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

Analytical Profile of Bilastine Oral Solution

Analytical Profile No.: Bilas OS 081/082/AP 166

Bilastine Oral Solution contains not less than 90.0% and not more than 110.0% of the stated amount of Bilastine.

Usual Strength: 2.5 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 reference solution.

2. Assay: *Determine by liquid chromatography*

2.1 Diluent: 90% Methanol solution in HPLC grade water

2.2 Test solution: Weigh a quantity of sample solution equivalent to 4 mg of Bilastine to 200 ml volumetric flask and add 130 ml of diluent, sonicate for about 10 minutes, cool the solution to room temperature, and make up the volume with diluent.

2.3 Reference solution: Weigh accurately about 20.0 mg of Bilastine WS and transfer to a 100 ml completely dried volumetric flask. Dissolve in 70 ml of diluent with the aid of ultrasound for 3 minutes and make up the volume with the same diluent. Again, dilute 5 ml of the solution to 50 ml with the diluent and, mix.

2.4 Chromatographic system:

Column: C18 (4.6mmX 250-mm, 5µm)

Flow rate: 1.5 ml/min

Wavelength: 270 nm

Injection volume: 10 µl

Column Temperature: 40ºC

Mobile Phase: Eluent A: Eluent B in 20:80 ratio

Eluent A: Weigh 6.8 g of Potassium dihydrogen orthophosphate and 2.16 g of 1-Octance sulfonic sodium salt in 1000 ml of HPLC grade water then adjust pH to 2.5 with diluted orthophosphoric acid and filter it with 0.45-micron filter paper.

Eluent B: Mix Acetonitrile, methanol, and buffer in the ratio of 400:250:350. Mix well and filter it with 0.45-micron filter paper.

2.5 Procedure: Inject the reference solution five times and test the 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 Bilastine.

3. Other tests: As per Pharmacopoeial requirements.