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

Analytical profile of Saxagliptin Tablets

Analytical Profile No.: Saxag 082/083/AP 178

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

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

2.1 Dissolution Parameters:

Apparatus: Paddle

Medium: 900 ml phosphate buffer 6.8

Speed and Time: 75 rpm and 45 minutes

Withdraw a suitable volume of the medium and filter.

2.2 Test Solution: Use the filtrate.

2.3 Reference Solution: Weigh 10.0 mg of Saxagliptin RS accurately and transfer in 100 ml of a completely dried volumetric flask. Add 60 ml of mobile phase, sonicate for 10 minutes, and make up the volume to 100 ml with the mobile phase. 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 Saxagliptin.

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

3. Uniformity of content:

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

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Test Solution: Place one tablet in each of 10 separate 50 ml volumetric flasks. Dissolve in about 30 ml mobile phase with the aid of sonication for 10 minutes, and make up the volume to 50 ml with the same solvent.

4. Assay: *Determine by liquid chromatography*

4.1 Test solution: Weigh the contents of 20 tablets and calculate the average weight. Weigh the powder equivalent to 10 mg of Saxagliptin in a 100 ml dry volumetric flask, add 60 ml of the mobile phase, sonicate for 10 minutes, and cool the sample solution to room temperature. Make up the volume with the mobile phase and mix.

4.2 Reference solution: Weigh accurately about 10 mg of Saxagliptin RS and transfer to a 100 ml completely dried volumetric flask. Dissolve in 60 ml of the mobile phase with the aid of ultrasound for 10 minutes and make up the volume with the mobile phase and mix.

4.3 Chromatographic system:

Column: C18 (4.6mmX 250-mm, 5µm)

Flow rate: 1.0 ml/min

Wavelength: 236 nm

Injection volume: 20 µl

Column Temperature: 30ºC

Mobile Phase: Acetonitrile: Phosphate buffer pH 5.8: 26:74 (V/V)

4.4 Procedure: Inject the reference solution five times and the 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 Saxagliptin.

5. Other tests: As per Pharmacopoeial requirements.

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