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RP-HPLC Estimation of Cefdinir in Capsules

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A simple efficient and reproducible method for the determination of cefdinir in capsules has been developed using reversed phase high performance liquid chromatographic method. The elution was done using a mobile phase consisting of 0.01 N KH_2PO_4 (pH 6.9) and methanol (80:20% v/v) on Water's- Spherisorb ODS 4.6x150 mm analytical column with flow rate of 1 ml/min with detection at 285 nm. An external standard calibration method was employed for quantitation. The elution time was 2 min. The linearity range was 5-10 µg/ml for cefdinir.

Cefdinir[1] is a cephalosporin antibiotic. Chemically the drug is (6R-[6α,7β(Z)]]-7-[[2-aminothiazolyl)(hydroxyimino) acetyl]amino]-3-ethenyl-8-oxo-5-thia-1-azabicyclo[4.2.0]oct-2ene-2-carboxylicacid. A capsule formulation is available, which contains 300 mg cefdinir. HPLC-based analytical methods have been reported for the estimation of cefdinir in biological fluids[2,3]. These methods describe the determination cefdinir and related substances or estimation of cefdinir in plasma. No method has so far been reported for the estimation of cefdinir from pharmaceutical dosage forms. The present paper aims at reporting an isocratic RP-HPLC method for the determination of cefdinir in capsules.

The apparatus used was a Shimadzu HPLC SPD 10-A chromatograph equipped with fixed wavelength UV detector and model 7725i Rheodyne injector with 20 µl external loop. The column used was Water's Spherisorb ODS 4.6x150 mm analytical column the elution was carried out isocratically at the flow rate of 1 ml/min using KH_2PO_4 (0.1 N) at pH 6.99 and methanol 80:20% v/v as mobile phase. The detector was set at wavelength of 285 nm. Responses of peak areas were recorded and integrated using software.

Cefdinir was obtained from Unichem Pharmaceutical Limited, Mumbai with certificate of analysis. Methanol HPLC grade and potassium dihydrogen orthophosphate AR grade were obtained from S. D. Fine Chemicals Ltd., Mumbai.

Standard stock solutions of the drug were prepared by dissolving 25 mg of cefdinir in KH_2PO_4, pH 6.99 and made up to 25 ml with the same (solution A, 1000 µg/ml). From the above solution 1 ml was taken and made up to 10 ml (100 µg/ml.). From the above solution 2.5 ml was taken and made up to 25 ml (10 µg/ml) (solution B). The gradient dilutions were prepared by taking 5, 6, 7, 8 and 9 ml of solutions B and made up to 10 ml in a standard flask with mobile phase. These standard solutions were injected and peak area was obtained. A calibration graph was constructed.

Not less than 20 capsules (Sefdin, Unichem laboratories Ltd., Mumbai) were weighed and emptied. A quantity of

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TABLE 1: ANALYSIS RESULTS

Drug	Amount (mg/cap)		% label claim*	% recovery*
	Labeled	Found*		
Cefdinir	300	304.5±0.21	101.5±0.12	98.7±0.15

*Mean of 6 observations

TABLE 2: SYSTEM SUITABILITY PARAMETERS

Parameters	Cefdinir
Resolution	-
Capacity factor	1.2
Asymmetry factor	1
Number of theoretical plates	13,001
LOD (ng/ml)	0.01
LOQ (ng/ml)	0.1

Figures indicate ideal chromatographic separation of cefdinir.

powder equivalent to 1 mg of cefdinir was then extracted with 10 ml buffer. From this 0.6 and 0.9 ml samples were taken and their volume was made up to 10 ml each. A chromatogram of these solutions was obtained by injecting 20 µl of each sample into the chromatographic system. The amount of cefdinir present per capsule and percentage labeled claim was shown in Table 1. There was no interference from diluents and lubricants. Analytical recovery studies were carried out from a series of spiked concentrations added to the pre analyzed dosage form. (Table 1). The drug solution stored under refrigeration was stable up to 12 h, while the solution stored under room temperature was stable up to half an hour only.

The retention time of the drug was 2 min. The system suitability parameters were calculated to confirm the specificity of the developed method and shown in Table 2. The high percentage recovery and low percentage deviation (Table 1) was satisfactory and confirms the accuracy, precision and reliability of the method. The present method can be used for the routine analysis of cefdinir in formulation.

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Visible Spectrophotometric Methods for the Determination of Azithromycin in Tablets

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Two visible spectrophotometric methods have been developed for the estimation of azithromycin in pure and in pharmaceutical formulations. The first method (A), a visible spectrophotometric

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