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

Analytical profile of Bilastine Tablets

Analytical Profile No.: Bilas 080/81/AP 154

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

Usual Strength: 20 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 certified reference solution.

2. Dissolution: *Determine by liquid chromatography*

2.1 Dissolution Parameters:

Apparatus: Paddle

Medium: 900 ml 0.1N Hydrochloric acid

Speed: 50 rpm

Time: 45 minutes

Withdraw a suitable volume of the medium and filter.

2.3 Test Solution: Use the filtrate.

2.4 Reference Solution: Weigh accurately 50.0 mg of Bilastine WS and transfer in 100 ml completely dried volumetric flask using diluent and shake to dissolve and make up the volume with diluent. Dilute 2 ml of the solution to 50 ml with dissolution media.

2.5 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 Bilastine.

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

3. Uniformity of Content

Determine by liquid chromatography, as described in the Assay, using the following test solution.

3.1 Test Solution: Transfer 1 tablet to 100 ml volumetric flask. Add 60 ml of diluent and sonicate for 15 minutes. Cool to room temperature, dilute with diluent to volume and mix. Centrifuge the sample for 10 minutes. Dilute 5 ml of sample to 50 ml with diluent and mix.

3.2 Reference Solution: Same as assay.

4. Assay: *Determine by liquid chromatography*

4.1 Test solution: Weigh 20 tablets and calculate average weight. Weigh accurately the powder equivalent to 50 mg of Bilastine in 100 ml of dry volumetric flask, add 70 ml of diluent sonicate for 15 minute. Make up the volume with diluent. Dilute 2 ml of the solution to 50 ml with diluent.

4.2 Reference solution: Weigh accurately 50.0 mg of Bilastine WS and transfer in 100 ml completely dried volumetric flask. Add 70 ml of diluent, sonicate to dissolve. Make up the volume with diluent. Dilute 2 ml of the solution to 50 ml with diluent.

4.3 Chromatographic system:

Column: C18 (4.6mmX 250-mm, 5µ)

Flow rate: 1.5 ml/min

Wavelength: 270 nm

Injection volume: 10 µl

Column Temperature: 40°C

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

Eluent A (Buffer): Weigh 6.8 gm. Of Potassium dihydrogen orthophosphate and 2.16 gm. Of 1-Octane sulfonic sodium salt in 1000 ml of HPLC grade water the adjust pH 2.5 with dilute orthophosphoric acid.

Eluent B: Mix Acetonitrile, methanol and buffer in the ratio of 400:250:350. Mix well and filter.

Diluent: 90.0 % methanol in water.

4.4 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 Bilastine in Bilastine Tablets.

5. Other tests: As per Pharmacopoeial requirements.