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Research Article

DEVELOPMENT OF UV SPECTROPHOTOMETER METHOD OF CEFIXIM IN BULK AND PHARMACEUTICAL TABLET DOSAGE FORMULATION

P.G.Bhange[1]*, A.P.Mehere[2], P.P.Katolkar[2]

1. Department of Chemistry, Manoharbhai Patel Institute of B.Pharmacy College, Gondia.
2. Department of Chemistry, Shared Pawar College of Pharmacy, Nagpur

***Corresponding Author: Email** poo200511@yahoo.co.in

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ABSTRACT

The simple, precise and economic UV methods have been developed for estimation of Cefixime in single component. Cefixime has the absorbance maxima in zero order spectra in 230 nm (method A). Method B applied was first order derivative for the analysis of Cefixime at 238.5 nm .Method C applied was area under curve in the wavelength range of 234-228 nm. Drug followed Beer-Lamberts law in the concentration range of 503.5 µg/ml for zero order, 10-60 µg for area under curve methods and first order derivative spectrum. The percentage recovery of Cefixim ranged from 98.05 to 101.075 in pharmaceutical dosage from result of analysis was validated statistically and by recovered study.
Keywords: Cefixim, ultraviolet spectrophotometer, zero order spectra, first order spectra and area under curve.

INTRODUCTION

Cefixime (CFX) ((6*R*, 7*R*)-7-[(Z)-2-(2-amino-4-thiazolyl)-2-(carboxy-methoxyimino)acetamido]-8-oxo-3 vinyl-5-thia-1-azabicyclo-[4,2,0]-oct-2-ene-2-carboxylic acid), is an Orally absorbed third generation cephalosporin antibiotic. It has a broad antibacterial spectrum against various gram-positive bacteria and gram-negative bacteria, including Haemophilus influenzae, Neisseria gonorrhoeae, Escherichia coli, and Klebsiella pneumoniae resistant to ampicillin, cephalexin, cefaclor, and trimethoprim- sulfamethoxazole. Ambroxol, (AMB) *trans*-4-(2-amino-3, 5-dibromobenzylamino) cyclohexanol hydrochloride is a compound with potent mucolytic activity, for which it is used as an expectorant and bronchosecretolytic in therapeutics [1-5]. The structures of drugs are shown in (Fig.1). Literature survey revealed many chromatographic methods for determination of Cefixime alone or in combinations with other drugs from pharmaceutical formulations and biological fluids [6-10].. Aim of present work was to develop simple, economical,rapid, precise and accurate method for determination of single drug by using spectrophotometer.(U.V).

MATERIAL AND METHODS:

Method: Material

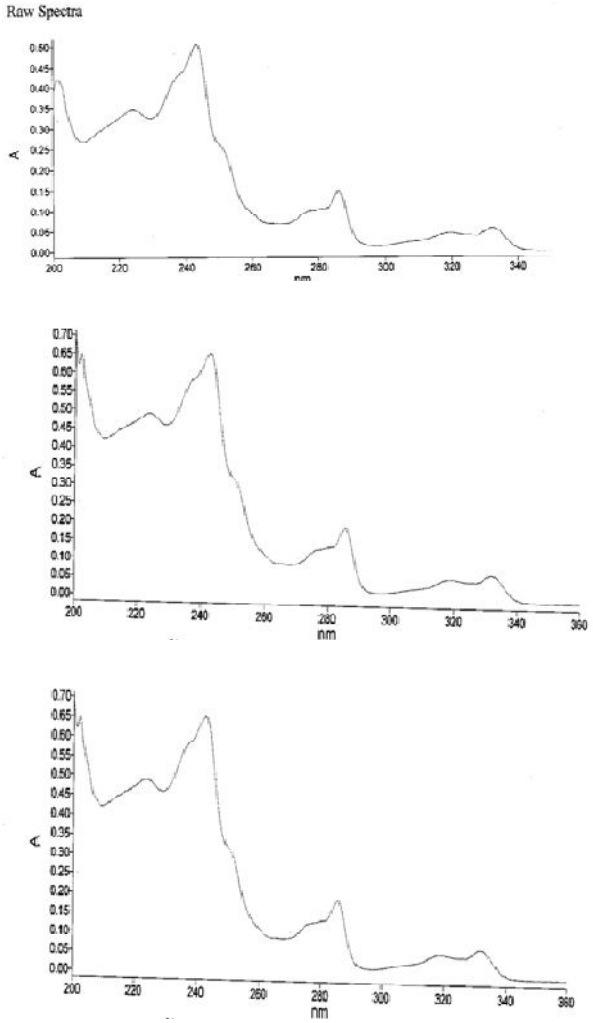
Accurately about 10mg of cefixim was weighed and transferred to 100 ml volumetric flask, 25ml methanol added to dissolve drug then volume was made up with distilled water up to the mark to give the drug stock solution of concentration 100g/ml. Aliquots of standard stock solution were pipette out and suitable diluted with distilled water to get final concentration of standard solution. in zero order

spectrum method at n=6 showed a sharp peak at 230nm.(fig1).the absorbance difference at n=(d A/D)is calculated by the inbuilt source of the instrument which was directly proportional to the concentration of the standard solution. the standard drug solution was diluted so as to get the final concentration in the range of 5-35 g/ml and scanned in zero order spectra. The calibration curve of dA/d against concentration of the drug showed linearity (table2).similarly for first order derivative same method was employed at n=6 showed a sharp peak at 238.5nm (fig 2). The standard drug solution was diluted so as to get the final concentration in the range of 10-50microgram/ml and scanned in first order derivative spectra. The calibration curve of dA/d against concentration of the drug showed linearity (table 3).

The AUC method involves the calculation of integrated value of absorbance with respect to the wavelength between two selected wavelength lambda1 and lambda2 area calculation processing item calculation the area bound by the curve and the horizon axis (fig 3). The horizons axis is selected by entering the wavelength range over which the area has to be calculated .the wavelength range is selected on the basis of repeated observation so as to get the linearity between area under curve and concentrated (tablet).Suitable dilution of standard stock solution (100m/g)of the drug were prepared and scanned in the spectrum mode from the wavelength range 400-200nm and the calibration curve was plotted. All the three methods were checked by analyzing the sample with known concentration. All three methods were validated according to ICH guidelines by carrying out analysis of single component.

For estimation of cefixime in tablet formulation twenty tablet of the brand were weighed and triturated to fine powder. The powder equivalent to 10mg of cefixim was weighed and dissolved in 25ml alcohol and further dilute with quantity of sufficient with distilled water. It was kept for ultra sonification for 45min this was then filtered whatman filter paper no 41 to get stock solution of concentration of 100microgram /ml various dilution of the tablet solution were prepared and analyzed for six times and concentration was calculate by using the calibration curve (table-5). recovery study were carried out at three different level i.e. 80%,100% and 120% by adding the pure drug (8,10 and 12mg) to previsiously analyzed tablet powder sample from the amount drug founds, percentage recovery was calculated (table 7)

Fig. Raw Spectra



RESULT AND DISCUSSION

All the three methods A, B and C for estimation of cefixim in single component from were found to be simple , accurate and reproducible, beer lambert law was obeyed in the concentration range of 10-60mg/ml for first order and area under curve method and 5-35mg/ml for zero order in the derivative spectra (table 1). The validation of the proposed method was further confirmed by recovery study data clearly indicate the reproducibility and accuracy of method. The value of standard deviation was satisfactory (table 6). The recovery value for cefixim ranged from 98.05 to 101.07% (table 7).

Table 1: Optical characteristic and other for cefixim.

Parameters	method A	method B	method C
Max(nm)/wavelength range (nm)	230	238.5	234-228
Beer 'lamberts range (nm)	5-35(mg/ml)	10-60	10-60
Coefficient of correlation ($r^{2)}$	0.9994	0.9994	0.9995
Regression equation's=mx+c	0.0259x-0.0038	0.0025+.004	0.1893x-0.0684
A-slope (m)	0.0259	-0.0025	0.1893
b- Intercept (c)	-0.0038	0.0004	-0.0684
LOD	0.0229	0.33	0.0038
LOQ	0.694	1	0.0118
Molar absorptive	$5.2*10^2$	$1.18*10^3$	$3.94*1^2$

Table 2: Statistical validation by zero order spectrum method

Parameter	Means	S.D	C.O.V	S.E
r^2	0.9994	0.00018	0.018	0.000073
Slope	0.026	0.00049	1.88	0.0002
Intercept	0.0	0.0	0.0	0.0

Table 3: Statistically validation by first order spectrum method

Parameter	Means	S.D	C.O.V	S.E
r^2	0.9994	0.00025	0.025	0.0001
Slope	0.0027	0.09	3333	0.036
Intercept	0.0	0.0	0.0	0.0

Table 4: Statistically validation by first order under curve method

Parameter	Means	S.D	C.O.V	S.E
r^2	0.9995	0.00023	0.023	0.0009
Slope	0.1893	0.00000007	0.000037	$02.9*10^{-18}$
Intercept	0.0	0.0	0.0	0.0

Table5: Analysis of tablet formulation

Sr. no	Tablet sample	Amount % (mg/tab)	Amount found (mg/Tab)	% of tablet claim
1	T1	10	10.05	100.5
2		10	9.85	98.5
3		10	10.14	101.5

Table6: analysis of tablet formulation

Sr. no	Tablet sample	% mean	S.D	C.O.V	S.E
1	T1	100.16	1.2	1.243	0.716

Table7: Statistical evaluation of tablet formulation

Ingredient	Level of Addition	Tablet amount	Amount added	Amount recovered	% recovery	Average recovery
1	80	10	8	17.65	98.05	99.43
2	100	10	10	20.34	101.7	
3	120	10	12	21.68	98.54	

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