ANALYTICAL METHOD VALIDATION COMMITTEE FOR NON PHARMACOPOEIAL PRODUCT
DEPARTMENT OF DRUG ADMINISTRATION
National Medicines Laboratory

Ornidazole Tablets

Analytical Profile No.: ORNI 075/076/AP046

Ornidazole Tablets contain not less than 95 percent and not more than 105 percent of the stated amount of Ornidazole.

1. Identification:

In the assay, the principle peak in the chromatogram obtained with the sample solution should correspond to the peak in the chromatogram obtained with the reference standard solution of Ornidazole.

Tests:

2. Dissolution: Determine by UV Spectroscopy

2.1 Dissolution Parameters:

Apparatus: Paddle
Medium: 900 ml of 0.1M hydrochloric acid
Speed and time: 75 rpm and 30 minutes

Withdraw the suitable volume of the medium and filter.

2.2 Test Solution*:*

Dilute 2 ml of this solution to 50 ml with dissolution medium. Filter the solution through 0.2 µm membrane filter.

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. Filter the final solution through 0.2 µm membrane filter.

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.

2.6 Limit:

D. Not less than 80 per cent of the stated amount of Ornidazole.

3. Assay: Determine by Liquid Chromatography

3.1 Buffer: Weigh 0.55 g of potassium dihydrogen phosphate (KH_2PO_4) in 400 ml of HPLC grade water. Dissolve by stirring.

3.2 Test solution:

Weigh individually 20 tablets and 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. Filter the final solution through 0.2 µm membrane filter.

3.3 Reference 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. Filter the solution through 0.2 µm membrane filter.

3.4 Chromatographic system:

Column: C18, 25 cm x 4.6 mm, 5 µm
Injection volume: 20 µl
Flow rate: 1.0 ml per minute Wavelength: 318nm
Detector: UV
Mobile phase: a mixture of 60 volumes of buffer and 40 volumes of methanol

3.5 Procedure:

Inject the reference solution. The test is not valid unless the column efficiency is not less than 2000 theoretical plates, the tailing factor is not more than 2.0 and the relative standard deviation for replicate injections is not more than 2.0 per cent.Inject the reference solution and the test solution.

Calculate % release of ornidazole.

4. Other tests:

As per pharmacopoeial requirements.