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

Tranexamic Acid Capsules

Analytical Profile No.: Tranex 079/080/AP 123

Tranexamic Acid Capsules contains not less than 90.0% and not more than 110.0% of the stated amount of Tranexamic Acid.

Usual Strength: 250 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 reference solution.

2. Dissolution: *Deteremine by liquid chromatography*

2.1 Dissolution Parameters:

Apparatus: Paddle (use sinker)

Medium: 900ml 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 27.8 mg of Tranexamic acid WS to 100 ml volumetric flask (amber color), add about 70 ml of dissolution media, sonicate to dissolve, cool to room temperature and make up the volume with same solvent.

2.4 Procedure: Use the chromatographic system as described in the Assay using 80 µl as injection volume. Inject the reference solution and the test solution.

Calculate the percent release of Tranexamic Acid.

2.5 Limit: Not less than 75 percent (D) of the stated amount of Tranexamic Acid.

3. Assay: *Determine by liquid chromatography*

3.1 Diluent: Water

3.2 Test solution: Transfer the capsule powder equivalent to 100 mg of tranexamic into 100 ml volumetric flask, add 70 ml of diluent to it and sonicate for 15 minutes. Make up the volume with diluent.

3.3 Reference solution: Weigh accurately about 50 mg of Tranexamic acid WS to a 50 ml volumetric flask (amber color); dissolve it with 35 ml of diluent and sonicate. Make up the volume with same solvent.

3.4 Chromatographic system:

Column: C18 (4.6mmX 150mm, 5µ)

Flow rate: 1.5 ml/min

Wavelength: 220 nm

Injection volume: 50µl

Column Temperature: 40ºC

Mobile Phase: A mixture of 85 volume of buffer and 15 volume of acetonitrile.

Buffer preparation: Dissolve 10.5 gm of sodium dihydrogen phosphate monohydrate in 1000 ml of water. Add 8 ml of triethylamine and 2.3 gm of sodium lauryl sulphate. Adjust pH to 2.5 with dilute orthophosphoric acid.

[Note: Equilibrate the column for at least 2 hours]

3.5 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 Tranexamic Acid in Tranexamic Acid Capsules.

4. Other tests: As per pharmacopoeial requirements.