Int. J. Chem. Sci.: 8(2), 2010, 983-990

SIMPLE U.V. SPECTROPHOTOMETRIC METHODS FOR THE ESTIMATION OF OFLOXACIN IN PHARMACEUTICAL FORMULATIONS

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ABSTRACT

The present work was aimed to develop two simple and sensitive UV spectrophotometric methods for the estimation of ofloxacin in bulk and in dosage forms. Ofloxacin is one of the most promising newer members of the fluoroquinolone family of antibacterials. Ofloxacin shows the obsorption maxima at 284.0 nm in pH 6.8 phosphate buffer and 286.0 nm in pH 7.2 phosphate buffer with an apparent molar absorptivities of 4.1558×10^4 and 3.0717×10^4, respectively and obeyed the Beer's law in the concentration range of 1-6 µg/mL and 1-10 µg/mL. Both the proposed methods were applied for the estimation of different ofloxacin tablets with mean percent accuracies of 99.2 ± 3.1 and 104.6 ± 1.89, respectively with method A and 99.01 ± 0.45 and 99.24 ± 0.34, respectively with method B.

Key Words: Ofloxacin, UV Spectrophotometry, Pharmaceutical.

INTRODUCTION

Ofloxacin is a synthetic anti-bacterial agent[1,2] belong to the class of fluoroquinolones. It is chemically 9-fluoro-2,3-dihydro-3-methyl-10-(4-methyl-1-piperzinyl)-7-oxo-7H-pyrido (1,2,3,-de) -1,4-benzoxazine-6-corboxylic acid. Several methods were reported for the determination of this drug[3,4]. Ofloxacin is official in I.P., USP & EP. A method of analysis of bulk drug is based upon non-aqueous titration[5]. From the literature review, it is evident that there is a need to develop a simple method for the estimation of ofloxacin in its dosage forms. In the present work, an attempt was made to develop two simple, sensitive and economical methods in UV region with greater precision and accuracy for the determination of ofloxacin in pure drug and its formulations.

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EXPERIMENTAL

Systronics UV-Visible spectrophotometer 117 Model with resolution accuracy of 0.1 nm, wavelength accuracy of ± 1 nm and spectral band width of ± 2 nm with 10 mm quartz cell attached to a scanning speed of 250 nm/min was employed for all absorbance measurements.

Ofloxacin USP was a gift. Lactose (Merck), starch (Merck), polyvinyl pyrrolidine K30 (SRL), sodium dihydrogen phosphate (Merck), sodium hydroxide (Merck), Oflastar (Akun's Drugs & Pharmaceuticals Ltd), Selof (Walksman Selman Pharmaceuticals Ltd). Oflomac (Macleods Pharmaceuticals Ltd) were purchased from local market. Buffer solutions were prepared using double distilled water.

Method A

Preparation of standard curve

Phospate buffer of pH 6.8 was used to prepare a solution of ofloxacin to give a stock solution having 1000 μg/mL concentration. Aliquots of stock solution was suitably diluted with pH 6.8 phospate buffer to give final concentrations of 1, 2, 3, 4, 5 and 6 μg/mL. The absorption spectra of above solutions were recorded between 230-400 nm against a blank using 10 mm quartz cell in a Systronics UV-visible spectrophotometer. The observed values of absorbance at λmax of 284.0 nm were plotted against the concentration to obtain the calibration curve and results are shown in Table 1.

Procedure for analysis of ofloxacin in tablet formulations by method A

20 Tablets of each of the two marketed preparations of ofloxacin were weighed separately and ground to a fine powder. Tablet powder equivalent to 200 mg of drug was transferred to 100 mL volumetric flask and it is dissolved and made up to mark with 6.8 phosphate buffer solution. The solution was filtered through Whatmann filter paper No. 41 and it is suitably diluted to obtain a solution having concentration of 4 μg/mL. Now this solution was analysed by the method described above and the results were shown in Table 2.

Procedure for the drug content estimation in ofloxacin infusion using method A

Ofloxacin infusion was procured from local market. The quantity of ofloxacin infusion (5 mL) equivalent to 10 mg of drug was transferred to a 100 mL volumetric flask and made up to volume with pH 6.8 phospate buffer. Aliquots of above solution were transferred into different 100 mL volumetric flasks and made up to volume with pH 6.8

phosphate buffer. From the absorbance values, the drug content of ofloxacin infusion was determined and the results are shown in Table 2.

Method B

Preparation of standard curve

Accurately weighed (100 mg) quantity of ofloxacin was transferred into 100 mL volumetric flask and dissolved in pH 7.2 phosphate buffer solution and made upto mark with the same buffer to give a stock solution having 1000 µg/mL concentration Aliquots of stock solution were suitably diluted with pH 7.2 phospate buffer to give final concentrations from 1-10 µg/mL. The absorbance values of above stated concentrated solutions were measured at λmax of 286.0 nm against blank. The results were given in Table 1.

Procedure for determination of ofloxacin in tablet formulations by method B

Two commercial brands of ofloxacin were procured; each brand containing label claim 200 mg of ofloxacin. 20 Tablets of each brand were weighed and ground to fine powder. Tablet powder equivalent to 200 mg drug was transferred into 100 mL volumetric flask and it was dissolved and made up to mark with pH 7.2 phosphate buffer solution. The solution was filtered through Whatmann filter paper No. 41 and it was suitably diluted to obtain a solution having concentration of 10 µg/mL. Now this solution was analysed by the method described above and the results were shown in Table 2.

Procedure for determination of drug content in ofloxacin infusion using method B

Commercial ofloxacin infusion was procured from local market. The quantity of ofloxacin infusion (5 mL) equivalent to 10 mg of drug was taken and transferred into a 100 mL volumetric flask and made up to volume with pH 7.2 phosphate buffer. This solution was suitably diluted to get the required concentrations from the absorbance values. The content of ofloxacin in infusion was estimated and the results are shown in Table 2.

Determination of ofloxacin in the presence of additives

10 mg of ofloxacin USP and lactose (tablet excipient) were taken in a 100 mL volumetric flask and to this. pH 7.2 or pH 6.8 phosphate buffer solutions were added. The contents were mixed, filtered and the drug content was estimated in a similar manner to that as given in the determination of drug content in tablet dosage forms of method A and B. The same method was adapted for other tablet additives such as starch or PVP K30.

Recovery studies

To evaluate the accuracy and reproducibility of the proposed methods, known amounts of pure drug were added to the previously analysed pharmaceutical preparations and the mixtures were analysed by the proposed methods. The amount of ofloxacin present in the mixture was determined and the percentage recovery was calculated. The results are given in Table 3.

RESULTS AND DISCUSSION

In the proposed methods, ofloxacin showed absorbance maxima at 284.0 nm in method A and 286.0 nm in method B. The calibration curves were found to be linear in the concentration ranges of 1.0 to 6.0 µg/mL in method A and 1.0 to 10 µg/mL in method B. From the results (Table 1), the proposed methods for the determination of ofloxacin showed molar absorptivites of 4.1558 x 10^4 and 3.0717 x 10^4, respectively in method A and method B. Linear regression equations, correlation coefficients and % relative standard deviations of proposed methods are given in Table 1.

Table 1: Spectral and statistical data of ofloxacin

Parameters	Value	
	Method A	**Method B**
Absorption maxima (λ_{max}) (nm)	284.0	286.0
Beer's law range (µg/mL)	1-6	1-10
Molar absorptivity (L. $mole^{-1}.cm^{-1}$)	4.1558×10^4	3.0717×10^4
Sandell's sensitivity (µg/cm^2/0.001abs.units)	0.0087	0.01177
Correlation coefficient (r)	0.9999	0.9999
Regression equation (Y)*	Y = 0.0028 + 0.1168 X	Y = 0.00087 + 0.0866 X
Slope (b)	0.1168	0.0866
Intercept (a)	0.0028	0.00087
% Relative standard deviation**	0.578	1.487
Standard error of estimate	0.1502	0.2085

*Y = a + b X where Y is absorbance and X is the concentration of ofloxacin in µg/mL
**Denotes for six replicates

Studies undertaken using tablet additives such as lactose, starch and PVP K30 indicate that they did not interfere with the estimation of ofloxacin by both methods; A and method B.

The applicability of proposed methods was tested by the determination of ofloxacin in commercially available tablets and infusion and the results obtained are presented in Table 2.

The mean recovery percentages of the three ofloxacin concentrations in tablets and infusion were found to be 98.69 ± 0.369, 99.35 ± 0.437, 99.52 ± 0.172 (n = 3) in method A and 99.27 ± 0.242, 99.56 ± 0.401, 99.36 ± 0.42 (n = 3) in method B (Table 3).

Table 2: Results of analysis of ofloxacin in marketed tablets and infusion

Name of the dosage form	Label claim (mg)	Method A		Method B	
		Amount estimated (mg)	% label claim ± S.D	Amount estimated (mg)	% label claim ± S.D
Tablets	200	195.7		198.09	
(a) Oflastar	200	194.0	99.2 ± 3.1	198.29	99.01 ± 0.45
	200	205.5		197.07	
(b) Selof	200	205		198.88	
	200	212	104.6 ± 1.89	197.68	99.24 ± 0.349
	200	211		198.9	
(c) Ofloxacin infusion Oflomac	200	198.49		199.2	
	200	199.0	99.84 ± 0.83	202.3	100.45 ± 0.78
	200	201.6		201.2	

The results show that both the proposed methods are accurate, very simple, precise and reproducible, which indicates that the proposed methods can be used for the routine analysis of ofloxacin in bulk and its formulations.

Table 3: Recovery studies

Amount of drug taken	Amount of standard drug added (mg)	Method A			Method B		
		Amount found* (mg)	% recovery ± S.D	Standard error	Amount found* (mg)	% recovery ± S.D	Standard error
Tablets 100 mg	10	108.56	98.69 ± 0.369	0.5042	109.2	99.27 ± 0.242	0.3306
100 mg	15	114.26	99.35 ± 0.437	0.5969	114.5	99.56 ± 0.401	0.5478
Infusion 100 mg	20	119.43	99.52 ± 0.172	0.2349	119.24	99.36 ± 0.42	0.5737

*Mean of three replicates

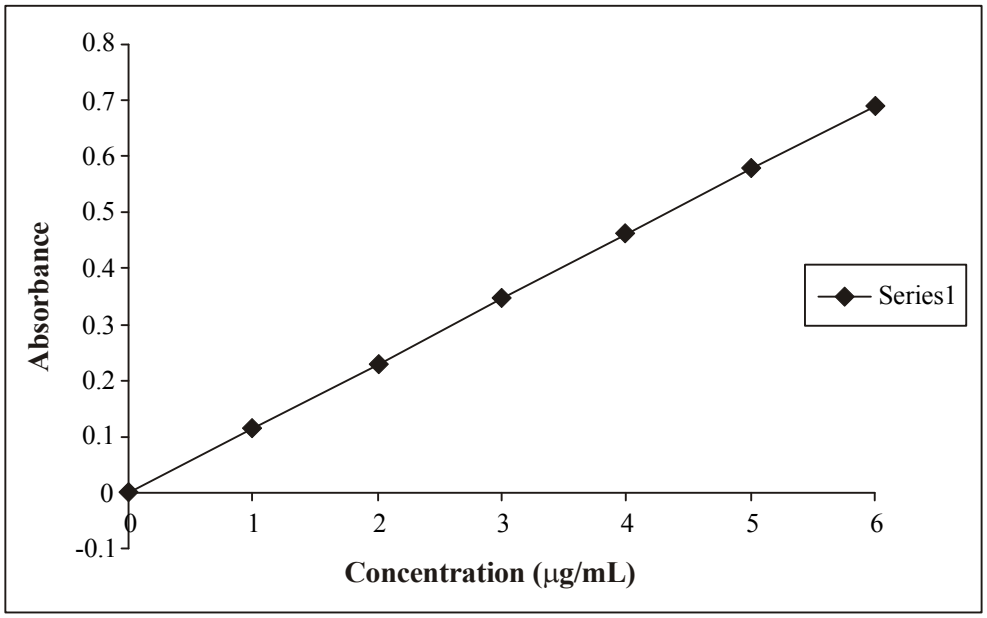

Fig. 1: Calibration curve of ofloxacin in pH 6.8 phosphate buffer

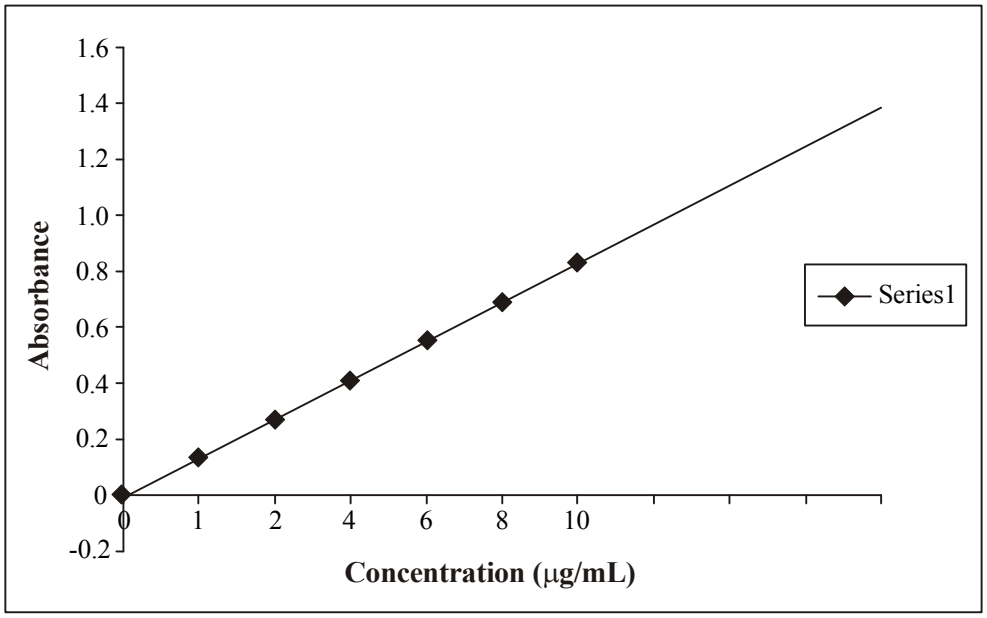

Fig. 2: Calibration curve of ofloxacin in pH 7.2 phosphate buffer

ACKNOWLEDGEMENTS

The authors are thankful to M/s. Walksman Selman Pharmaceuticals Limited, Anantapur for providing gift sample of ofloxacin to carry out this work.

REFERENCES

1. H. B. John and M. B. John, Wilson and Gisvold's Text book of Organic Medicinal and Pharmaceutical Chemistry, Quebecor world, U.S.A., (2004) p. 247.
2. Indian Pharmacopoeia, The Indian Pharmacopoeia Commission Ghaziabad, **Vol. 3**. (2007) p. 1468.
3. T. Kitade, H. Konda, S. Takegami, K. Ishii, C. Ishikawa and K. Kitamura, Chem. Pharm. Bull. (Tokyo), **51**, 53 (2003).
4. A. Z. Tuncel, Pharmazie, **47**, 642 (1992).
5. USPXXV/NFXX, Asian Edition, United States Pharmacopoeial Conventions, Inc, MD USA, (2002) p. 1263.
6. C. J. Eboka, S. O. Aigbavboa and J. O. Akerele, J. Am. Chemo., **39**, 639 (1997).

7. M. S. Garcia, M. I. Albero, C. S. Pedreno and M. S. Abuherba, Eu. J. Pharm. Bio. Pharm, **61**, 87 (2005).

8. S. K. Basu and B. Krishna Moorthy, Asian. J. Chem., **20**, 5223 (2008).

9. D. A. Williams and T. L. Lemke, Foye's Principles of Medicinal Chemistry, Wolter's Kluwer Health (India) Pvt. Ltd., New Delhi (2002) p. 289.

10. Remington, The Science and Practise of Pharmacy, B.I. Publications Pvt. Ltd., U.S.A., (2005) p. 1658.

Accepted : 02.02.2010