Cefpodoxime Proxetil and Potassium Clavulanate Dispersible Tablets

Analytical Profile No.: Cefpo Clav DT 076/077/AP 075

Cefpodoxime Proxetil and Potassium Clavulanate Dispersible Tablets contain not less than 90 percent and not more than 110 percent of the stated amount of Cefpodoxime Proxetil and Potassium Clavulanate.

1. Identification:

1.1 Cefpodoxime Proxetil:

In the assay, the principle peaks of Cefpodoxime proxetil S-epimer and Cefpodoxime proxetil R-epimer in the chromatogram obtained with the test solution should correspond to the peak in the chromatogram obtained with the reference solution.

1.2 Potassium Clavulanate:

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.

Tests:

2. Dissolution:

2.1 Cefpodoxime: *Determine by UV-Vis spectroscopy*

2.1.1 Dissolution Parameters:

Apparatus: Paddle

Medium: 900 ml buffer of pH 3.0

Speed and time: 75 rpm and 30 minutes

Buffer pH 3.0: Dissolve 18.18 g of Glycine, 20.22 g of Sodium Chloride in 3000 ml of purified water and add 4.8 ml of Hydrochloric acid cautiously with swirling. Adjust pH to 3.0 ± 0.05 with dil NaOH and dilute the solution to 6000 ml with purified water and mix.

Withdraw the suitable volume of the medium and filter.

2.1.2 Test Solution:

Dilute the filtrate, if necessary, with dissolution medium.

2.1.3 Reference Solution:

Weigh accurately about 25 mg of Cefpodoxime proxetil RS in to a 100 ml clean and dry volumetric flask. Add 5 ml methanol, sonicate to dissolve and make up the volume to 100 ml with dissolution medium. Further dilute 5 ml of this solution to 50 ml with dissolution medium.

2.1.4 Procedure:

Measure the absorbance of test solution and reference solution at 259 nm using dissolution medium as blank solution.

Calculate the percentage release of Cefpodoxime in each tablet at specified time.

2.1.5 Limit:

Not less than 70 % (D) of the stated amount of Cefpodoxime.

2.2 Clavulanic acid: *Determine by liquid chromatography*

2.2.1 Dissolution Parameters:

Apparatus: Paddle

Medium: 900 ml of water

Speed and time: 75 rpm and 30 minutes

Withdraw the suitable volume of the medium and filter.

2.2.2 Test Solution:

Dilute the filtrate, if necessary, with dissolution medium. Filter the resulting solution through 0.2 µm membrane filter paper.

2.2.3 Reference Solution:

Weigh accurately about 33 mg of Potassium Clavulanate diluted RS in 100 ml clean and dry volumetric flask. Add about 70 ml dissolution medium, sonicate to dissolve and make up the

volume to 100 ml with dissolution medium. Further dilute 5 ml of this solution to 50 ml with dissolution medium. Filter the resulting solution through 0.2 µm membrane filter paper.

2.2.4 Chromatographic System and Procedure:

Proceed as directed for the assay.

Calculate the percentage release of Clavulanic acid in each tablet at specified time.

2.2.5 Limit:

Not less than 80 % (D) of the stated amount of Clavulanic acid.

3. Assay: *Determine by Liquid Chromatography*

3.1 Test solution:

Weigh individually 20 tablets and crush the tablet into fine powder. Weigh accurately powder equivalent to 100 mg of Cefpodoxime in 100 ml clean and dry volumetric flask, add 70 ml of solvent mixture, sonicate for 15 minutes to dissolve and make volume to 100 ml with same solvent. Further dilute 5 ml of this solution to 100 ml with same solvent. Filter the resulting solution through 0.2 µm membrane filter paper.

3.2 Reference solution:

Weigh accurately about 69 mg Cefpodoxime proxetil RS and 73.5 mg of Potassium Clavulanate diluted RS into 100 ml clean and dry volumetric flask. Add about 70 ml of solvent mixture and sonicate for about 15 minutes with intermittent shaking in cool condition and make up the volume to 100 ml with same solvent. Further dilute 5 ml of this solution to 50 ml with same solvent. Filter the resulting solution through 0.2 µm membrane filter paper.

3.3 Chromatographic system:

Column:	a stainless steel column 25 cm x 4.6 mm, packed with octadecylsilane bonded to porous silica (5 µm)
Flow rate:	1.2 ml per minute
Wavelength:	220 nm

Detector: UV

Injection volume: 20 µl

Column temperature: 25 ^{0}C

Sample compartment temperature: 10 ^{0}C

Mobile phase: a mixture of 680 volumes of buffer prepared by dissolving 1 ml of orthophosphoric acid in 1000 ml water and 320 volumes of acetonitrile.

Solvent Mixture: Mixture of 60 volumes of Water and 40 volumes of Acetonitrile

3.4 Procedure:

Inject 20 µl of standard preparation five 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 20 µl of each of the sample solution separately. Inject blank solution to check any interference.

Calculate the content of Cefpodoxime and Clavulanic acid in each tablet.

4. Other tests: As per pharmacopoeial requirements.