DEPARTMENT OF DRUG ADMINISTRATION
National Medicines Laboratory
ANALYTICAL METHOD VALIDATION COMMITTEE

Cefpodoxime Dispersible Tablets

Analytical Profile No.: CEFPO 075/076/AP048

Cefpodoxime Dispersible Tablets contain not less than 90 % and not more than 110 % 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 test solution should correspond to the peak in the chromatogram obtained with the reference solution.

Tests:

2. Dissolution: *Determine by UV Spectrocopy*

2.1 Dissolution Parameters:

Apparatus: Paddle

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

Speed and Time: 75 rpm and 30 minutes

Withdraw a suitable volume of the medium and filter

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

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

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

2.5 Limit: Not less than 70.0 % (D) of the stated amount of Cefpodoxime.

3. Assay: *Determine by liquid chromatography*

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

3.2 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. Filter the resulting solution through 0.2 µm membrane filter.

3.3 Reference Solution: Dissolve a quantity of Cefpodoxime proxetil reference standard in solvent mixture to obtain a solution containing about 30 µg per ml. Filter the resulting solution through 0.2 µm membrane filter.

3.4 Chromatographic system:

Column: C18, (250x4.6 mm), 5 µm
Injection volume: 20 µl
Flow rate: 1.0 ml/min
Wavelength: 235 nm
Column Temperature: 30°C
Detector: UV
Mobile Phase: 0.02 M ammonium acetate : ACN (60:40)

3.5 Procedure: Inject the reference solution five times and test solution. 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%. Inject the test solution. Calculate the content of Cefpodoxime in the tablets.

4. Other tests: As per pharmacopoeial requirements.