S (-) Pantoprazole Enteric Coated Tablets

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

S (-) Pantoprazole Enteric Coated Tablets contain not less than 90 per cent and not more than 110 per cent of the stated amount of S (-) Pantoprazole.

1. Identification: In the assay, the principle peak in the chromatogram obtained with the test solution should correspond to the peak in the chromatogram obtained with the reference solution of S (-) Pantoprazole.

Tests:

2. Dissolution Test:

2.1 Acid stage: *Determine by liquid chromatography*

2.1.1 Dissolution Parameters:

Apparatus:	Paddle
Medium:	1000 ml of 0.1 M Hydrochloric acid
Speed and time:	100 rpm and 120 minutes
Temperature:	37 ± 0.5 ℃

2.1.2 Test solution: Withdraw the medium completely and place the intact tablet in 100 ml volumetric flask. Add 60 ml of mobile phase and sonicate for 30 minutes. Cool; make up the volume to 100 ml with mobile phase and centrifuge. Filter the supernatant liquid through 0.2 micron membrane filter.

2.1.3 Reference solution: Weigh accurately about 20 mg S (-) Pantoprazole reference standard and transfer into 100 ml volumetric flask. Dissolve with 70 ml of mobile phase and make up the volume to 100 ml with same solvent. Filter it through 0.2 micron membrane filter.

2.1.4 Chromatographic system:

Use the chromatographic system as described under assay

2.1.5 Procedure: Inject 10 µl of reference solution five times and obtain the respective chromatogram as per above mentioned chromatographic conditions. After injecting reference solution inject 10 µl of test solution and blank solution. Measure the peak responses.

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

2.1.6 Limit: Not more than 10 per cent of the stated amount.

2.2 Buffer stage: *Determine by UV spectroscopy*

2.2.1 Dissolution Parameters:

Apparatus: Paddle

Medium: 1000 ml of tris-acetate buffer pH 8.5, prepared by dissolving 0.294 g of calcium chloride and 12.11 g of tris(hydroxymethyl) aminomethane in 990 ml water, adjust the pH to 8.5 with 5 M acetic acid and dilute to 1000 ml with water.

Speed and time: 75 rpm and 60 minutes

Temperature: 37±0.5°C

2.2.2 Test solution: Run method 2.1.1 on another 6 tablets and discard the medium completely and fill the empty vessel with the dissolution medium. After completion of dissolution withdraw a suitable volume of medium and filter. Dilute the filtrate, if necessary, with the dissolution medium.

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

2.2.4 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 of S-Pantoprazole in buffer.

2.2.5 Limit: Not less than 75 per cent (D) of the stated amount.

3. Assay: *Determine by liquid chromatography*

3.1 Test Solution: Weigh individually 20 tablets and place 10 tablets (equivalent to about 200 mg of S (-) Pantoprazole) in 100 ml volumetric flask. Add about 70 ml of mobile phase and sonicate for 30 minutes. Cool; make up the volume to 100 ml with mobile phase and centrifuge. Dilute 2 ml of the supernatant liquid to 20 ml with mobile phase. Filter it through 0.2 micron membrane filter.

3.2 Reference solution: Weigh accurately about 20 mg S (-) Pantoprazole reference standard and transfer into 100 ml volumetric flask. Dissolve with 70 ml of mobile phase and make up the volume to 100 ml with same solvent. Filter it through 0.2 micron membrane filter.

3.3 Chromatographic system:

Column:	a stainless steel column 25 cm x 4.6 mm, packed with octadecyl silane bonded to porous silica (5 µm)
Injection volume:	10 µl
Flow rate:	1.5 ml per minute,
Detector:	spectrophotometer set at 290 nm

Mobile phase: a mixture of 50 volumes of buffer solution prepared by dissolving 6.8 g potassium dihydrogen orthophosphate and 1 g hexane sulphonic acid sodium salt in 1000 ml water, adjusted to pH 7.3 with 1 M sodium hydroxide and 50 volumes of acetonitrile.

3.4 Procedure: Inject 10 µl of standard preparation five/six times. 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%. After the completion of the system suitability test parameter, inject 10 µl of each of the sample solution separately. Calculate the content of S (-) Pantoprazole in each tablet.

4. Other tests: As per pharmacopoeial requirements.