

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

Analytical profile of Nimesulide Tablets

Analytical Profile No.: NIMES 075/076/AP051

Nimesulide Tablets contains not less than 90.0% and not more than 110.0% 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.

2. Dissolution: *Determine by UV/VIS Spectroscopy.*

2.1 Dissolution Parameters:

Apparatus: Paddle

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

Speed & Time: 100 rpm & 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 dissolution medium.

2.3 Reference Solution: Weigh accurately about 25 mg Nimesulide WS 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 using UV/VIS Spectrophotometer. Use dissolution media as blank. Calculate the % release of Nimesulide.

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

3. Assay: *Determine by UV/VIS 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 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.

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3.2 Reference Solution: Weigh accurately about 50 mg Nimesulide 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 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 using UV/VIS Spectrophotometer. Use methanol as blank. Calculate the content of Nimesulide.

4. Other tests: As per Pharmacopoeial requirements.