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

Analytical profile of Aceclofenac Sustained Release Tablets

Analytical Profile No.: AST 074/075/ AP 032

Aceclofenac Sustained Release Tablets contains not less than 90.0% and not more than 110.0% of the stated amount of Aceclofenac.

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:

2.1 Dissolution Parameters: *Deteremine by UV-Vis spectrophotometry*

Apparatus: Paddle

Medium: 900ml of Phosphate buffer pH 7.5 (6.8 g of monobasic potassium phosphate and 1.4 g sodium hydroxide in 1000 ml water and adjust the pH to 7.5 ± 0.05 with sodium hydroxide solution)

Speed and Time: 50 rpm and 1st hour, 4th hour, 8th hour and 16 th hour

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 44.4 mg of Aceclofenac RS in 100 ml volumetric flask. Add 70 ml of dissolution medium and sonicate for 15 min and make up volume with same medium. Dilute 5 ml of the solution to 100 ml with dissolution medium.

2.4 Procedure: Measure the absorbance of standard and sample solution at about 273 nm using dissolution medium as blank. Calculate the percentage release of Aceclofenac

2.5 Limit:
1st hour - NMT 25%
4 th hour – NLT 20% and NMT 50 %
8 th hour – NLT 50% and NMT 80 %
16 th hour - NLT 80 % of the stated amount

3. Assay: *Deteremine by liquid chromatography*

3.1 Diluent: 45 volume of Water and 55 volume of Acetonitrile

3.2 Test Solution: Weigh and powder 20 tablets. Weigh powder eq. to 100 mg of Aceclofenac in 100ml volumetric flask. Add about 70ml of diluent and sonicate for 10 minutes, make up the volume to 100 ml with same solvent. Filter and dilute 5 ml of the filtrate to 50 ml with diluent.

3.3 Reference Solution: Weigh accurately about 25 mg of Aceclofenac RS in 25 ml volumetric flask and add about 15 ml of diluent and sonicate for about 10 min. Cool and make volume to 25 ml with same solvent. Dilute 5 ml of the solution to 50 ml with diluents.

3.4 Chromatographic System

Column: Octyldecylsilane (C18), (150 x 4.6 mm), 5 µm

Flow rate: 1.5 ml/min

Detector: UV Detector

Wavelength: 275 nm

Injection volume: 10 µl

Oven temperature: Ambient

Mobile phase: 55 volume of Buffer and 45 volume of Acetonitrile

Buffer: 1 ml of glacial acetic acid in 1000 ml of water

3.5 Procedure: Inject test solution five times & test 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 in not more than 2.0%. Measure the peak response. Calculate the content of Itopride in Itopride SR tablet.

4. Other tests: As per pharmacopoeial requirements.