DEPARTMENT OF DRUG ADMINISTRATION
National Medicines Laboratory
ANALYTICAL METHOD VALIDATION COMMITTEE

Cefdinir Tablets

Analytical profile no.: Cefdi T 077/078/AP 096

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

Usual Strength: 300 mg

1. Identification:

In the Assay, the principle peak in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with the reference solution.

Tests:

2. Dissolution:

2.1 Dissolution Parameters: *Deteremine by UV-Vis spectrophotometer*

Apparatus: Paddle

Medium: 900ml of 0.05M phosphate Buffer PH 6.8. Phosphate buffer prepared by dissolving 1.701g potassium phosphate and 0.224g sodium hydroxide in 1000ml of water and adjust pH to 6.8 with 1 M sodium hydroxide.

Speed and Time: 50 rpm and 30 minutes

Withdraw a suitable volume of the medium and filter.

2.2 Test Solution: Dilute 1 ml of the filtrate to 25 ml with dissolution medium.

2.3 Reference Solution: Weigh accurately about 33 mg of Cefdinir WS in 100 ml volumetric flask. Add about 70 ml of dissolution medium and sonicate to dissolve, dilute to 100 ml with dissolution medium and mix. Further dilute 1 ml of the solution to 25 ml with dissolution medium.

2.4 Procedure: Measure the absorbance of the reference and test solutions at the wavelength of maxima at 3290 nm using dissolution medium as blank.

Calculate the content of Cefdinir.

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

3. Assay: *Determine by liquid chromatography*

3.1 Solvent Mixture: Buffer solution of 10.7g/l of dibasic sodium phosphate and 3.4g/l of monobazsic potassium phosphate and Adjusting with phosphoric acid or sodium hydroxide to a pH of 7.0±0.05.

3.2 System Suitability Solution: Weigh and transfer accurately about 50 mg of cefdinir WS and 175mg m-hydroxybenzoic acid into 2 different clean and dry 100ml volumetric flask. Add about 50ml of solvent mixture in both volumetric flask, sonicate for about 10 minutes and dilute to mark with same solvent. Pipette out 5ml of resulting solution from both flask into a 50ml volumetric flask and dilute to mark with solvent.

3.3 Test Solution: Weigh individually 20 tablets & crush the tablet into fine powder. Weigh a quantity of powder equivalent to 25 mg of cefdinir in 100 ml volumetric flask, add about 70 ml of solvent mixture, sonicate for 15 minutes and make volume to 100 ml with same solvent. Further dilute 5 ml of this solution to 25 ml with same solvent.

3.4 Reference Solution: Weigh accurately about 25 mg of cefdinir WS in 100ml volumetric flask. Add about 70 ml of solvent mixture and sonicate to dissolve, dilute to 100 ml with same solvent and mix. Further dilute 5 ml of the solution to 25 ml with same solvent.

3.5 Chromatographic system:

- **Column:** C18, (150 x 4.6 mm), 5 µm
- **Flow rate:** 1.5 ml/min
- **Wavelength:** 254 nm
- **Injection volume:** 15 µl
- **Detector:** UV
- **Mobile Phase:** Methanol, tetrahydrofuran, and solution A (111:28:1000)

  Solution A: 7g/l citric acid monohydrate. Adjust with phosphoric acid to a pH of 2.0±0.05.

3.6 Procedure: Inject system suitability solution. The test is not valid unless the resolution between cefdinir and m-hydroxybenzoic acid is greater than 3. Inject the reference solution. The test is not valid unless the column efficiency is not less than 2000 theoretical plates, tailing factor is not more than 2.0 and the relative standard deviation for replicate injections is not more than 2.0%.

Calculate the content of cefdinir in the tablets.

4. Other tests: As per pharmacopoeial requirement.