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

Analytical profile of Metronidazole & Diloxanide Furoate Tablets

Analytical Profile No.: Metr Dilo 075/076/ AP 013

Metronidazole & Diloxanide Furoate Tablets contain not less than 90.0% and not more than 110.0% of the stated amount of Metronidazole & Diloxanide Furoate.

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 (Metronidazole):

2.1 Dissolution Parameters:

Apparatus: Paddle

Medium: 900ml of 0.1 N HCl

Speed and Time: 100 rpm and 60 minutes

Withdraw a suitable volume of the medium and filter.

2.2 Test Solution: Dilute 5 ml of the filtrate to 50 ml with mobile phase.

2.3 Standard solution: Weigh accurately about 44.4 mg of Metronidazole RS and transfer into 100 ml volumetric flask. Dissolve with dissolution medium and make up the volume to 100 ml with dissolution medium. Dilute 5 ml of the resulting solution to 50 ml with mobile phase.

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 Metronidazole.

2.5 Limit: Not less than 80 % D of the stated amount of metronidazole.

3. Assay:

3.1 Test Solution: Weigh 20 tablets individually and powder the tablet. Weigh accurately the powdered sample equivalent to 100 mg of the metronidazole and transfer into 100 ml volumetric flask. Add about 70 ml of the mobile phase, sonicate for 15 minutes, cool to room temperature and make up the volume to 100 ml with mobile phase. Filter and dilute 5 ml of the resulting solution to 50 ml with mobile phase.

3.2 Reference Solution: Weigh accurately about 100 mg of Metronidazole RS and 125 mg of Diloxanide furoate RS and transfer into 100 ml volumetric flask. Add about 70 ml of mobile phase, sonicate for 15 minutes, cool to room temperature and make up the volume to 100 ml with mobile phase. Dilute 5 ml of the resulting solution to 50 ml with mobile phase.

3.3 Chromatographic system

Column: Octyldecylsilane (C18), (250 x 4.6 mm), 5 µm

Flow rate: 1.0 ml/min

Detector: UV Detector

Wavelength: 241 nm

Injection volume: 20 µl

Oven temperature: 30 °C

Mobile phase: 20 volume of Acetonitrile, 50 volume of Methanol and 30 volume of phosphate buffer pH 5.5

Phosphate buffer pH 5.5: Dissolve 1.625 g of KH_2PO_4 and 0.300 g of K2HPO4 in 550 ml water

3.4 Procedure: Inject the reference solution five 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 is not more than 2.0%. Measure the peak responses. Calculate the content of Metronidazole & Diloxanide Furoate.

4. Other tests: As per pharmacopoeial requirements.