DEPARTMENT OF DRUG ADMINISTRATION

National Medicines Laboratory

ANALYTICAL METHOD VALIDATION COMMITTEE

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 test solution should correspond to the peak in the chromatogram obtained with the reference solution of Cefdinir.

Tests:

2. Dissolution:

2.1 Dissolution Parameter:

Apparatus: Paddle

Medium: 900 ml of 0.05 M Phosphate buffer pH 6.8

Speed and time: 50 rpm and 30 minutes

Temperature : 37˚C ± 0.5˚C

Withdraw the suitable volume of the medium and filter.

2.2 Test Solution: Use the filtrate, dilute if necessary with dissolution medium to obtain a solution having concentration similar to that of reference solution. Filter through 0.22 micron filter paper.

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. (13.2 ppm)

2.4 Procedure: Measure the absorbance of the reference and test solution at about 290 nm using dissolution medium as blank solution.

Calculate the percentage release of Cefdinir in each tablet by comparison with the reference solution.

2.5 Limit: Not less than 80 % (D) of the stated amount.

3. Assay: *Determine by Liquid Chromatography*

3.1 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

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

3.3 Test solution: Weigh individually 20 tablets and crush them into fine powder. Weigh accurately the powdered sample equivalent to 25 mg of cefdinir and transfer into 100 ml 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 supernatant solution to 25 ml with buffer and filter through 0.2 micron filter paper.

3.4 Reference Solution: Weigh accurately about 25 mg of working standard of Cefdinir and transfer into 100 ml 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. (50 ppm).

3.5 Chromatographic Condition:

Column: a stainless steel column 15 cm x 4.6 mm, packed with octadecyl silane bonded to porous silica (5 µm),

Flow rate: 1.5 ml per minute,

Wavelength: 254nm

Detector: UV

Injection volume: 15 µl

Column temperature: ambient

Mobile phase: a mixture of 111 volumes of methanol, 28 volumes of tetrahydrofuran and 1000 volumes of solution A,

3.6 System suitability solution: 50 µg/ml of Cefdinir RS and 175 µg/ml of m-hydroxybenzoic acid in buffer.

3.7 Procedure: Inject 15 µl of reference solution five times as per above mentioned chromatographic conditions. 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 %. The resolution should not be less than 3.0 between cefdinir and m-hydroxybenzoic acid (System suitability solution). Inject 15 µl of the test solution and blank solution and calculate the content of Cefdinir in each tablet.

4. Other tests: As per pharmacopoeial requirements.