

DEPARTMENT OF DRUG ADMINISTRATION
National Medicines Laboratory
ANALYTICAL METHOD VALIDATION COMMITTEE

Nimesulide Tablets

Analytical Profile No.: NIMES 075/076/AP051

Nimesulide Tablets contain not less than 90 % and not more than 110 % of the stated amount of Nimesulide.

1. Identification:

The final solution obtained in the assay shows concordant spectrums with that of the standard spectrum i.e; peak maxima at about 298 nm.

Tests:

2. Dissolution: *Determine by UV Spectroscopy*

2.1 Dissolution Parameters:

Apparatus: Paddle

Medium: 1000 ml of Phosphate buffer pH 7.4 + Tween 80 1% m/v

Speed and Time: 100 rpm and 60 minutes

Withdraw the suitable volume of the medium and filter.

2.2 Test Solution: Dilute 5 ml of this solution to 50 ml with dissolution medium.

2.3 Reference solution: Weigh accurately about 25 mg Nimesulide RS in 1000 ml volumetric flask. Add 800 ml dissolution medium, sonicate to dissolve and make up the volume to 1000 ml with same solvent. Further dilute 20 ml of this solution to 50 ml with same solvent.

2.4 Procedure: Measure the absorbance of both standard and sample solution at about 398 nm taking dissolution medium as blank.

Calculate the % release of by comparison.

2.5 Limit: NLT 75 % (D) of the stated amount

3. Assay: *Determine by UV Spectroscopy*

3.1 Test Solution: Weigh individually 20 tablets & crush the tablet into fine powder. Weigh a quantity of powder equivalent to 50 mg of Nimesulide in 100 ml volumetric flask, add 70 ml of

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methanol, sonicate for 10 minutes to dissolve and make volume to 100 ml with same solvent. Dilute 2 ml of this solution to 50 ml with same solvent.

3.2 Reference Solution: Weigh accurately about 50 mg Nimesulide RS 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 2 ml of this solution to 50 ml with same solvent.

3.3 Procedure: Measure the absorbance of both the standard and sample solution at about 298 nm.

Calculate the content of Nimesulide by comparison.

4. Other tests: As per pharmacopoeial requirements.