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

Analytical profile of Cefpodoxime Dispersible Tablets

Analytical Profile No.: CEFPO 075/076/AP048

Cefpodoxime Proxetil Dispersible Tablets contains not less than 90.0% & not more than 110.0% of the stated amount of Cefpodoxime.

1. Identification:

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 solution.

2. Uniformity of Dispersion: As per Indian Pharmacopoeia (latest edition)

3. Disintegration Time: As per Indian Pharmacopoeia (latest edition)

4. Dissolution: *BY UV-Vis spectrophotometry*

4.1 Dissolution parameter

Apparatus: Paddle

Medium: 900ml of a solution prepared by dissolving 3.03g of glycine and 3.37 g of sodium chloride in about 500ml of water, adding cautiously with swirling 0.8ml of hydrochloric acid, adjusting the pH to 3.0 and diluting to 1000ml with water

Speed & Time: 75rpm & 30 minutes

Withdraw a suitable volume of the medium and filter.

4.2 Test Solution: Dilute 5 ml of the filtrate to 50 ml with dissolution medium.

4.3 Reference Solution: Weigh accurately about 10 mg of Cefpodoxime proxetil RS in 100ml volumetric flask, dissolve in minimum quantity of methanol and make up volume to 100ml with dissolution medium. Dilute 2 ml of above solution to 20 ml with dissolution medium.

4.4 Procedure: Measure the absorbance of both standard and sample solution at about 259 nm taking dissolution medium as blank. Calculate the % release of Cefpodoxime Proxetil.

4.5 Limit: NLT 70% (D) of the stated amount

5. Assay:

5.1 Solvent Mixture: Water:ACN (60:40)

5.2 Test Solution: Weigh individually 20 tablets & crush the tablet into fine powder. Weigh a quantity of powder equivalent to 20 mg of Cefpodoxime in 100 ml volumetric flask, add 70 ml of solvent mixture, sonicate to dissolve and make volume to 100 ml with same solvent. Dilute 5 ml of this solution to 100 ml with solvent mixture and mix.

5.3 Standard Solution: Dissolve a quantity of Cefpodoxime proxetil WS in solvent mixture to obtain a solution containing about 30 µg per ml.

5.4 Chromatographic system:

Column: Octadecylsilane (C18), (250x4.6 mm), 5 µm

Flow rate: 1.0 ml/min

Wavelength: 235 nm

Injection volume: 20 µl

Column Temperature: 30°C

Mobile Phase: A mixture of 60 volume of 0.02M ammonium acetate & 40 volume of Acetonitrile.

5.5 Procedure: Inject the reference solution five/six times and sample solutions. The test is not valid unless the relative retention time for Cefpodoxime proxetil S-epimer is about 0.9 and for Cefpodoxime proxetil R-epimer is about 1.0, resolution between Cefpodoxime proxetil S-epimer and Cefpodoxime proxetil R-epimer is not less than 2.0, column efficiency is not less than 2000 theoretical plates, tailing factor for Cefpodoxime proxetil R-epimer is not more than 1.5 and the relative standard deviation determined from the sum of areas of Cefpodoxime proxetil S-epimer and Cefpodoxime proxetil R-epimer peaks for replicate injections is not more than 2.0%. Measure the peak responses. Calculate the content of Cefpodoxime.

6. Other tests: As per pharmacopoeial requirement.