium.

2.4 Procedure: Use the chromatographic system as described in the Assay. Inject the reference solution and the test solution. Measure the peak responses and calculate the % release of the drug.

2.5 Limit:

In 1st hour - NMT 30%

In 6th hour – NLT 55% & NMT 85 %

In 12th hour – NLT 80 % of the stated amount

3. Assay: *Determine by liquid chromatography*

3.1 Test Solution: Weigh and powder 20 tablets. Weigh a quantity of powder equivalent to 50 mg of Desvenlafaxine into 50 ml volumetric flask, add about 30 ml of methanol, sonicate, cool and make volume to 50 ml with same solvent. Centrifuge the solution at 2000 rpm for 10 minutes. Dilute 5 ml of this solution to 50 ml with methanol.

3.2 Reference Solution: Weigh accurately about 35 mg of Desvenlafaxine Succinate WS in 50 ml volumetric flask. Add about 30 ml of methanol, sonicate to dissolve, cool and make volume to 50 ml with same solvent. Further dilute 5 ml of this solution to 25ml with same solvent.

3.3 Chromatographic system:

- **Column:** C18, (150 x 4.6 mm), 5 µ particle size
- **Flow rate:** 0.6 ml/min
- **Wavelength:** 222 nm
- **Column Oven Temperature:** 40 ºC
- **Injection volume:** 10 µl
- **Detector:** UV
- **Mobile Phase:** A mixture of 50 volumes of buffer solution prepared by dissolving 1.54 g of ammonium acetate in 1000ml of water, 30 volumes of methanol & 20 volumes of acetonitrile

3.4 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 Desvenlafaxine in the tablets.

4. Other tests: As per pharmacopoeial requirements.