

## SIMULTANEOUS ESTIMATION OF CEFIXIME AND OFLOXACIN IN TABLET DOSAGE FORM

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### ABSTRACT

Two accurate, precise, sensitive and economical procedures for simultaneous estimation of Cefixime and ofloxacin in tablet dosage form have been developed. The methods employed were Simultaneous equation method (Vierodt's method) (A) and Absorbance Ratio Method (B). The method A employs estimation of a drug concentration by selecting  $\lambda_{\max}$  where the absorbances of these drugs are maximum. So  $\lambda_{\max}$  for ofloxacin and Cefixime is 284 nm and 224 nm respectively. The method B employs 261.6 nm as  $\lambda_1$  (Isobestic point) and 284 nm as  $\lambda_2$  ( $\lambda_{\max}$  of ofloxacin) for formation of equations. Both the drugs obey Beer's law in the concentration range 10-80  $\mu\text{g mL}^{-1}$ . The results of analysis have been validated statistically and by recovery studies.

**Keywords:** Cefixime, Ofloxacin, Vierodt's Method.

### INTRODUCTION

Cefixime (CFX) 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 gonorrhoea, otitis media, pharyngitis, lower respiratory-tract infections such as bronchitis, and urinary-tract infections. Ofloxacin (OFL) is a fluoroquinolone derivative. Chemically, it is ( $\pm$ )-9-fluoro-2, 3-dihydro-3-methyl-10-(4-methyl-1 piperazinyl)-7-oxo-7H-pyrindo-[1,2,3-de]- 1,4-benzoxazine -6-carboxylic acid<sup>1</sup>. Literature review reveals that Cefixime can be estimated spectrophotometrically<sup>2</sup> and Ofloxacin can be estimated spectrophotometrically<sup>3</sup> in combination with other drugs. One method is reported for estimation of Cefixime and Ofloxacin in combination by UV – Visible spectroscopy using methanol as solvent<sup>3</sup>. One method is also reported for estimation of Cefixime and Ofloxacin in combination by using RP-HPLC<sup>5</sup>. So here an attempt has been made to develop simple, accurate, sensitive, rapid and economic method for simultaneous estimation

of Cefixime and Ofloxacin from tablet dosage forms using UV – Visible spectroscopy along with its degradation studies.

### EXPERIMENTAL

#### Instrumentation

The instrument used in the present study was SYSTRONICS double beam UV/Visible spectrophotometer (Model 2201) with slit width fixed at 2 nm. All weighing was done on electronic balance (Model Shimadzu AY -120).

#### REAGENTS AND CHEMICALS

Analytically pure sample of CFX and OFL was kindly supplied by Torrent Pharmaceuticals Limited and used as such without further purification. The pharmaceutical dosage form used in this study was a Nicholas Piramal India Limited labeled to contain 200 mg of CFX and 200 mg of OFL.

#### Solvent

Methanol (AR Grade) was used as solvent, procured from Universal Laboratories Private limited, Mumbai.

**Stock Solution**

100 mg of Cefixime (CFX) and 100 mg of Ofloxacin (OFL) were weighed separately and transferred to two separate 100 ml volumetric flasks. Each drug was dissolved in 20 ml of methanol and shaken gently for 10 min. The volume was made up to the mark with 0.2 M sodium hydroxide and the final strength obtained was 1000 µg/ml.

**Procedure****Spectral characteristics of CFX and OFL**

Solutions of CFX and OFL (100 µg/ml, each), were prepared separately by appropriate dilution of standard stock solution. Both the solutions were scanned in the spectrum mode from 400 nm to 200 nm. Overlay absorption spectra were recorded (Fig. 1).

**Preparation of calibration curves**

Appropriate dilutions of the standard stock solution were done separately to get 10, 20, 30, 40, 50, 60, 70, 80, 90 and 100µg/ml of CFX and OFL, respectively. The absorption spectra of all solutions were recorded between 200-400 nm. The absorbances were measured at 224.0 nm ( $\lambda_{max}$  of CFX), 284.0 nm ( $\lambda_{max}$  of OFL) and 261.6 nm (iso-absorptive point). Beer's lamberts range for CFX and OFL were selected and working calibration curves of both the drugs were plotted separately.

**Determination of Absorptive Value of CFX and OFL**

Appropriate dilutions of the standard stock solution were done to get 40 µg/ml of each CFX and OFL, respectively. The absorbances were measured for CFX and OFL at 224.0 nm ( $\lambda_{max}$  of CFX), 284.0 nm ( $\lambda_{max}$  of OFL) and 261.6 nm (iso-absorptive point). The absorptivity values of the drugs were determined at the selected wavelengths. These absorptivity values are the mean of six determinations.

**Application of the proposed method for the determination of CFX and OFL in tablets**

Twenty tablets were weighed and average weight was calculated. The tablets were crushed to obtain fine powder. Tablet powder equivalent to 40 mg of CFX was transferred to 100.0 ml volumetric flask, methanol added, ultrasonicated for 10 minutes and volume was made-up to the mark with 0.2 M sodium hydroxide solution and. The solution was then filtered through a Whatmann filter paper (No. 41). The filtrate was further diluted with distilled water to obtain 40µg/ml of CFX and 40µg/ml of OFL. The concentration of both CFX and OFL were determined by measuring the absorbance of the sample at 224.0 nm, 284.0 nm (method A, simultaneous equation method) and at 284.0 nm and 261.6 nm (method B, absorbance ratio method). Concentration of sample solution was determined by using following equations:

**Method A- Vierodt's Method of simultaneous equation**

A set of two simultaneous equations obtained by using mean absorptivity values are given below

$$A1 = 27250 \text{ CCEF} + 32825 \text{ COFL} \text{ -----}$$

( $\lambda_{max}$  at 224.0 nm)

$$A2 = 20850 \text{ CCEF} + 46650 \text{ COFL} \text{ -----}$$

( $\lambda_{max}$  at 284.0 nm)

Where A1 and A2 are absorbance of the sample at 224.0 nm and 284.0 nm respectively, 27250 and 20850 are the absorptivity values of CFX at 224.0 nm and 284.0 nm respectively. Similarly 32825 and 46650 are the absorptivity value of OFL at 224.0 and 284.0 nm respectively. CCEF is the concentration of CFX and COFL is the concentration of the OFL.

**Method B- The Graphical Absorption Ratio Method (Q-Analysis)**

From the following set of equations the concentration of each component in sample can be calculated.

**For Cefixime:**

$$C_x = \frac{Q_m - Q_y}{Q_x - Q_y} \times \frac{A1}{a}$$

**For Ofloxacin:**

$$C_y = \frac{Q_m - Q_x}{Q_y - Q_x} \times \frac{A1}{a}$$

Where,

C<sub>x</sub> = Concentration of CFX,

C<sub>y</sub> = Concentration of OFL,

A1 = Absorbance of sample at iso-absorptive wavelength 261.6 nm,

a = Mean absorptivity of CFX and OFL at iso-absorptive wavelength 261.6 nm,

$$Q_m = \frac{\text{Absorbance of sample solution at 284.0 nm}}{\text{Absorbance of sample solution at 261.6 nm}}$$

$$Q_x = \frac{\text{Absorptivity of CFX at 284.0 nm}}{\text{Absorptivity of CFX at 261.6 nm}}$$

$$Q_y = \frac{\text{Absorptivity of OFL at 284.0 nm}}{\text{Absorptivity of OFL at 261.6 nm}}$$

### Linearity Studies

Linearity studies were carried out at different level of concentrations. Both the drugs obey Beer's law in the concentration range 10-80  $\mu\text{g mL}^{-1}$ . Results are reported in table 1.

### Recovery studies

The accuracy of the proposed method was checked by recovery studies, by addition of standard drug solution to pre analyzed sample solution at three different concentration levels (80%, 100%, and 120%) within range of linearity for both the drugs. Results are reported in table 2.

### Degradation studies

Degradation studies were carried out on CFX and OFL. Results are reported in table 3.

## RESULT AND DISCUSSION

### Method I: Simultaneous Equation Method

UV-spectrophotometric method using simultaneous equation was developed. CFX showed absorbance maxima at 234 nm and OFL at 296.0 nm. Linearity was observed in the concentration range of 10 - 80  $\mu\text{g/ml}$  for CFX and OFL correlation coefficient was found to be 0.993 and 0.98 at 284 nm and 224 nm respectively. The proposed method was applied for pharmaceutical formulation and %

label claim for CFX and OFL was found to be 99.9 and 99.96, respectively. The method is accurate and precise and can be used for routine pharmaceutical analysis.

### Method II: Absorbance Ratio Method

UV-spectrophotometric method by using absorbance ratio method was developed. Absorbances selected were 261.6 nm (isoabsorptive point) and 284 nm ( $\lambda$  max of Ofloxacin) Linearity was observed in the concentration range of 10 - 80  $\mu\text{g/ml}$  and correlation coefficient was found to be 0.992 and 0.990 respectively The proposed method was applied for pharmaceutical formulation; % label claim for CFX and OFL was found to be 99.63 and 100.24, respectively. The low % RSD indicates method is accurate and precise.

## CONCLUSION

The methods discussed in the present work provide a convenient and accurate way for simultaneous analysis of Cefixime and Ofloxacin in tablet dosage form. This method is fast, accurate, precise and sensitive hence it can be employed for routine quality control of Ofloxacin tablets in QC laboratories and industries.

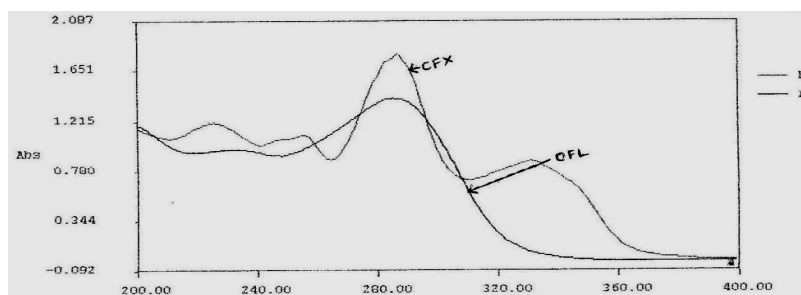
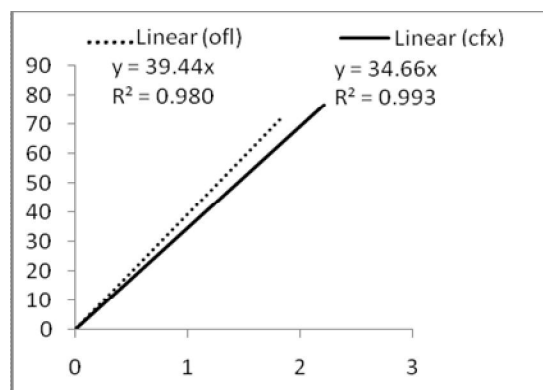
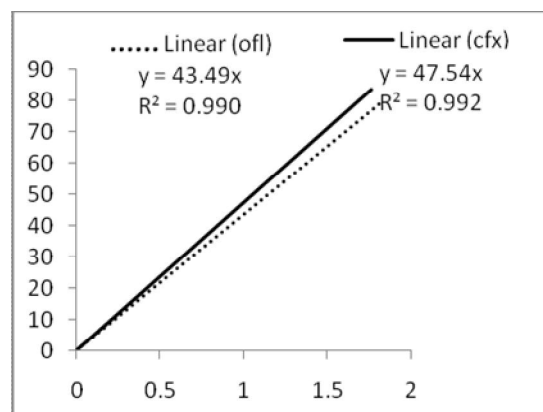


Fig. 1: Overlay spectra of CFX and OFL



Method A



Method B

Fig. 2: Linearity curve of CFX and OFL

Table 1: Linearity Studies of CFX and OFL

Method	Range( $\mu\text{g mL}^{-1}$ )		Equation of line		r2	
	CFX	OFL	CFX	OFL	CFX	OFL
A	10-80	10-80	$y = 34.66x$	$y = 39.44x$	0.993	0.98
B	10-80	10-80	$y = 47.54x$	$y = 43.49x$	0.992	0.99

Table 2: Tablet Analysis and Recovery Studies of CFX and OFL

Method	Label Claim(mg/tab)		Amount Found* (%)		Standard Deviation		(% ) Recovery	
	CFX	OFL	CFX	OFL	CFX	OFL	CFX	OFL
A	200	200	99.9	99.96	$\pm 0.7683$	$\pm 0.1881$	$99.21 \pm 0.1735$	$100.09 \pm 0.1103$
B	200	200	99.63	100.24	$\pm 0.6553$	$\pm 0.1491$	$99.23 \pm 0.6165$	$100.22 \pm 0.1564$

\*denotes n=6, average of six estimations

Table 3: Degradation Studies of CFX and OFL

S. No.	Method	% Degraded	
		CFX	OFL
1	0.01 M Na OH at 85°C for 1 hr	25.00	1.00
2	0.1 M Na OH at 85°C for 1 hr	100.0	6.00
3	0.01 M HCl at 85°C for 2.5 hr	30.00	3.00
4	0.1 M HCl at 85°C for 7 hr	100.0	10.00
5	1% H <sub>2</sub> O <sub>2</sub> 25°C for 3.5 hr	24.00	100.0
6	1% H <sub>2</sub> O <sub>2</sub> 80°C for 10 min	100.0	100.0

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