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

Analytical Profile of Bilastine Orodispersible Tablets

Analytical Profile No.: Bilas DT 081/082/AP 165

Bilastine Tablets contain not less than 90.0% and not more than 110.0% of the stated amount of Bilastine.

Usual Strength: 10 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. Dissolution: *Determine by liquid chromatography*

2.1 Dissolution Parameters:

Apparatus: Paddle

Medium: 900 ml 0.1 N Hydrochloric Acid

Speed and Time: 50 rpm and 30 minutes

2.2 Test Solution: After completion of the test withdraw a specimen from the dissolution medium.

2.3 Reference Solution: Weigh 25.0 mg of Bilastine WS accurately and transfer in 100 ml of a completely dried volumetric flask. Add 70 ml of diluent and sonicate to dissolve and make up the volume with the same and mix. Dilute 2 ml of the solution to 50 ml with the dissolution medium and mix.

2.4 Procedure: Use the chromatographic system described in the Assay. Inject the reference solution and the test solution. Calculate the percent release of Bilastine.

2.5 Limit: NLT 75 % (Q) of the stated amount.

3. Assay: *Determine by liquid chromatography*

3.1 Diluent: 90% Methanol solution in HPLC grade water

3.2 Test solution: Weigh the content of 20 tablets and calculate the average weight. Weigh the powder equivalent to 50 mg of Bilastine in 100 ml of dry volumetric flask, add 70 ml of diluent, and sonicate to dissolve. Cool the sample solution to room temperature and make up the volume with diluent. Then centrifuge the sample for 5 minutes. Dilute 2 ml of supernatant liquid to 50 ml with diluent and mix.

3.3 Reference solution: Weigh accurately about 50.0 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 and make up the volume with water. Again, dilute 2 ml of the solution to 50 ml with the diluent and mix.

3.4 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.

3.5 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.

4. Uniformity of content: Determine by HPLC as described in the test for assay

4.1 Test Solution: Place one tablet in each of 10 separate 50 ml volumetric flasks. Dissolve in about 30 ml water with the aid of sonication to fully disperse and make up the volume to 50 ml with diluent. Centrifuge the sample for 10 minutes then dilute 2 ml of supernatant liquid to 20 ml with diluent. Mix and filter through 0.25-micron filter paper.

4.2 Reference solution: Use the standard solution prepared in the assay.

5. Other tests: As per Pharmacopoeial requirements.