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DETERMINATION OF CEFIXIME TRIHYDRATE AND CEFUROXIME AXETIL IN BULK DRUG AND PHARMACEUTICAL DOSAGE FORMS BY HPLC

***K. Azhagesh Raj, Divya Yada, Deepthi Yada, C. Prabu, S. Manikantan**

Department of Pharmacy, Annamalai University, Annamalai Nagar, Chidambaram,

Post Code No.608002, Tamil Nadu, India.

****E-mail: azhageshraj@yahoo.com***

ABSTRACT: The simple, reliable and reproducible HPLC methods were developed for analysis of cefixime trihydrate and cefuroxime axetil. The column used was Merck C-18 analytical column(100 x 4.6 mm,5µm packing). The mobile phase used was a mixture of methanol:water (90 : 10 v/v) and run at the flow rate of 1ml/min with UV detector at 254 nm at ambient temperature. Evaluation of cefixime and cefuroxime from tablet were carried out using methanol. Assay of cefixime and cefuroxime were carried out and potency was found to be 99 and 99 respectively. The method is suitable for routine analysis of the drug.
KEY WORDS: Cefixime trihydrate, Cefuroxime axetil, HPLC analytical method.

INTRODUCTION

The chemical name of cefixime trihydrate[9] is 5-Thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylic acid, 7-[[(2-amino-4- thiazolyl) [(caroxymethoxy) imino] acetyl]amino]-3-ethenyl-8-oxo-trihydrate.[3][5]

The chemical name of cefuroxime axetil[9] is 5-Thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylic acid, 3-[[(amino carbonyl) oxy] methyl]-7-[[2-furanyl (methoxy imino)acetyl] amino-8-oxo-1-(acetoxy)ethyl ester.[3][5]

Cefixime is effective against a wide spectrum of sensitive Gram –Ve, Gram +Ve and anaerobic bacterial pathogens including β- lactamase producing strains.

Cefuroxime is effective against β- lactamase, Haemophilus influenzae, Neisseria gonorrhea and lyme disease.

EXPERIMENTAL WORK

Apparatus and chromatographic condition

The analysis was performed by using HPLC, column used is Merck C -18 analytical column (100 x 4.6 mm, 5µm packing) with flow rate of 1ml/min. The mobile phase consists of a mixture of methanol : water (90 :10 v/v). An injection volume was 20µl from 100µg/ml solution and UV detector was used at 254nm[2][4].

Reagents and solutions

Pure cefixime trihydrate and cefuroxime were obtained/ collected from Atoz Pharmaceutical Pvt. Ltd., Solvent Water and Methanol used were of HPLC and milli-q-grade[6].

Standard preparation

1000µg/ml solution of drug was prepared by weighing 50mg of the pure drug into 50ml volumetric flask and dissolving the material in about of 10ml of water and diluted to 50ml with mobile phase is filled in flask. A 100µg/ml stock solution was prepared by diluting 5ml of the 1000µg/ml solution and diluted to 50ml with mobile phase. Standard solution of 100µg/ml was prepared[4].

Sample preparation

20 tablets were weighed and the average weight was found. Tablets were powdered. Tablet powdered.

Tablet powder equivalent to 50mg of cefixime trihydrate and cefuroxime axetil was weighed accurately into 50ml volumetric flask and material was dissolved in about 10ml of water and diluted with 50ml of mobile phase. A 100µg/ml solution was prepared by diluting 5ml of 1000µg/ml solution diluted to 50ml with mobile phase. Solution containing 100µg/ml was prepared[4].

Assay

20µl of standard and sample solution were injected into an injector of liquid chromatography, from the peak area of liquid chromatography, from the peak area of cefixime and cefuroxime, amount of drug in samples were computed.[1][7-8]

RESULTS AND DISCUSSION

The HPLC procedure was optimized with a view to develop an accurate andstable assay method. Merck C -18 analyical column (100 x 4.6 mm ,5µm packing) with mobile phase of a mixture of methanol : water (90 : 10 v/v). The flow rate was 1ml/min, ideal compounds were analyzed at 254nm. Evaluation of two drugs was performed with UV detector at 254nm. Peak area for all peaks and graphs were obtained. Fig – 1 for Cefixime trihydrate and Fig- 2 for Cefuroxime axetil respectively.

The assay procedures were repeated for six times and the percentage of drugs were found to be given in table 1 and potency was found to be 99.

CONCLUSION

The proposed HPLC method gives good resolution between Cefixime and Cefuroxime with short analysis time (less than 8 min).The method is simple, rapid and no complicated sample preparation is needed.

Table 1: Analysis of cefixime and cefuroxime

drug	Brand name	Wt. of the std(gm)	Average weight (gm)	Weight of the sample(gm)	Standard area(%)	Area of test	Content (mg)
Cefixime	Biotax	49.7	200.42	75.13	100	3265.555	99.7
Cefuroxime	Ceftum	49.7	136.58	51.5	100	2637.321	249.6

FIG NO 1: HPLC Chromatogram for Cefixime trihydrate

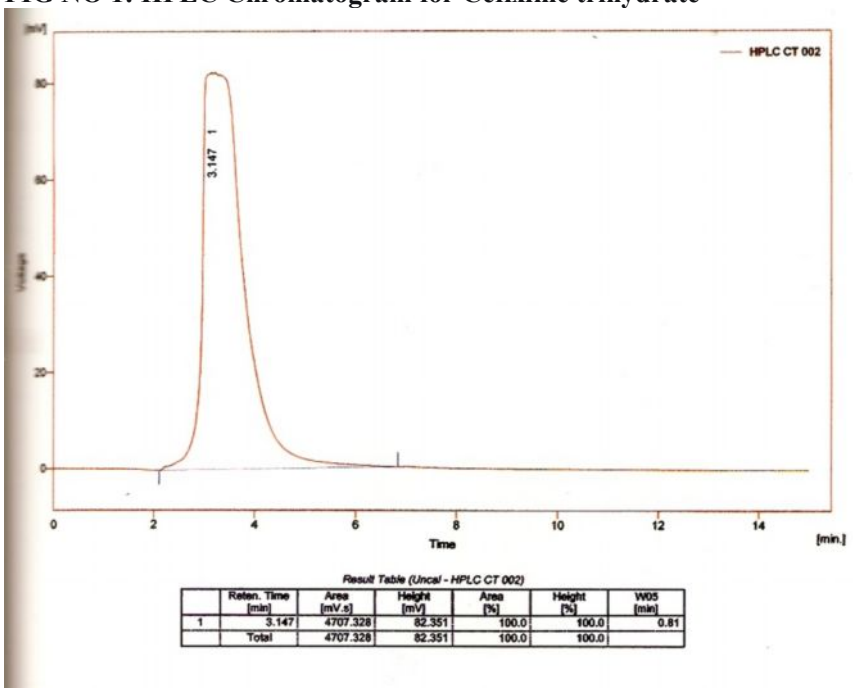
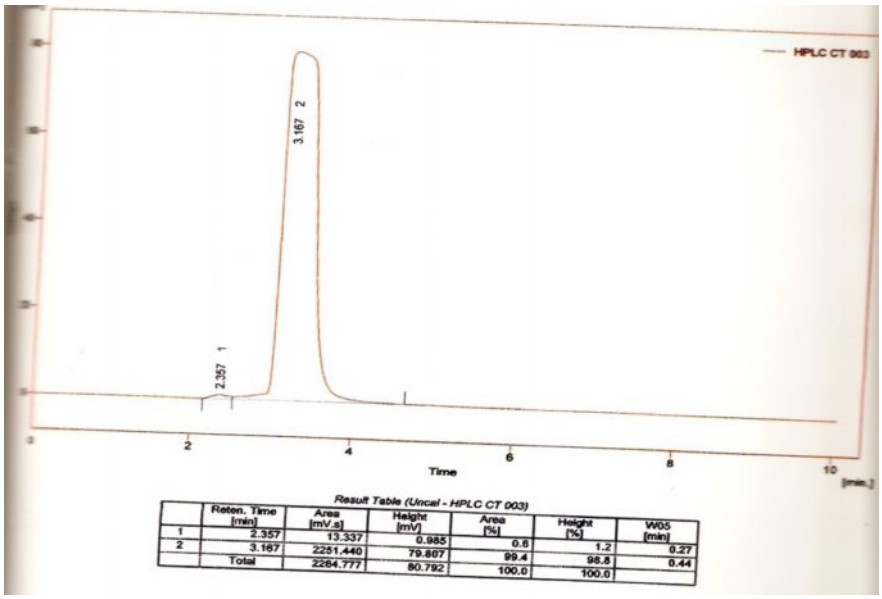


FIG NO 2: HPLC Chromatogram for Cefuroxime axetil



Result Table (Uncal - HPLC CT 003)

	Reten. Time [min]	Area [mV.s]	Height [mV]	Area [%]	Height [%]	W05 [min]
1	2.357	13.337	0.985	0.6	1.2	0.27
2	3.167	2251.440	79.807	99.4	98.8	0.44
	Total	2264.777	80.792	100.0	100.0	

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