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

Analytical profile of Silodosin Capsules

Analytical Profile No.: SIL 074/075/AP 028

Silodosin Capsules contains not less than 90.0% and not more than 110.0% of the stated amount of Silodosin.

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 Test:

2.1 Dissolution Parameters:

Apparatus: Basket

Medium: 500ml of 0.1 N HCl

Speed and Time: 50 rpm and 30 minutes

Withdraw a suitable volume of the medium and filter.

2.2 Diluent: 0.1 % Orthophosphoric acid: Methanol (6:4)

2.3 Test Solution: Use the filtrate.

2.4 Reference Solution: Weigh accurately about 16 mg of Silodosin RS and transfer into 200 ml volumetric flask. Add about 100 ml of diluents and dissolve by sonicating for about 10 minutes and make up the volume to 200 ml with diluent. Dilute 2 ml of the resulting solution to 20 ml with diluents.

2.5 Procedure: Use the chromatographic system as described in the Assay. Inject the reference solution and the test solution. Calculate the percent release of Silodosin.

2.6 Limit: Not Less Than 75 % D 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: Place one capsule in a 100 ml volumetric flask, add about 70 ml of diluents. Dissolve by sonicating for about 15 minutes. Cool and make up the volume to 100 ml with diluent. Centrifuge or filter the resulting solution. Dilute 3 ml of the filtrate to 25 ml with diluents.

4. Assay:

4.1 Diluent: 0.1 % Orthophosphoric acid: Methanol (6:4)

4.2 Test Solution: Take 20 capsules, determine the average fill weight. Weigh accurately the powder equivalent to 5 mg of Silodosin and transfer into 50 ml volumetric flask. Add about 35 ml of diluents, dissolve by sonicating for about 15 minutes and make up the volume to 50 ml with same diluents. Dilute 2 ml of the resulting solution to 20 ml with diluents.

4.3 Reference Solution: Weigh accurately about 25 mg of Silodosin RS and transfer into 100 ml volumetric flask. Add about 70 ml of diluents, dissolve by sonicating for about 15 minutes and make up the volume to 100 ml with same diluents. Dilute 2 ml of the resulting solution to 50 ml with diluents.

4.4 Chromatographic system:

Column: 250 X 4.6 mm (C 18)

Flow rate: 1.0 ml/min

Wave length: 225 nm

Injection volume: 20 µl

Column Oven Temperature: 35 ºC

Mobile phase: 50 volume of Buffer, 30 volume of Methanol & 20 volume of Acetonitrile and adjust the pH of the solution to 3.5 with potassium hydroxide solution or dilute orthophosphoric acid

Buffer: 0.1 % Ortho Phosphoric Acid

4.5 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 Silodosin.

5. Other tests: As per pharmacopoeial requirements.