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Spectrophotometric estimation of Cefixime and Ofloxacin in tablet formulation

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ABSTRACT

The study aims to develop simple, sensitive, rapid, accurate and precise spectrophotometric method for estimation of cefixime and ofloxacin in tablet dosage forms. Pure drug samples of cefixime and ofloxacin were dissolved in a mixture of methanol and 0.1N HCl (1:1). Two wavelengths selected for formation and solving the simultaneous equations were 285.8nm for cefixime and 296.6nm for ofloxacin. Absorptivity coefficients for cefixime at 285.8nm and 296.6nm were 61.14cm-1gm-1l and 65.68cm-1gm-1l, respectively, while the respective values for ofloxacin were 75.33cm-1gm-1l and 103.62cm-1gm-1l. The recovery studies were found close to 100 % that indicates accuracy and precision of the proposed methods. The statistical analysis was carried out and results of which were found satisfactory. Standard deviation values were found low that indicated reproducibility of the proposed methods. Based on results the developed methods could be used for routine estimation of cefixime and ofloxacin from combined dosage formulations.

Keywords: Spectrophotometric, cefixime, ofloxacin, Quantitative estimation.

INTRODUCTION

Cefixime (CEF) is an oral third generation cephalosporin antibiotic. Chemically, it is (6*R*,7*R*)-7-{[2-(2-amino-1,3-thiazol-4-yl)-2-(carboxymethoxyimino)acetyl]amino}-3-ethenyl-8-oxo-5-thia-1-azabicyclo-[4.2.0]oct-2-ene-2- carboxylic acid, clinically used in the treatment of susceptible infections including gonorrhea, otitis media, pharyngitis, lower respiratory-tract infections such as bronchitis, and urinary-tract infections [1]. Ofloxacin (OFL) is a fluoroquinolone derivative.

Chemically, it is (±)-9-fluoro-2, 3-dihydro-3-methyl-10- (4-methyl-1-piperazinyl)-7-oxo-7H-pyrido-[1,2,3-de]- 1,4-benzoxazine -6-carboxylic acid [2]. It is mainly used as antibacterial for the treatment of urinary tract infection and sexually transmitted diseases. Ofloxacin is official in USP [3] and BP [4]. Literature survey reveals that cefixime can be estimated spectrophotometrically [5], HPLC [6-10] and by HPTLC [11] individually or with other drugs in bulk drugs and in human plasma. A number of methods have been reported for estimation of ofloxacin individually or in combination with other drugs [12-18]. However, there is no analytical method reported for the estimation of CEF and OFL in a combined dosage formulation. Present work describes simultaneous estimation of CEF and OFL in tablet formulations.

EXPERIMENTAL SECTION

Materials

Shimadzu UV 1700, UV/Vis double beam spectrophotometer with spectral bandwidth of 1nm, wavelength accuracy of ±0.3nm and 1cm matched quartz cells was used for analytical method development. All the chemicals and reagents used were of analytical grade. Double distilled water was used for the preparation of 0.1N HCl. The tablet samples of combined dosage forms of cefixime and ofloxacin [ZIMNIC-O and ZOFIXI-OF] were procured from the local market.

Methods

Pure drug samples of cefixime and ofloxacin were dissolved in a mixture of methanol and 0.1N HCl (1:1) so as to give five dilutions of standard in concentration range of 5-40µg/ml for cefixime and 2.5-20µg/ml for ofloxacin. All the solutions were scanned in the wavelength range of 285.8nm and 296.6nm. Figure 1 represents the overlain spectra of cefixime and ofloxacin. Two wavelengths selected for formation and solving the simultaneous equations were 285.8nm for cefixime and 296.6nm for ofloxacin. Linearity was observed for cefixime (CEF) in the concentration range of 5-40 µg/ml and for ofloxacin (OFL) in the concentration range of 2.5-20 µg/ml (Figure 2). Absorptivity coefficients of both the drugs were determined at selected wavelengths. Absorptivity coefficients for cefixime at 285.8nm and 296.6nm were 61.14cm-1gm-1l and 65.68cm-1gm-1l, respectively, while the respective values for ofloxacin were 75.33cm-1gm-1l and 103.62cm-1gm-1l.

$$A1 = 61.14\ Cx + 75.33\ Cy \quad \text{..... (1)}$$
$$A2 = 65.68\ Cx + 103.62\ Cy \quad \text{..... (2)}$$

Where, *A1* and *A2*=Absorbance of sample solution at 226.4nm and 263.2nm, respectively. *Cx* and *Cy*= Concentration of cefixime and ofloxacin, respectively, in sample solution in gm/l. The validity of the above equations were checked by preparing five mixed standards using pure samples of the two drugs, results of which are reported in Table 1.

Procedure for analysis of tablet formulation

Twenty tablets (Cefixime 200 mg and Ofloxacin 200 mg) were weighed accurately and average weight per tablet was determined. The tablets were finely powdered and powder equivalent to 100mg cefixime was weighed. The mixed powder was extracted with 50ml of a mixture of methanol and 0.1N HCl (1:1) and sonicated for 10 minutes. The resultant mixture was filtered

through Whatmann filter paper number 41 into 100ml volumetric flask. The filter paper was washed several times with 0.1N HCl. The washings were added to the filtrate and the final volume was made up to the mark with the same. 10ml of this solution was diluted to 100ml to get a concentration of 100µg/ml. The filtrate (1 ml) of the sample solution was diluted to 10ml with a mixture of methanol and 0.1N HCl (1:1). The absorbance of this final dilution was measured at 285.8 nm and 296.6 nm. Finally, the concentration of the two drugs in sample was calculated using above framed simultaneous equations (1) and (2), results of which are reported in table 2.

Standardization of the method by analysis of laboratory prepared sample:

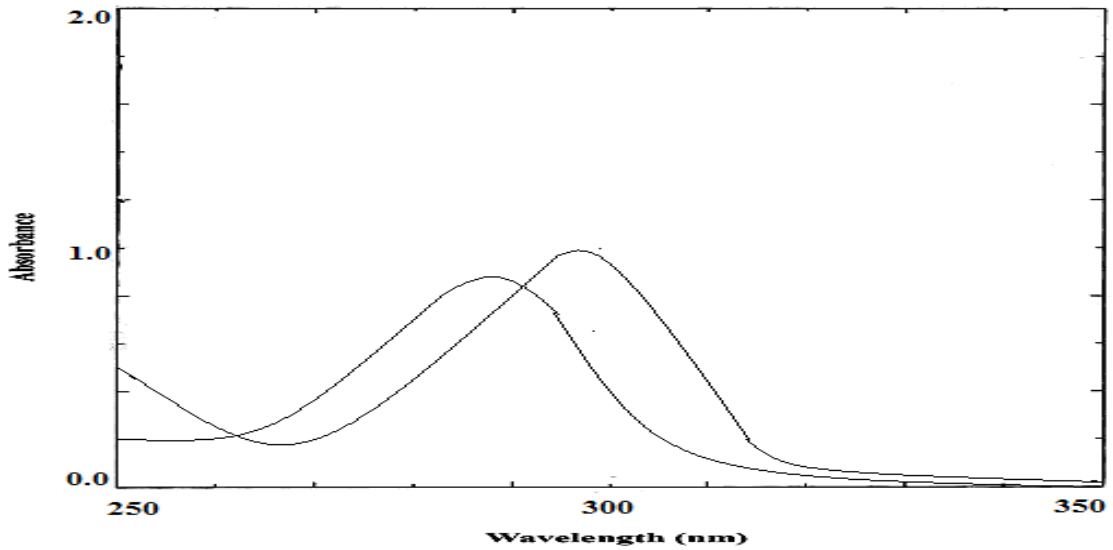
To check the validity of above framed equations five mixed standards were prepared using pure sample of two drugs. The absorbance of these mixed standards were measured at respective wavelengths and compared with absorbance calculated using above framed equations. The concentrations of two components of mixed standards were calculated using above framed equations.

Recovery studies:

Recovery studies were carried out for both the formulations by addition of known amount of standard drug solution to pre-analyzed tablet sample solution at three different concentration levels. The resulting solutions were analyzed by proposed method. The results of recovery studies were found to be satisfactory and are results are reported in table 3.

RESULTS AND DISCUSSION

Figure 1: Overlain spectra of cefixime and ofloxacin in methanol and 0.1 N HCl



The developed method involves formation and solving of simultaneous equations. The method is simple and requires only accurately determined absorptivity values of two drugs at two selected wavelengths. Framed equations are validated using laboratory prepared mixed standards of two drugs which give satisfactory results. Percentage label claim of two drugs from different brands of tablet were found to be in the range of 98.40 % to 99.60 % for both cefixime (CEF) and ofloxacin (OFL) and respective values of standard deviation were in the range of 0.330- 0.374

for cefixime (CEF) and 0.287-0.340 for ofloxacin (OFL). For this work UV/Visible double beam spectrophotometer (model 1700) with 1 cm matched quartz cell was used. The method requires only methanol and 0.1 N HCl in addition to pure drug sample and instrument.

Figure 2: Calibration curve of cefixime and ofloxacin.

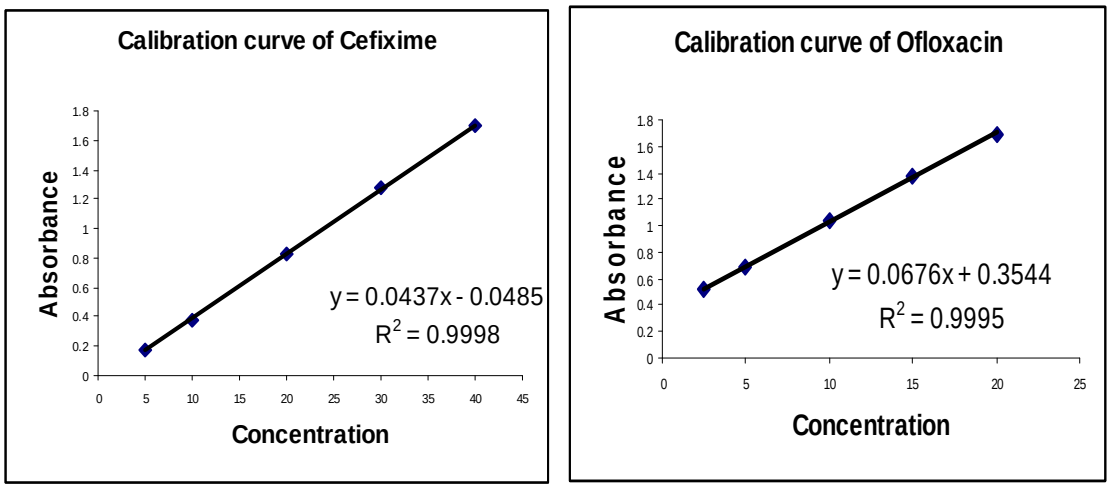


Table 1: Result of validation studies of simultaneous equation method using mixed standards

S. No.	Concentration		Absorbance		% Concentration	
	CEF	OFL	285.8 nm	296.6 nm	CEF	OFL
1	5	15	1.427	1.873	99.20	99.46
2	12.5	7.5	1.323	1.590	99.44	99.60
3	10	10	1.351	1.676	99.20	98.90
4	7.5	12.5	1.393	1.779	99.06	99.68
5	15	5	1.285	1.493	99.66	98.60

Table 2: Results of analysis of commercial formulations

Brand Name	Label Claim (mg/tablet.)		% Label Claim Estimated		Standard Deviation		Coefficient of Variance	
	CEF	OFL	CEF	OFL	CEF	OFL	CEF	OFL
ZIMNIC-O	200	200	98.96	99.06	0.330	0.340	0.333	0.343
ZOFIXI-OF	200	200	99.20	99.23	0.374	0.287	0.377	0.289

** Each value is an average of five determinations*

Table 3: Results of recovery studies

Brand Name	Label Claim (mg/tablet.)		Amt. Added to Final Dilution (µg/ml)		Amt. Recovered (µg/ml)		% Recovery	
	CEF	OFL	CEF	OFL	CEF	OFL	CEF	OFL
ZIMNIC-O	200	200	2.5	2.5	2.45	2.46	98.00	98.40
			5	5	4.93	4.95	98.60	99.00
			7.5	7.5	7.44	7.47	99.20	99.60
ZOFIXI-OF	200	200	2.5	2.5	2.48	2.46	99.20	98.40
			5	5	4.96	4.94	99.20	98.80
			7.5	7.5	7.45	7.44	99.33	99.20

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