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NOTE

Spectrophotometric Estimation of Ofloxacin in Pure and Pharmaceutical Dosage Forms

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The present work was aimed to develop a spectrophotometric method in ultraviolet region for the estimation of ofloxacin in pure form and pharmaceutical formulations. Ofloxacin is an antibacterial agent and belongs to the class of fluoroquinolones used in the treatment of respiratory tract infections. Ofloxacin exhibited maximum absorbance at 291.6 nm in 0.1 N hydrochloric acid with an apparent molar absorptivity of 3.175×10^4. Beer's law was obeyed in the concentration range of 1-10 µg/mL. Results of the analysis were validated by recovery studies.

Key Words: Ofloxacin, Ultraviolet spectrophotometry, λ_{max}.

Ofloxacin is a synthetic antibacterial agent[1,2] and belongs to the fluoroquinolone class. Ofloxacin is chemically 9-fluoro-2,3-dihydro-3-methyl-10-(4-methyl-1-piperzinyl)-7-oxo-7*H*-pyrido[1,2,3-de]-1,4-benzoxazine-6-carboxylic acid. It is useful in the treatment of variety of serious systemic infections like infections of lower respiratory tract including chronic bronchitis and pneumonia and also effective in the treatment of pelvic inflammatory disease (PID), UTI, Prostatitis and infections of soft tissues and skin.

The elimination half-life of ofloxacin ranges from 4.5 to 7 h. It has low solubility in water and ethanol[3]. The information about ultraviolet spectrophotometric methods used to analyze the ofloxacin concentration was rather scanty. In the present work an attempt was made to develop a simple, sensitive and economical method in UV region with greater precision and accuracy for the determination of ofloxacin in pure drug and in its formulations.

Systronics UV-Visible spectrophotometer 117 Model with resolution of 0.1 nm, wavelength accuracy of ± 1 nm and spectral band width of ± 2 nm.

Procedure for method development: Accurately weighed (100 mg) quantity of ofloxacin is transferred into 100 mL volumetric flask and dissolved in 0.1 N hydrochloric acid and made up to mark with 0.1 N HCl to give a stock solution having 1000 µg/mL concentration. Aliquot of stock solution was suitably diluted

with 0.1 N HCl to give final concentrations of 1, 2, 4, 6, 8 and10 µg/mL. The absorbance values of above concentrated solutions were measured at λ_{max} of 291.6 nm against 0.1N HCl as blank. It obeyed Beer's law in these concentration ranges and results were shown in Table-1.

TABLE-1
SPECTRAL AND STATISTICAL DATA OF OFLOXACIN

Parameters	Values
Maximum wavelength (λ_{max})	291.6
Beer's law limit (µg/mL)	1-10
Molar extinction coefficient (absorbance unit/mol cm/dm^3)	3.175×10^4
Regression equation	Y = 0.0028 + 0.0994X
Slope (b)	0.0994
Intercept (a)	0.0028
Correlation coefficient (r)	0.9999

Procedure for analysis of ofloxacin in tablet formulation: Two commercial brands of ofloxacin were procured, each brand containing label claim of 200 mg of ofloxacin per Tablet. Twenty tablets of each brand were weighed and ground to 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 0.1 N HCl. The solution was filtered through Whatmann filter paper No. 41 and it is suitably diluted to obtain a solution having a concentration of 10 µg/mL. Now this solution was analyzed by the method described above and the results were shown in Table-2.

TABLE-2
RESULTS OF ANALYSIS OF OFLOXACIN IN MARKETED TABLETS

Tablet formulation	Label claim (mg)	Amount found (mg)	% Labelled claim* Mean ± SD
A	200	198.09 198.29 197.68 197.07	98.89 ± 0.2683
B	200	198.88 197.68 198.49 198.90	99.11 ± 0.2793

*Average of four determinations.
A = Oflastar – 200 mg manufactured by Akun's Drugs and Pharmaceuticals Ltd., Haridwar.
B = Selof – 200 mg manufactured by Walksman Selman Pharmaceuticals Ltd., Anantapur.

Recovery studies: Recovery studies were carried out in order to check the accuracy, reproducibility and precision of the proposed method. Recovery studies were conducted at 3 different levels by adding 2.0, 4.0 and 8.0 mg of pure ofloxacin drug samples to the preanalyzed tablet powder and the concentration of drug present in samples were analyzed. Results were shown in Table-3.

TABLE-3
RECOVERY STUDIES

Amount of drug taken from tablets (mg)	Amount of standard drug added (mg)	Amount found (mg)	% Recovery ± SD
100	2	101.06	99.08 ± 0.01
100	4	103.19	99.22 ± 0.02
100	8	107.44	99.48 ± 0.02

SD = Standard deviation, the results are mean of three readings (n = 3).

In the proposed method ofloxacin showed absorbance maxima at 291.6 nm by taking 0.1 N hydrochloric acid in reference cell and drug solution (in 0.1N HCl) in test cell. The calibration curve was found to be linear in the concentration range of 1.0 to 10.0 µg/mL from the results shown in Table-1.The proposed method for the determination of ofloxacin showed molar absorptivity of 3.175×10^4 (absorbance unit/mol cm/dm^3), Linear regression equation Y = 0.0028 + 0.0994X with correlation coefficient (r) = 0.9999. A relative standard deviation of 0.2683 and 0.2793 % was observed on analysis of 4 replicate samples of 2 brands A and B, respectively. The per cent recovery stated that the values lie between 99.08 and 99.48 %, which was concluded that the excipients present in the formulation do not interfere in the estimation of ofloxacin. The developed method was found to be simple, sensitive, precise and reproducible which indicates that the proposed method can be used for the routine analysis of ofloxacin in pure drug and its formulations.

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