**Government of Nepal**
**Ministry of Health and Population**
**Department of Drug Administration**
**National Medicines Laboratory**
**Quality and Method Validation Section**
**Analytical profile of Cefdinir Dispersible Tablets**

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

Cefdinir Dispersible Tablets contains not less than 90.0% and not more than 110.0% of the stated amount of Cefdinir.

**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:** *Deteremine by UV Vis spectrophotometer*

**2.1 Dissolution Parameters:**

**Apparatus:** Paddle

**Medium:** 900ml of 0.05 M Phosphate buffer PH 6.8 **(**Dissolve 6.8 g of potassium dihydrogen orthophosphate in 1000 ml of water and adjust the pH to 6.8 with dilute sodium hydroxide.)

**Speed and Time:** 50 rpm and 30 minutes

Withdraw a suitable volume of the medium and filter.

Determine by *UV Vis spectrophotometer.*

**2.2 Test Solution:** Use the filtrate.

**2.3 Reference Solution:** Weigh accurately about 33 mg of cefdinir RS in 100 ml volumetric flask. Dissolve in 70ml of dissolution medium and make up the volume to 100 ml with dissolution medium. Further dilute 2 ml of this solution to 50 ml with dissolution medium.

**2.4 Procedure:** Measure the absorbance of the reference and test solution at about 290 nm. Calculate the % release of Cefdinir.

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

**3. Assay:** *Deteremine 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 before dilution.

**3.2 Test 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 mix

**3.3 Reference solution:** Weigh accurately about 25 mg of Cefdinir RS 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 mix.

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

**3.5 Chromatographic System:**

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

**Flow rate:** 1.5 ml/min

**Wavelength:** 254 nm

**Injection volume:** 15 µl

**Temperature:** Ambient

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

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

**3.6 Procedure:** Inject 15 µl of reference solution of Cefdinir as per above mentioned chromatographic condition. In the chromatogram obtained from the reference solution, 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 test solution. Measure the peak response and calculate the content of cefdinir.

**4. Other tests:** As per pharmacopoeial requirement.