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

Analytical profile of Ibandronate Sodium Tablets

Analytical Profile No.: Iban 075/076/AP054

Ibandronate Sodium Tablets contains not less than 90.0% and not more than 110.0% of the stated amount of Ibandronate Sodium.

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: *Determine by liquid chromatography*

Apparatus: Paddle

Medium: 500 ml of Water

Speed and Time: 50 rpm and 45 minutes

Withdraw a suitable volume of the medium and filter.

2.2 Test Solution: Use the filtrate

2.3 Reference Solution: Weigh accurately about 16.87 mg of Ibandronate sodium WS in 100 ml volumetric flask. Add about 70 ml of water and sonicate for about 10 minutes, cool and make up the volume to 100 ml with same solvent.

2.4 Procedure: Use the chromatographic system as described in the Assay using 20 µl as injection volume. Inject the reference solution and the test solution.
Calculate the percent release of Ibandronate Sodium.

2.5 Limit: Not less than 70% (D) of the stated amount of Ibandronate Sodium.

3. Assay:

3.1 Test Solution: Weigh individually 20 tablets and calculate average weight. Weigh and transfer powdered sample eq. to 28 mg of Ibandronate sodium into 100 ml volumetric flask, add

70 ml of water & sonicate for about 10 minutes with intermittent shaking, cool and make volume to 100 ml with same solvent.

3.2 Reference Solution: Weigh accurately about 28 mg of Ibandronate sodium WS (equivalent to 25mg of Ibandronic acid) in 100 ml volumetric flask. Add about 70 ml of water and sonicate for about 10 minutes, cool and make up the volume to 100 ml with same solvent.

3.3 Chromatographic system:

Column: Octadecylsilane (C18), (250x4.6 mm), 5 µm

Flow rate: 1.2 ml/min

Wavelength: 195 nm

Injection volume: 20 µl

Column Temperature: Ambient

Mobile phase: Buffer: Acetonitrile (95:5)

Buffer: Dissolve 1g of 1-Hexane sulphonic acid sodium salt in 1000ml of water.

3.4 Procedure: Inject the reference solution five times and sample solutions. The test is not valid unless the theoretical plates is not less than 2000, 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 responses. Calculate the content of Ibandronate Sodium.

4. Other tests: As per pharmacopoeial requirements.