ANALYTICAL METHOD VALIDATION COMMITTEE FOR NON PHARMACOPOEIAL PRODUCT

DEPARTMENT OF DRUG ADMINISTRATION

Cefdinir Dispersible Tablets

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

1. Identification:

1.1. Cefdinir

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: Cedinir

2.1 Dissolution Parameter:

2.1.1 Medium : 0.05 M Phosphate buffer PH 6.8
2.1.2 Volume :900 ml
2.1.2 Apparatus : Paddle
2.1.3 Rotation : 50 RPM
2.1.4 Temperature : 37˚C ± 0.5˚C
2.1.5 Time : 30 minutes

2.1.6. Dissolution Medium Preparation:

Dissolve 6.8 g of potassium dihydrogen orthophosphate in 1000 ml of water and adjust the pH to 6.8 with dilute sodium hydroxide.

2.1.7 Standard Preparation:

Weigh accurately about 33 mg of working standard of cefdinir and trasfer in 100 ml of voumetric 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.

2.1.9. Procedure:

Measure the absorbance of the standard and sample solution at about 290 nm. Calculate the content of the cefdinir in the dissolution medium by comparision with the cefdinir standard preparation.

2.1.10 Calculation:

Cefdinir (%):

$$=\frac{Area\ of\ spl}{Area\ of\ std} \times \frac{conc.of\ std}{conc.of\ spl} \times std\ potency\ \% \times \frac{100-LOD/WC}{100}\ x\ \mathbf{100}\ \%$$

Result : Cefdinir in %

2.1.11 Tolerance Limit: Not less than 80% D of the stated amount

3 Assay:

3.1 Cefdinir

3.1.1 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 before dilution.

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

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

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

3.1.5 Standard solution: Weigh accurately about 25 mg of working standard of cefdinir and trasfer in 100 ml of voumetric 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.

3.1.6 Sample solution: Weigh 20 tablets individually and crush 20 tablets. Weigh accurately the powder sample equivalent to 25 mg of of cefdinir and trasfer in 100 ml of voumetric 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.

3.1.7 Chromatographic Condition:

Column: C 18 (150 x 4.6 mm; 5 micron)

Temperature: Ambient

Wavelength: 254 nm

Flow rate: 1.5 ml/min

3.1.8 System suitability:

Inject 15 µl of standard solution of Cefdinir as per above mentioned chromatographic condition. 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 not more be 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 result from the formula given below.

3.1.9 Calculation:

Cefdinir per tablet:

$$=\frac{Area\ of\ spl}{Area\ of\ Std} \times \frac{Conc.\ of\ std}{Conc.of\ spl} \times \frac{Potency\ of\ std}{100} \times \frac{100-Water\ \%}{100} \times Average\ Wt.$$

Note

1. Weight variation, friability test and uniformity of dispersion should be as per the Pharmacopoeia recognized by drug advisory committee.