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

Analytical profile of Benfotiamine Capsules

Analytical Profile No.: Benfot 080/81/AP 159

Benfotiamine Capsules contain not less than 90.0% and not more than 125.0% of the stated amount of Benfotiamine.

Usual Strength: 150 mg

1. Identification:

In the Assay, the principal 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 Water

Speed & Time: 100 rpm & 45 minutes

Withdraw a suitable volume of the medium and filter.

2.2 Test Solution: Dilute 3 ml the filtrate to 10 ml dissolution medium.

2.3 Reference Solution: Weigh accurately 25.0 mg of Benfotiamine WS and transfer in 50 ml of completely dried volumetric flask using the mobile phase and shake to dissolve and make up the volume with the mobile phase. Dilute 5 ml of the solution to 50 ml with the same solvent.

2.4 Procedure: Use the chromatographic system as described in the Assay using 10 µl as injection volume. Inject the reference solution and the test solution.

Calculate the percent release of Benfotiamine.

2.5 Limit: NLT 80 % (Q) of the stated amount.

3. Assay: *Determine by liquid chromatography*

3.1 Diluent: Mobile phase

3.2 Test solution: Weigh the content of 20 capsules and calculate the average weight. Weigh accurately the powder equivalent to 120.0 mg of Benfotiamine in 100 ml of dry volumetric flask, add 70 ml of mobile

phase, sonicate for 10 minutes, and cool the sample solution to room temperature. Make up the volume with the mobile phase and filter the solution through filter paper. Dilute 2 ml of the solution to 50 ml with the mobile phase.

3.3 Reference solution: Weigh accurately 25.0 mg of Benfotiamine WS and transfer to a 50 ml completely dried volumetric flask. Make up the volume with the mobile phase. Dilute 5 ml of the solution to 50 ml using the mobile phase.

3.4 Chromatographic system:

Column: C18 (4.6mmX 150-mm, 5µ)

Flow rate: 1.0 ml/min

Wavelength: 244 nm

Injection volume: 10 µl

Column Temperature: 40ºC

Mobile Phase: Buffer: Methanol: 80:20

Buffer: Weigh 1.17 gm. of 1-Octane sulfonic acid sodium salt in 1000 ml of HPLC grade water, and mix. Add 10 ml of Triethylamine and adjust pH 2.0 with dilute orthophosphoric acid.

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, 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 Benfotiamine in Benfotiamine Capsules.

4. Other tests: As per Pharmacopoeial requirements.