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REVERSE PHASE HPLC METHOD FOR THE ANALYSIS OF CEFADROXIL IN PHARMACEUTICAL DOSAGE FORM

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ABSTRACT

A Simple, rapid and precise reverse phase liquid chromatographic method has been developed for the analysis of cefadroxil in bulk drug and tablet dosage form using C18 column. The mobile phase methanol: water (60:40 v/v) was pumped at flow rate of 1.0 ml/min and eluent was monitored at 264nm. Linearity was obtained in the concentration range of 5-30 µg/ml. the method was statistically validated and RSD was found to be less than 2% indicating high degree of accuracy and precision of proposed HPLC method. Due to its simplicity, rapidness, high precision and accuracy, the proposed HPLC method may be used for determining Cefadroxil in bulk drug and in pharmaceutical dosage form.

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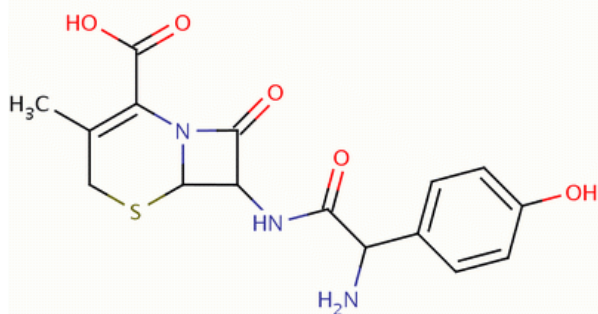
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Key Words

Cefadroxil, High Performance
Liquid Chromatography,
Estimation.

INTRODUCTION

Cefadroxil chemically a 7-[[2-amino-2-(4-hydroxyphenyl) acetyl] amino]-3-methyl-8-oxo-5-thia-1-azabicyclo, [4.2.0] oct-2-ene-2-carboxylic acid^[1].



It is Long-acting, broad-spectrum, cephalosporin derivative. Like all beta-lactam antibiotics, cefadroxil binds to specific penicillin-binding proteins (PBPs) located inside the bacterial cell wall, causing the inhibition of the third and last stage of bacterial cell wall synthesis. Cell lysis is then mediated by bacterial cell wall autolytic enzymes such as autolysins; it is possible that cefadroxil interferes with an autolysin inhibitor. Literature survey reveals that

UV^[2,3], HPLC^[4,5] methods have been reported for the estimation of Cefadroxil. New methods by using hydrotope are there for the determination of cefadroxil^[6]. Also cefadroxil was qualitatively assayed in biological fluids either individually or in presence of other antibacterial drugs using liquid chromatography^[7]. However no simple, economic, rapid HPLC method was proposed for the estimation of cefadroxil in bulk and pharmaceutical dosage forms. The aim of this work is to develop and validate an analytical method by using HPLC for the estimation of cefadroxil in bulk and pharmaceutical dosage forms as per ICH guidelines^[8].

MATERIAL AND METHOD: -

EXPERIMENTAL

Cefadroxil was obtained as gift sample from Shri. Swami Samarth Pharmaceuticals Ltd., Maharashtra, India. Methanol used was of HPLC grade (Qualigens). All other reagents used in the study were of AR grade (Qualigens).

An isocratic HPLC system (Younglin Instrument) with UV detector and RP- C18 column (25cm×4.6mm i.d; 5 μ) was used with Autochrom-3000.

Preparation of stock solution

Cefadroxil (CF) Standard Stock Solution: (1000 μ g/ml)

Standard CF (10mg) was accurately weighed and transferred to 10 ml volumetric flask and dissolved with methanol and volume was made up to the mark with methanol.

Chromatographic Conditions:

The mobile phase consisting of Methanol: Double distil water (60:40) were filtered before use through 0.45 μ membrane filter and was pumped at a flow rate of 1 ml/min in the ratio of 60:40. The separation was carried out on aC18 column (5 μ m, 250X 4.6mm i.d). The column temperature was maintained at 28 $^{\circ}$ C. The sample was injected and was analyzed by variable wavelength detector set at 264.0 nm. The data was acquired, stored and analyzed using Autochrom-3000.

Procedure:

The standard stock solution of each drug was suitably diluted with the mobile phase to obtained standard solutions of different concentrations. Each standard solution was injected six times into the column at a flow rate of 1 ml/min. The optical parameters and system suitability parameters are as mentioned in table 1. Good linearity was obtained in the concentration range 5-30 μ g/ml.

Table No. 1: ASSAY OF TABLET FORMULATION

Formulation	Actual concentration (mg)	% CF (n =3)
Tablet	500	100.014 \pm 0.039

Assay of tablet formulation:

Twenty tablets were weighed accurately and the average weight was determined and triturated to a fine powder. A quantity equivalent to 500 mg of CF was weighed and transferred to a 50 ml volumetric flask. The contents were sonicated for 20 min. and made up the volume with methanol (I). Take 1 ml from (I) and made up the volume to 10ml with mobile phase (II).

Again take 1ml from (II) and diluted to 10ml with mobile phase (III). Take suitable aliquot of the (III) solution was further diluted with mobile phase to obtain sample solution within the concentration range for CF. The sample solution was injected into sample injector with 20 μ l loop three times under the chromatographic conditions described above. The area under the curve of each peak was measured at 264.0 nm. The amount of drug present in the sample solution was determined using the prepared calibration curves of standard CF.

The developed HPLC method was used to quantify CF in the formulation. The % drug content was found to be 99.66. The result of formulation analysis and its statistical analysis are given in Table No.1 which

indicates high degree of precision of the proposed method. The proposed HPLC method was also validated as per ICH guidelines.

Precision:

ICH has defined the precision to contain three components: repeatability, intermediate precision and reproducibility. Repeatability and Intraday and Inter day precision was determined by repeating assay three times on same day for intraday and on different days for inter day precision (Table No.2 and Table No. 3 respectively.).

Table No. 2. REPEATABILITY OF CF

Sr. No.	Concentration (μ g/ml)	Area of CE	t _R of CF
1	10	1567.5974	3.7167
2	10	1568.3652	3.7100
3	10	1567.1641	3.7133
4	10	1567.5438	3.6967
5	10	1568.1641	3.7033
6	10	1566.1641	3.7133
7	10	1567.9528	3.7000
8	10	1566.3888	3.6833
9	10	1568.1156	3.6933
10	10	1567.2653	3.6956
Mean		1567.4721	3.7026
S.D		0.743	0.011
R.S.D		0.047	0.289

Table No. 3 DETERMINATION OF PRECISION FOR CF

Conc. (mg/ml)	Intra-day (n=3)	CV	Inter-Day (n=3)	CV
5	827.970 ± 0.263	0.032	824.462 ± 0.637	0.077
10	1570.335 ± 0.869	0.055	1567.523 ± 0.634	0.040
15	2835.530 ± 0.547	0.019	2825.891 ± 0.304	0.011

Accuracy:

To check the accuracy of the proposed method, recovery studies were carried out at 80, 100 and 120 % of the test concentration as per ICH guidelines. The

results of the recovery studies and its statistical validation data given in Table No.4 indicate high accuracy of the proposed method.

Table No.4 RECOVERY STUDIES AND ITS STATISTICAL VALIDATION DATA

Sr. No.	Amt of drug sample	Amt. of drug added	Amount Recovered (n=3)*	% Recovery (n=3)*	S.D.	% R.S.D.	STD. Error
1	10	8	7.96	99.56	0.65	0.65	0.3751
2	10	10	10.01	100.10	0.78	0.78	0.4491
3	10	12	11.98	99.87	0.41	0.41	0.2347

* Denotes average of three determinations at each level of recovery.

Ruggedness:

To evaluate the ruggedness different analysts were used and the results are given in Table No.5

Table No. 5: DETERMINATION OF RUGGEDNESS

Sr. No.		% Label Claim Estimated
		CE
1	Analyst I	99.904
2	Analyst II	99.825
	Mean	99.86
	SD	0.056
	%RSD	0.06
	Standard Error	0.039

Robustness:

To evaluate the robustness of the developed method, deliberate variations were made in the method parameters such as the flow rate, ratio of mobile phase and the column temperature.

RESULTS AND DISCUSSION

The goal of this study was to develop a rapid and sensitive HPLC method for the analysis of CF in bulk drug samples and its formulation using the most commonly employed RP-HPLC with C18 column with UV detection. The mobile phase consisted of Methanol and double distilled water in the ratio of 60:40. The retention time for CF was 3.733 min (Figure 1). The peak areas of the drugs were reproducible as indicated by RSD values which are less than 2%. The results of the formulation analysis, recovery studies and its statistical validation data (Table No.6) indicate high degree of precision and accuracy of the proposed method.

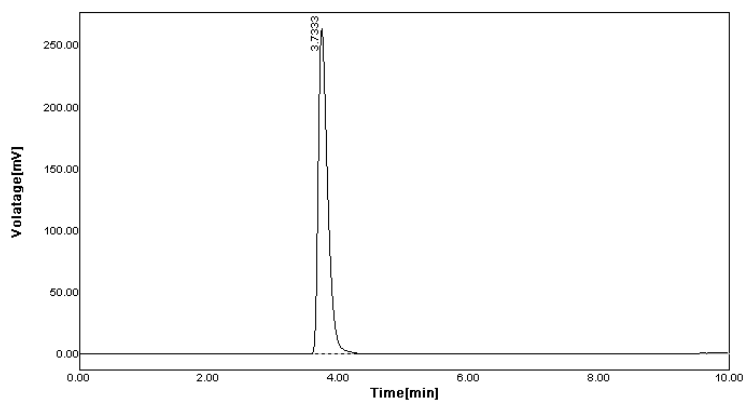


Figure 1: Typical Chromatogram of Cefadroxil.

Table No.6 VALIDATION AND SYSTEM SUTIALITY STUDIES

Parameters	CF
Linear Range (mg/ml)	5-25 mg/ml
Slope	207.7
Intercept	-324.5
C.V.	0.9955
Retention Time (t_R)	3.733
Theoretical Plate Number (N)	2782.4
Tailing Factor (A_s)	1.5

Hence it can be concluded that the developed RP-HPLC method can be employed successfully for the estimation of Cefadroxil in both bulk and Pharmaceutical formulation.

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