

Simultaneous Spectrophotometric Determination of Satranidazole and Ofloxacin in Combined Dosage Form

Sherje AP^{1*}, Tawade AP², Vyas M²

¹School of Pharmacy & Technology Management, SVKM's NMIMS Deemed-to-be University, Vile Parle (W), Mumbai- 400 056 (M.S.) India

²STES's Sinhgad Institute of Pharmacy, Narhe, Pune- 411 041 (M.S.) India

*Corres.author: sherje.atul@rediffmail.com
Telephone: 91-22-42332000

ABSTRACT:Two simple, accurate and precise spectrophotometric methods have been developed for simultaneous determination of satranidazole and ofloxacin in pharmaceutical fixed dosage form. The method A involves formation and solving of simultaneous equation using 297.3 and 317.0 nm as the wavelengths of detection while method B is two wavelength method where 281.5nm, 309.0nm were selected as λ_1 and λ_2 for determination of satranidazole and 300.0 nm, 333.1nm were selected as λ_1 and λ_2 for determination of ofloxacin. Both the methods were validated statistically and recovery studies were carried out. The Beer's law limits for each drug individually and in mixture was within the concentration range of 5- 25 $\mu\text{g/ml}$. Linearity of satranidazole and ofloxacin were in the range of 80-120% of the label claim. The proposed methods have been applied successfully to the analysis of the cited drugs either in pure form or in pharmaceutical formulations with good accuracy and precision. The method herein described can be employed for quality control and routine analysis of drugs in pharmaceutical formulations.

Key words: Satranidazole, Ofloxacin, Spectrophotometry, Simultaneous estimation

INTRODUCTION

Satranidazole (STZ), chemically 1-Methylsulfonyl-3-(1-methyl-5-nitro-2-imidazolyl)-2-imidazolidinone is an antiamoebic drug. It has been determined in pharmaceutical formulations by different methods like UV-Visible spectrophotometry^[1], HPTLC^[2-3], HPLC^[4]. Ofloxacin (OFLOX) chemically (\pm)-9-fluoro-2,3-dihydro-3-methyl-10-(4-methyl-1-piperazinyl)-7-oxo-7H-pyridol[1,2,3-de]-1,4benzoxazine-6-carboxylic acid is a fluoroquinolone antibiotic and is used in the treatment for gonorrhea^[5-6]. Several methods such as spectrophotometry^[7], HPTLC^[8], spectrofluorometry^[9], HPLC^[10] are reported in literature for determination of ofloxacin in dosage form and in biological samples. A fixed dose combination containing STZ and OFLOX is available commercially in the market as tablet dosage form. Literature survey revealed that no method is reported for simultaneous estimation of these drugs in combined dosage form. Hence, an attempt has been made to develop two simple spectrophotometric

methods for simultaneous estimation of these drugs from their combined formulation.

MATERIALS AND METHODS

Reference standard of STZ was obtained from Alkem Laboratories Ltd, Mumbai, India and OFLOX was obtained from Aventis Ltd, Baroda, India. All the reagents/ chemicals were of AR/ spectroscopy grade. All the solutions were freshly prepared with double distilled water. Spectral and absorbance measurements were made with Jasco V-630 double beam spectrophotometer with 1 cm matched quartz cell.

Preparation of standard solutions and study of spectra

Standard stock solution of STZ and OFLOX were prepared in methanol. The stock solutions were further diluted and mixed standard solutions were prepared containing 16 $\mu\text{g/ml}$ of STZ and 8 $\mu\text{g/ml}$ of OFLOX. The resulting solutions were scanned in the range of

400-200nm. The UV absorption overlain zero order spectrum for STZ and OFLOX is depicted in Fig. 1. From the overlain spectra 297.3 and 317.0 nm were used as the wavelengths of detection for simultaneous equation (Method A) method while for two wavelength method (method B) two wavelengths 281.5nm, 309.0nm were selected as λ_1 and λ_2 for determination of satranidazole and 300.0 nm, 333.1nm were selected as λ_1 and λ_2 for determination of ofloxacin.

RESULT AND DISCUSSION

Simultaneous Equation method

The stock standard solutions were diluted to obtain concentration range of 5 -25 μ g/ml for each drug. The absorbances were recorded at selected wavelengths and calibration curves were plotted. Both the drugs obey Beer's law individually and in laboratory mixture within the concentration range 5-25 μ g/ml. The absorptivity values ($A_{1\%}^{1\text{cm}}$) for each drug at both the wavelengths were determined. The concentration of drugs in laboratory mixture was determined by substituting the absorbance and absorptivity values in the following equation-

$$C_x = \frac{A_2 a_{y1} - A_1 a_{y2}}{a_{x2} a_{y1} - a_{x1} a_{y2}} \text{ and } C_y = \frac{A_1 a_{x2} - A_2 a_{x1}}{a_{y1} a_{x2} - a_{y2} a_{x1}}$$

Where, C_x and C_y are the concentration of STZ and OFLOX respectively, A_1 and A_2 are the absorbance at 297.3 nm and 317.0 nm respectively, a_{x1} and a_{x2} are absorptivities of STZ at 297.3 nm and 317.0 nm respectively, a_{y1} and a_{y2} are absorptivity values of OFLOX at 297.3 and 317.0 nm respectively.

Two wavelength method

The prior criterion for two wavelength method (method B) is existence of two such wavelengths where interfering component shows same absorbance whereas component of interest shows significant difference in absorbance. Based on this criteria, two wavelengths 281.5 nm, 309.0 nm were selected as λ_1 and λ_2 for estimation of STZ where OFLOX shows same absorbance but STZ shows significant difference in absorbance. Similarly, wavelengths 300.0 nm and 333.1 nm were selected as λ_1 and λ_2 for estimation of OFLOX. For calibration curve, the standard stock solutions of these drugs were diluted in the concentration range of 5- 25 μ g/ml and absorbances were recorded at selected at wavelengths. Both the drugs obey Beer's law individually and in mixture within the concentration range of 5- 25 μ g/ml. From standard stock solutions five laboratory mixtures (samples) and one as standard were prepared containing 16 μ g/ ml of STZ and 8 μ g/ml of OFLOX. The absorbance of the resulting solutions were measured at the selected wavelengths and concentration of each drug was determined using the following equation-

$$C_u = \frac{A_u}{A_s} \times C_s \times C_d \text{ where, } C_u \text{ is the concentration of unknown, } C_s \text{ is the concentration of standard, } A_u \text{ is the absorbance of unknown, } A_s \text{ is the absorbance of standard and } d \text{ is the dilution factor.}$$

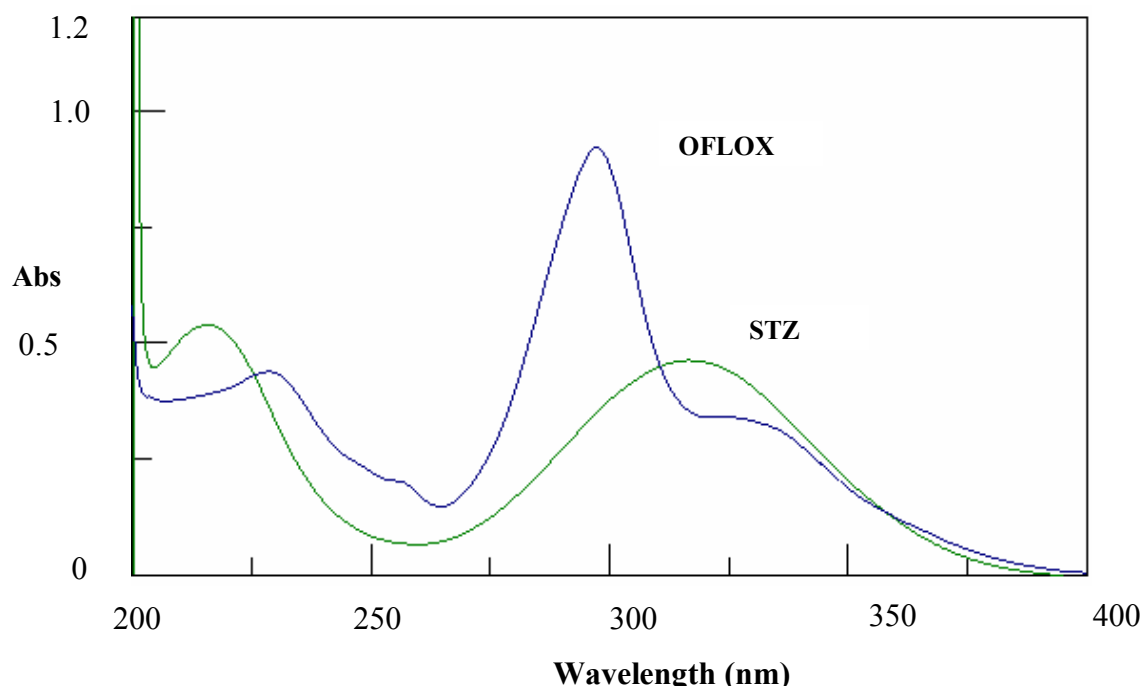


Fig.1. UV absorption spectra of Satranidazole (STZ) and Ofloxacin (OFLOX)

Table dosage form analysis

For analysis of commercial formulation twenty tablets were weighed, contents removed and finely powdered. The tablet powder equivalent to 50 mg of STZ was weighed accurately and taken in a 100ml volumetric flask. The contents were dissolved and volume made up to the mark. It was passed through 0.45 μ membrane filter. An aliquot of filtrate was pipetted and diluted appropriately to obtain a final concentration of 16 μ g/ml of STZ and 8 μ g/ml of OFLOX. The absorbances of these solutions were measured at 297.3nm and 317.0nm for method A, and 300.0 nm, 333.1 nm, 309.0nm, 281.5 nm for method B. The absorbance values were substituted in the respective equations to obtain concentration of each drug in tablet formulation.

Validation

The recovery studies were carried out at different level of concentration by spiking a known concentration of standard drug to the preanalyzed sample and contents were reanalyzed by proposed methods. The results of marketed formulation analysis and recovery studies are depicted in table 1. The methods were validated statistically as per ICH/USP guidelines for parameter like accuracy, precision, ruggedness, linearity and range. Accuracy was ascertained on the basis of recovery studies. Precision was studied by analyzing

five replicates of sample solution and concentrations were calculated. Ruggedness was established by carrying out experiment at different time within a day (intraday), different day (interday) and by different analyst. Linearity and range were determined by analyzing 80-120% of test concentrations of each drug.

CONCLUSION

In the proposed method for analysis of STZ and OFLOX in tablet formulations, method A employs two wavelengths 297.3 and 317.0 nm (λ_{max} of OFLOX and STZ respectively) for analysis of drugs. Method B involves four wavelengths for estimation of two drugs. The wavelengths 309.0nm and 281.5nm were selected for estimation of STZ where OFLOX shows same absorbance but LAN shows significant difference in absorbance whereas 300.0nm and 333.1nm satisfies the criteria for estimation of DOM. The proposed method was successfully used to estimate STZ and OFLOX in marketed tablet formulation. The assay value was in good agreements with the corresponding labeled claim. The recovery study shows accuracy of the method. On observing the validation parameters both the methods were found to be accurate, precise and specific. Hence the methods can be employed for routine analysis of tablet containing STZ and OFLOX.

Table No. 1- Results of Commercial Sample Analysis and Recovery Study

Method	Drug	Labeled drug (mg/tab)	Amount obtained (mg)	% Drug obtained	\pm S.D.*	Recovery (%)	\pm S.D.
A	STZ	300	299.09	99.69	0.8113	100.45	0.7398
	OFLOX	200	201.17	100.58	0.7802	98.81	0.9069
B	STZ	300	298.09	99.36	0.9413	98.87	0.5794
	OFLOX	200	202.97	101.48	1.0802	99.11	0.8567

\pm S.D.* indicates \pm Standard deviation, n= 5

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