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

Analytical profile of Apixaban Tablets

Analytical Profile No.: Apixa 080/081/AP 135

Apixaban Tablets contains not less than 90.0% and not more than 110.0% of the stated amount of Apixaban

Usual Strength: 2.5 mg and 5 mg

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 certified reference solution.

2. Dissolution: *Determine by liquid chromatography*

2.1 Dissolution Parameters:

Apparatus: Paddle

Medium: 900 ml of 0.05M Sodium Dihydrogen Phosphate, 0.05% Sodium Lauryl Sulphate and 0.1% w/v Sodium Hydroxide, adjust pH-6.8 with Sodium Hydroxide

Speed and Time: 75 rpm and 45 minutes

Withdraw a suitable volume of the medium and filter.

2.3 Test Solution: Use the filtrate.

2.4 Reference Solution: Weigh accurately 28 mg of Apixaban WS to 100 ml volumetric flask, add about 70 ml of diluent, sonicate to dissolve, cool to room temperature and make up the volume with same solvent. Further dilute 1 ml of this solution to 100 ml with dissolution medium [**for tablet of strength 2.5 mg**] or 2 ml of this solution to 100 ml [**for tablet of strength 5 mg**] and mix.

2.5 Procedure: Use the chromatographic system as described in the Assay using 50 µl as injection volume. Inject the reference solution and the test solution.

Calculate the percent release of Apixaban.

2.6 Limit: Not less than 70 percent (D) of the stated amount of Apixaban.

3. Uniformity of Content

Determine by liquid chromatography, as described in the Assay, using the following test solution.

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Test Solution: Place a tablet [**strength 2.5 mg**] in a 50 ml volumetric flask or a tablet [**strength 5 mg**] in 100 ml volumetric flask, add 30 ml of diluent, sonicate to disperse whole tablet with intermittent shaking. Cool, make up the volume to 50 ml with same solvent and mix.

4. Assay: *Determine by liquid chromatography*

4.1 Test solution: Transfer an accurately weighed powder equivalent to 5 mg of Apixaban into 100 ml volumetric flask. Add about 70 ml of diluent and sonicate to disperse the tablets. Further sonicate for 15 minutes with intermittent shaking. Cool and dilute to volume with same solvent and mix.

4.2 Reference solution: Weigh accurately 50 mg of Apixaban working standard into a 100 ml volumetric flask. Dissolve and dilute to volume with diluent. Dilute 5 ml of this solution to 50 ml with same solvent and mix.

4.3 Chromatographic system:

Column: C18 (4.6mmX 250-mm, 5µ)

Flow rate: 1.0 ml/min

Wavelength: 278 nm

Injection volume: 20µl

Column Temperature: 30ºC

Mobile Phase: A mixture of 50 volume of Potassium dihydrogen orthophosphate buffer and 50 volume of acetonitrile.

Buffer: Weigh about 2.87 gm of potassium dihydrogen orthophosphate in 1000 ml of HPLC water and adjust pH 4.0 with dilute orthophosphoric acid.

Diluent: A mixture of 500 volume of water and 500 volume of Acetonitrile.

4.4 Procedure: Inject the reference solution five times and sample solutions. The test is not valid unless the column efficiency is not less than 2000 theoretical plates, 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 Apixaban in ApixabanTablets.

5. Other tests: As per pharmacopoeial requirements.