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

Analytical profile of Cefpodoxime Proxetil and Potassium Clavulanate Tablets

Analytical Profile No.: Cefpo Clav 076/077/AP 074

Cefpodoxime Proxetil and Potassium Clavulanate Tablets contains not less than 90.0% and not more than 110.0% of the stated amount of Cefpodoxime and Clavulanic acid.

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 sample solution should correspond to the peak in the chromatogram obtained with the reference standard 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.

2. Dissolution:

2.1 Cefpodoxime: *By UV*

2.1.1 Dissolution Parameters:

Apparatus: Paddle

Medium: 900ml of buffer pH 3.0.

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

Speed and Time: 75rpm and 30 minutes

Withdraw a suitable volume of the medium and filter.

Determine by UV-Vis spectroscopy.

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 WS in 100 ml 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 against dissolution medium. Calculate the content of Cefpodoxime.

2.1.5 Limit: NLT 70.0% (D) of the stated amount

2.2 Clavulanic Acid:

2.2.1 Dissolution Parameters: *By liquid chromatography*

Apparatus: Paddle

Medium: 900ml of water.

Speed and Time: 75rpm and 30 minutes

Withdraw a suitable volume of the medium and filter.

Determine by liquid chromatography.

2.2.2 Test Solution: Dilute the filtrate, if necessary, with dissolution medium.

2.2.3 Reference Solution: Weigh accurately about 33 mg of Potassium Clavulanate diluted WS in 100 ml 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.

2.2.4 Procedure: Use the chromatographic system as described in the Assay.

Inject the reference solution and the test solution. Calculate the content of Clavulanic acid.

2.2.5 Limit: NLT 80.0% (D) of the stated amount

3. Assay: *By liquid chromatography*

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

3.2 Test Solution: Weigh individually 20 tablets & crush the tablet into fine powder. Weigh a quantity of powder equivalent to 100 mg of Cefpodoxime in 100 ml 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.

3.3 Reference Solution: Weigh accurately about 69 mg Cefpodoxime proxetil WS and 73.5 mg of Potassium Clavulanate diluted WS in 100 ml 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.

3.4 Chromatographic system:

- Column: C18, (250 x 4.6 mm), 5 µm
- - Flow rate: 1.2 ml/min
- Detector: UV
- Wavelength: 220 nm
- Injection volume: 20 µl
- Column Temperature: 25°C
- Sample compartment Temperature: 10°C
- Mobile Phase: A mixture of 680 volume of buffer prepared by dissolving 1ml of orthophosphoric acid in 1000 ml of waters and 320 volume of Acetonitrile

3.5 Procedure: Inject the reference solution and test solution. 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 response. Calculate the content of Clavulanic acid and Cefpodoxime in the tablets.

4. Other tests: As per pharmacopoeial requirements.