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NOTE

Validated HPLC Method for Simultaneous Estimation of Cefixime and Cloxacillin in Tablets

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A simple, fast precise and accurate, high performance liquid chromatographic method has been developed for the simultaneous determination of cefixime and cloxacilin in tablets. A kromasil C-18 RP (150 × 4.6 mm) X4μ column was used. The mobile phase used was mixture of buffer pH 6.5 and acetonitrile in 65:35 v/v. The flow rate was 1.2 mL/min and eluent was monitored at 225 nm. The retention times of cefixime and cloxacillin were 4.99 and 13.837, respectively. Recovery of cefixime and cloxacillin were 100.05 and 102%, respectively. The proposed method is precise, accurate selective, reproducible and rapid for the determination of cefixime and cloxacillin from marketed tablet formulation.

Key Words: Cefixime, Cloxacillin, HPLC.

Cefixime is third generation oral cephalosporin, effective against a wide spectrum of sensitive gram positive, gram negative and anaerobic bacterial pathogens including β-lactamase producing strains[1]. Cefixime is available as cefixime trihydrate. Cloxacillin is semi-synthetic penicillin, food interferes with its absorption from gut. Several spectroscopic and chromatographic methods are reported for the analysis of each drug individually[2-7].

The high performance liquid chromatographic instrument used was waters 2695 (separatin module) of model-alliance (auto sampler).

The solvents used were of HPLC grade and other chemicals used were of AR grade from Ranchem Ranbaxy. Standard cefixime and cloxacillin and formulation were procured from Alembic.

Chromatographic conditions: When several mobile phase were tried the mobile phase containing the mixtures of buffer pH 6.5 and acetonitrile (65:35 %) was found to be optimum. A reverse phase column kromosil C-18 RP (4.6 mm × 150 mm, X4μ packing) was used. Mobile phase flow rate was 1.2 mL/min and eluent was monitored at 225 nm. This wavelength was chosen because both drugs absorbed at this wavelength without interference from tablet excipients. Injection volume was 20 μL.

Preparation of stock solutions: 56 mg cefixime and 125 mg of cloxacillin sodium was weighed in 50 mL volumetric flask 20 mL of phosphate buffer with pH 7.2 was added into it and sonicated to dissolve. Then volume was made to 50 mL with phosphate buffer of pH 7.2 and mixed. 5 mL of resulting solution was further diluted to 25 mL with mobile phase.

Preparation of buffer pH 6.5: Diluted 50 mL of tetrabutyl ammonium hydroxide 20 % solution to 1000 mL of water and adjust the pH to 6.5 ± 0.05 with orthophosphoric acid.

Preparation of phosphate buffer pH 7.2: 6.8 g of potassium dihydrogen phosphate and 1.5 g of sodium hydroxide were transferred into 1 L beaker, in that 800 mL distilled water was added to dissolve it. pH was adjusted 7.2 by adding in NaOH and finally the volume was made up 1000 mL with distilled water.

Standard solution: 56 mg of cefixime and 125 mg of cloxacillin sodium were weighed accurately into 50 mL volumetric flask. Then 20 mL phosphate buffer of pH 7.2 was added and sonicated to dissolve. Volume was made up to 50 mL with phosphate buffer of pH 7.2 then mixed. It was further diluted 5 mL of resulting solution to 25 mL with mobile phase.

Sample preparation: Powder of tablets equivalent to 100 mg of cefixime and 250 mg of cloxacillin was accurately weighed and transferred into 100 mL volumetric flask and 75 mL of phosphate buffer of pH 7.2 was added into it and sonicated for 0.5 h. Then cooled to room temperature and diluted to 100 mL with phosphate buffer of pH 7.2. It was filtered with filter paper no. 1 and rejected first few mL of filtrate 5 mL of the filtrate was diluted to 25 mL with mobile phase.

Validation: The method was validated according to ICH guidelines for accuracy precision selectivity, linearity and range.

The proposed method gives good resolution between cefixime, cloxacillin and co-extracted tablet excipients within a short analysis time (< 10 min) The method is very simple, rapid and does not involve complicated sample preparation. Percentage of recovery shows that the method is free from interference of the excipients used in the formulation. Therefore, the method can be useful in routine quality control analysis of these drugs (Table-1).

TABLE-1

Cefixime			Cloxacillin		
Amount added (mg)	Amount found (mg)	Percentage recovery	Amount added (mg)	Amount found (mg)	Percentage recovery
5	5.03	100.04	5	5.08	100.01
10	10.04	100.04	10	10.24	102.40
12	12.02	100.16	12	12.40	103.30
	Mean	100.05		Mean	102.00

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