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

Analytical profile of S (-) Pantoprazole Enteric coated Tablets

Analytical Profile No.: S(-)PAN 075/076/AP039

S (-) Pantoprazole Enteric coated Tablets contains not less than 90.0% and not more than 110.0% of the stated amount of S (-) Pantoprazole.

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 reference solution.

2. Dissolution Test:

2.1 Dissolution Parameter (Acid phase):

Apparatus: Paddle

Medium: 1000ml of 0.1 M HCl

Speed & Time: 100 rpm & 2 hrs

2.2 Test Solution: Withdraw the medium completely and place the intact tablet in 100ml volumetric flask. Add 60ml of mobile phase and sonicate for 30 minutes. Cool; make up the volume to 100ml with mobile phase and centrifuge.

2.3 Reference Solution: Weigh accurately about 20 mg of working standard of S (-) Pantoprazole and transfer into 100 ml volumetric flask. Dissolve with 70ml of mobile phase and make up the volume to 100 ml with same solvent.

2.4 Chromatographic system:

Column: C18, (250 X 4.6) mm, 5µm

Flow rate: 1.5 ml/min

Wave length: 290 nm

Injection volume: 10 µl

Column Oven Temperature: 30˚C

Mobile phase: Phosphate buffer (pH 7.3): ACN (50:50)

Phosphate Buffer (pH 7.3): Dissolve 6.8 g of potassium dihydrogen orthophosphate and 1g of hexane sulphonic acid sodium salt in 1000ml of water, adjusted to pH 7.3 with 1M sodium hydroxide.

2.5 Procedure: Inject reference solution five/six times and test solution. 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 in not more than 2.0%. Calculate the percent release of drug.

Calculate the content of s-pantoprazole released in the acid medium by subtracting the content of s-pantoprazole in the test solution from the total content of s-pantoprazole determined in the assay.

% content of s-pantoprazole = % content of s-pantoprazole - % content of s-pantoprazole
in acid medium in assay in the test solution

2.6 Limit: Not more than 10% of the stated amount

2.7 Dissolution Parameter (Buffer phase):

Apparatus: Paddle

Medium: 1000ml of tris-acetate buffer pH 8.5

Tris-acetate Buffer pH 8.5: Dissolve 0.294 g of calcium chloride and 12.11 g of tris(hydroxymethyl) aminomethane in 990ml water. Adjust the pH to 8.5 with 5M acetic acid and dilute to 1000ml with water.

Speed & Time: 75 RPM & 60 min

2.8 Test Solution: Run acid phase dissolution on another 6 tablets and discard the medium completely and fill the empty vessel with the dissolution medium. After completion of dissolution withdraw the sample and filter. Dilute the filtrate, if necessary, with the dissolution medium.

2.9 Reference Solution: Weigh accurately about 25 mg of working standard of S (-) Pantoprazole and transfer into 50 ml volumetric flask; dissolve in 5ml of methanol and make up the volume to 50 ml with dissolution medium. Dilute 2 ml to 50 ml with dissolution medium.

2.10 Procedure:

Measure the absorbance of sample and standard solutions at maximum at about 290 nm against dissolution medium as blank and calculate the percent release.

2.11 Limit: Not less than 75% (D)of the stated amount

3. Assay:

3.1 Test Solution: Weigh individually 20 tablets and place 10 tablets (equivalent to about 200mg of S (-) Pantoprazole) in 100ml volumetric flask. Add about 70ml of mobile phase and sonicate for 30minutes. Cool; make up the volume to 100ml with mobile phase and centrifuge. Dilute 2ml to 20ml with mobile phase.

3.2 Reference Solution: Weigh accurately about 20 mg of working standard of S (-) Pantoprazole and transfer into 100 ml volumetric flask. Dissolve with 70ml of mobile phase and make up the volume to 100 ml with same solvent.

3.3 Chromatographic system:

Column: 250 X 4.6 mm, 5µm ODS (C18)

Flow rate: 1.5 ml/min

Wave length: 290 nm

Injection volume: 10 µl

Column Oven Temperature: 30˚c

Mobile phase: Phosphate buffer (pH 7.3): ACN (50:50)

Phosphate Buffer (pH 7.3): Dissolve 6.8 g of potassium dihydrogen orthophosphate and 1g of hexane sulphonic acid sodium salt in 1000ml of water, adjusted to pH 7.3 with 1M sodium hydroxide.

3.4 Procedure

Inject reference solution five/six times and test solution. The test is not valid unless the column efficiency is not less than 2000 theoretical plate; the tailing factor is not more than 2.0 and the relative standard deviation for replicate injections in not more than 2.0%. Calculate the content of S (-) Pantoprazole.

4. Other tests: As per pharmacopoeial requirements.