ANALYTICAL METHOD VALIDATION COMMITTEE FOR NON PHARMACOPOEIAL PRODUCT
DEPARTMENT OF DRUG ADMINISTRATION
National Medicines Laboratory

Cefdinir Dispersible Tablets

Analytical Profile No.: Cefdi 073/074/AP 007

Cefdinir Dispersible Tablets contains not less than 90% and not more than 110% of the stated amount of Cefdinir.

1. Identification:

In the assay, the principle peak in the chromatogram obtained with the sample solution should correspond to the peak in the chromatogram obtained with the reference standard solution of Cefdinir.

2. Dissolution Test:

2.1 Dissolution Parameter:

Apparatus: Paddle

Medium: 900ml 0.05 M Phosphate buffer pH 6.8

Speed and Time: 50 rpm and 30 minutes

2.2 Test Solution:

Place 1 tablet in each dissolution vessel and run the apparatus as per above condition and collect the sample solution from each jar at specified time. Filter the resulting solution, dilute if necessary with dissolution medium.

2.3 Reference Solution:

Weigh accurately about 33 mg of working standard of cefdinir and transfer in 100 ml of volumetric flask; dissolve it with about 70 ml of dissolution medium by sonicating for about 10

minutes. Allow the solution to cool to room temperature and make up the volume to 100 ml with dissolution medium. Dilute 2 ml of the resulting solution to 50 ml with dissolution medium.

2.4 Procedure:

Measure the absorbance of the standard and sample solution at about 290 nm.

Calculate the % release of the cefdinir.

2.6 Limit:

D. Not less than 80 % of the stated amount.

3. Assay: Determine by liquid chromatography

3.1 Test solution:

Weigh 20 tablets individually and crush 20 tablets. Weigh accurately the powdered sample equivalent to 25 mg of cefdinir and transfer in 100 ml of volumetric flask, dissolve it with about 70 ml of buffer by sonicating for about 10 minutes. Allow the solution to cool to room temperature and make up the volume to 100 ml with buffer. Centrifuge the solution. Dilute 5 ml of the resulting solution to 25 ml with buffer and filter through 0.2 micron filter paper.

3.2 Reference solution:

Weigh accurately about 25 mg of working standard of cefdinir and transfer in 100 ml of volumetric flask, dissolve it with about 70 ml of buffer by sonicating for about 10 minutes. Allow the solution to cool to room temperature and make up the volume to 100 ml with buffer. Dilute 5 ml of the resulting solution to 25 ml with buffer and filter through 0.2 micron filter paper.

3.3 Chromatographic Condition:

Column: C18 (150 x 4.6 mm; 5 micron)

Flow rate: 1.5 ml/min

Wavelength: 254 nm

Injection Volume: 15 µl

Column Temperature: Ambient

Detector: UV

Mobile Phase:

Buffer: 10.7 g/L of dibasic sodium phosphate and 3.4 g/L of monobasic potassium phosphate. Adjust the pH to 7.0 ± 0.05 with orthophosphoric acid or sodium hydroxide before dilution.

Solution A: 7 g/L citric acid monohydrate. Adjust the pH to 2.0 ± 0.05 with orthophosphoric acid

Mobile phase: Methanol, Tetrahydrofuran and solution A (111:28:1000)

3.4 Procedure:

Inject 15 µl of standard solution of Cefdinir (50 µg/ml of Cefdinir RS and 175 µg/ml of m-hydroxybenzoic acid in buffer – "system suitability solution"). In the chromatogram obtained from the standard preparation, the column efficiency determined from the major peak should not be less than 2000 theoretical plates, the tailing factor should be not more than 2.0 and the relative standard deviation of five replicate injections should be not more than 2.0%.

The resolution should be greater than 3.0 between cefdinir and m-hydroxybenzoic acid (System suitability solution). Inject 15 µl of the sample preparation and chromatograph as per above mentioned chromatographic condition.

Calculate the content of Cefdinir in the tablet.

4.Uniformity of Dispersion:

To pass through a sieve screen with a nominal mesh aperture of 710 µm (sieve number)

5. Other tests: As per pharmacopoeial requirement