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

Analytical profile of Ornidazole Tablets

Analytical Profile No.: ORNI 075/076/AP046

Ornidazole Tablets contain not less than 95.0% and not more than 105.0% of the stated amount of Ornidazole.

1. Identification:

In the Assay, the principal peak in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with the reference solution.

2. Dissolution:

2.1 Dissolution Parameters:

Apparatus: Paddle
Medium: 900 ml of 0.1M hydrochloric acid
Speed & Time: 75**rpm &** 30 **minutes**

Withdraw a suitable volume of the medium and filter.

2.2 Test Solution: Dilute 2 ml of the filtrate to 50 ml with dissolution medium.

2.3 Reference Solution: Weigh accurately about 55.5 mg Ornidazole WS in 100 ml volumetric flask. Add 70 ml dissolution medium, sonicate to dissolve and make up the volume to 100 ml with same solvent. Further dilute 2 ml of this solution to 50 ml with same solvent.

2.4 Procedure: Measure the absorbance of both standard and sample solution at about 277 nm taking dissolution medium as blank. Calculate the % release of Ornidazole.

2.5 Limit: NLT 80 per cent (D) of the stated amount

3. Assay:

3.1 Test Solution: Weigh individually 20 tablets & crush the tablet into fine powder. Weigh a quantity of powder equivalent to 50 mg of Ornidazole in 100 ml volumetric flask, add 70 ml of methanol, sonicate for 10 minutes to dissolve and make volume to 100 ml with same solvent. Dilute 5 ml of this solution to 50 ml with mobile phase.

3.2 Standard Solution: Weigh accurately about 50 mg Ornidazole WS in 100 ml volumetric flask. Add about 70 ml of methanol and sonicate for about 10 minutes to dissolve and make up the volume to 100 ml with same solvent. Dilute 5 ml of this solution to 50 ml with mobile phase.

3.3 Chromatographic system:

Column: Octadecylsilane (C18), (250*4.6 mm), 5 µm

Flow rate: 1.0 ml/min

Wavelength: 318 nm

Injection volume: 20 µl

Mobile Phase: A mixture of 60 volume of Buffer & 40 volume of Methanol

Buffer: Weigh 0.55gm of Potassium Dihydrogen Orthophosphate (KH_2PO_4) in 600ml of HPLC water. Dissolve by stirring.

3.4 Procedure: Inject the reference solution five/six 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 Ornidazole in Ornidazole Tablets.

4. Other tests: As per pharmacopoeial requirements.