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

Analytical Profile No.: Febu 073/074/ AP 017

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

1. Identification:

In the assay, the principle peak in the chromatogram obtained with the sample solution should correspond to the peak in the chromatogram obtained with the reference solution.

2. Dissolution:

2.1 Dissolution Parameters:

Apparatus: Paddle

Medium: 900ml of Phosphate buffer pH 6.0 (Dissolve 6.0 g of monobasic potassium phosphate in 1000 ml of water and adjust the pH to 6.0 ± 0.05 with sodium hydroxide solution.)

Speed and Time: 75 rpm and 30 minutes

Withdraw a suitable volume of the medium and filter.

2.2 Test Solution: Use the filtrate.

2.3 Reference Solution: Weigh accurately about 20 mg of febuxostat RS and transfer into 50 ml volumetric flask. Add about 35 ml of methanol and dissolve by sonicating for few minutes. Allow the sample to cool to the room temperature and make up the volume to 50 ml with methanol. Dilute 2 ml of the standard solution to 20 ml with the dissolution medium.

2.4 Procedure: Use the chromatographic system as described in the Assay. Inject the reference solution and the test solution. Measure the peak responses and calculate the % release of Febuxostat.

2.5 Limit: NLT 70 % D of the stated amount

3. Assay:

3.1 Test Solution: Weigh individually 20 tablets & crush the tablet into fine powder. Weigh accurately the powder eq. to 20 mg of Febuxostat and transfer into 50 ml volumetric flask. Add

about 35 ml of mobile phase and dissolve by sonicating for about 10 minutes. Allow the sample to cool to room temperature and make up the volume to 50 ml with the mobile phase. Filter or centrifuge the solution. Dilute 5 ml of the clear solution to 50 ml with mobile phase.

3.2 Reference Solution: Weigh accurately about 20 mg of febuxostat RS and transfer into 50 ml volumetric flask. Add about 35 ml of mobile phase and dissolve by sonicating for about 10 minutes. Allow the sample to cool to room temperature and make up the volume to 50 ml with the mobile phase. Dilute 5 ml of the resulting solution to 50 ml with mobile phase.

3.3 Chromatographic system

Column: Octyldecylsilane (C18), (150*4.6 mm), 5 µm

Flow rate: 1.0 ml/min

Detector: UV Detector

Wavelength: 220 nm

Injection volume: 20 µl

Oven temperature: 30 °C

Mobile phase: 25 volume of Orthophosphoric acid solution and 75 volume of Methanol

Orthophosphoric acid solution: Dilute 10 ml of the orthophosphoric acid to 1000 ml with water.

3.4 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 Febuxostat.

4. Other tests: As per pharmacopoeial requirements.