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

Analytical profile of Paracetamol and Meloxicam Bolus

Analytical Profile No.: Para Melo 081/82/AP 172

Paracetamol and Meloxicam Bolus contain not less than 90.0% and not more than 110.0% of the stated amount of Paracetamol and Meloxicam.

Usual Strength: 1500 mg (Paracetamol) and 100 mg (Meloxicam)

1. Identification:

In the Assay, the principal peaks in the chromatogram obtained with the test solution correspond to the peaks in the chromatogram obtained with the reference solution.

2. Assay: *Determine by liquid chromatography*

2.1 Test solution: Weigh the content of 10 bolus and calculate the average weight. Weigh the powder equivalent to 150 mg of Paracetamol in 100 ml of dry volumetric flask, add 10 ml of 0.1M NaOH, and make up the volume with the mobile phase. Dilute 5 ml of the above solution to 100 ml of volumetric flask and make the volume with the mobile phase, mix, and filter the solution through 0.25-micron filter paper.

2.2 Reference solution: Weigh accurately about 150.0 mg of Paracetamol WS and 10 mg of Meloxicam WS into a 100 ml completely dried volumetric flask. Add 10 ml of 0.1M NaOH and make up the volume with the mobile phase. Then, dilute 5 ml of the above solution to 100 ml of volumetric flask and make the volume with the mobile phase, mix, and filter the solution through 0.25-micron filter paper.

2.3 Chromatographic system:

Column: C18 (4.6mmX 250-mm, 5µm)

Wavelength: 244 nm

Injection volume: 20 µl

Flow Rate: 1.2 ml/minute

Column Temperature: 30ºC

Mobile Phase: A mixture of 50 volumes of Methanol and 50 volumes of Phosphate buffer (prepared by dissolving 6.8 g of Potassium dihydrogen orthophosphate, the pH is adjusted to 9.2 with Potassium hydroxide)

2.4 Procedure: Inject the reference solution at least five times and test the solutions subsequently. 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%. Measure the peak responses. Calculate the content of Paracetamol and Meloxicam.

3. Other tests: As per Pharmacopoeial requirements.