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Research Article

SPECTROPHOTOMETRIC ESTIMATION OF SPARFLOXACIN IN BULK AND PHARHARMACEUTICAL DOSAGE FORMS

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ABSTRACT

Two simple and sensitive visible Spectrophotometric methods [I and II] have been developed for the quantitative estimation of Sparfloxacin in bulk and Pharmaceutical dosage forms. Method-I is based on ion-pair complex formation between Sparfloxacin and Bromocresol purple, which shows yellow color and gives maximum absorption at 410.0 nm and obeys Beer's law in the concentration range of 5-25 µg/ml. Method-II is based on ion-pair complex formation between Sparfloxacin and Bromocresol green, which shows yellow color and gives maximum absorption at 420.0 nm and obeys Beer's law in the concentration range of 5-25 µg/ml.

Key words: Sparfloxacin, Method, Spectrophotometric, UV, BCP, BCG

INTRODUCTION

Sparfloxacin is chemically 5-amino-1-cycloproyl-7-[(3R, 5S) 3, 5- Dimethylpiperazine-1-yl]-6, 8-difluro-4-oxo-quinoline-3-carboxylic acid[1](Fig-1). The anti bacterial action of Sparfloxacin results from inhibition of the enzyme topoisomerase II (DNA gyrase) and topoisomerase IV which are required for bacterial DNA replication, transcription repair and recombination. It is not official in any Pharmacopoeia.

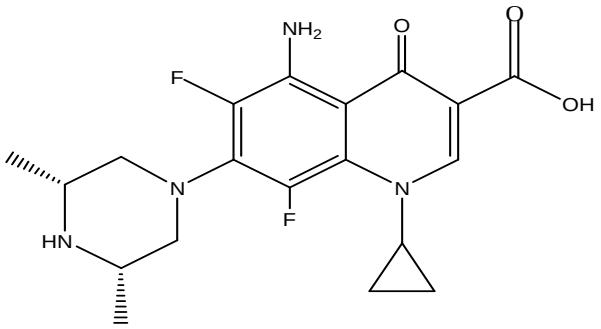

Fig-1

Few analytical methods for the estimation of Sparfloxacin from plasma[2-3], and metabolites including HPTLC[4-7], HPLC[8-9]are reported. However no Spectrophotometric methods have been reported for the estimation of the drug from the pharmaceutical dosage form. In view of the above fact, some rapid and sensitive analytical methods are in need for its quantitative estimation. The present work describes two simple and accurate Spectrophotometric methods for the estimation of Sparfloxacin in bulk and dosage form.

MATERIALS AND METHODS

A Shimadzu UV/VIS double beam spectrophotometer (model 1700) with 1 cm matched quartz cells, were used for all spectral measurements. All the chemicals used were of A.R. grade procured from Merck, S. d. fine chem., and spectrochem, Mumbai. Pure drug sample of Sparfloxacin was obtained from Dr.Reddy labs, Hyderabad and Tablets of Sparfloxacin were procured from market (Sparfloxacin from Dr.Reddy labs).

METHODOLOGY

The standard Sparfloxacin (10 mg) was weighed accurately and transferred into volumetric flask (100 ml). It was dissolved properly and diluted upto the mark with ethanol to obtained final concentration of 100µg/ml and the resulting solution was used as working standard solution. For

the sample solution each tablet containing 200mg of Sparfloxacin, 20 tablets were taken and weighed, their mean weight was determined and finely powdered. An equivalent weighed (10mg) of the tablet content was transferred into a100ml volumetric flask containing 50ml of ethanol, sonicated for 30 min and diluted to 100ml with ethanol. The resulting solution was sonicated for 30 min and filtered through Whatmann filter paper no.0.45. This solution was used as test solution for both the methods.

METHOD-A

Aliquots of standard solution of Sparfloxacin ranging from 5 to 25 ml (1ml= 100µg) were transferred into a series of 250ml separation funnel .To each funnel ,3.0ml of acid phthalate buffer (pH3.8)and 2.0ml of Bromocresol purple reagent was added and volume of aqueous phase in each flask was brought to 10ml with distilled water . The flasks were shaken gently for 5min. Then 10 ml of chloroform was added to each flak. The contents were shaken thoroughly for 5min and allowed to stand, so as to separate the aqueous and the aqueous and chloroform layers. The yellow colored chloroform layer was collected and the absorbance was measured at 410.0nm against the reagent blank. Calibration curve was prepared by plotting concentration versus absorbance and found to be linear over the concentration range 5-25µg/ml. Similarly, absorbance of sample solution was measured and the amount of Sparfloxacin was determined from standard calibration curve. The color was stable upto 30min.

METHOD-B

Aliquots of standard solution of Sparfloxacin ranging from 5 to 25 ml (1ml= 100µg) were transferred into a series of 250ml separation funnel .To each funnel ,3.0ml of acid phthalate buffer (pH3.8)and 2.0ml of Bromocresol green reagent was added and volume of aqueous phase in each flask was brought to 10ml with distilled water . The flasks were shaken gently for 5min. Then 10 ml of chloroform was added to each flak. The contents were shaken thoroughly for

5min and allowed to stand, so as to separate the aqueous and the aqueous and chloroform layers. The yellow colored chloroform layer was collected and the absorbances were measured at 420.0nm against the reagent blank. Calibration curve was prepared by plotting concentration versus absorbance and found to be linear over the concentration range of 5-25µg/ml. Similarly, absorbance of sample solution was measured and the amount of Sparfloxacin was determined from standard calibration curve. The colored species was stable up to 30min.

To test the accuracy and reproducibility of the proposed methods were performed by adding known amount of drug to preanalyzed formulation and reanalyzing the mixture by proposed methods. The results are shown in Table 1.

Table 1: Results of analysis of marketed tablets

Method	Formulation	Label claim (mg/tablet)	% of label claim estimated*	% Recovery**	Relative Standard Deviation
Method (A)	Tablet	200	199.13 ± 0.72	99.63	0.960
Method (B)	Tablet	200	198.95 ± 0.93	99.74	0.190

***Average of five determinations,**

****Average of recovery studies at three different concentrations levels.**

RESULTS

The first method is based on the formation of an ion-pair complex between Sparfloxacin and Bromocresol Purple (BCP) in acid medium and the subsequent extraction of the ion pair in chloroform. The yellow colored ion pair complex shows max absorption at 410.0nm and obeys beer's law concentration in the range of 5-25µg/ml It was found that 30minutes is required to form stable colored chromogen. The second method is based on the formation of an ion-pair complex between Sparfloxacin and Bromocresol Green (BCG) in acid medium and the subsequent extraction of the ion pair in chloroform. The yellow colored ion pair complex shows max absorption at 420.0nm and obeys beer's law concentration in the range of 5-25µg/ml. From

the calibration curve yielded correlation coefficient (r^2) for Method-I was 0.9973, for Method-II was 0.9977, over the Beer's law range of 5-25 µg/ml, respectively.

The regression equation for Method-I was found to be Y = 0.1183X + 0.0011 and for method B was found to be Y = 0.0331X + 0.003. The molar absorptivity (lit/mol.cm) for Method -I was found to be 2.938 x 10^4 for Method-II was found to be 3.152 x 10^4.The results of analysis of marketed formulation are shown in table 1.Reproducibility and accuracy of the methods were found to be good, which was evidenced by low relative standard deviation. The % recovery value indicates non interference from excipients used in formulations.

DISCUSSION

The objectives of the proposed work to develop some new and sensitive analytical methods for the determination and validation of Sparfloxacin in bulk and pharmaceutical dosage forms. The quantitative results obtained were subjected to statistical analysis to find out standard deviation and standard error values. The relative standard deviation values are given below 2% indicating the precision of the methodology and low standard error values shown the accuracy of the method. The validation of the proposed method was further confirmed by recovery studies, the %recovery values vary from 98.0 – 101.0 %.

CONCLUSION

The proposed visible Spectrophotometric methods were found to be simple, sensitive, selective, accurate, precise and economical and can be used in the determination of Sparfloxacin in bulk and pharmaceutical dosage forms in a routine manner.

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REFERENCES

1. O'Neil M.J, editor, The Merck Index – An Encyclopedia of Chemicals, Drugs and Biologicals, 13th Edn. Merck &Co., INC, 2001, p.1557.
2. Indian Pharmacopoeia Vol.I New Delhi: Controller of Publication; 1996: A-144.
3. Cho HY, Park SA, Lee YB. Improvement and validation of an HPLC method for examining the effects of the MDRI gene polymorphism on Sparfloxacin pharmacokinetics. J Chromatogr.2006 (834); 84-92.
4. Rizk M, Belal F, Ibrahim F, Enany N. Spectrofluorimetric analysis of certain 4-quinolone in pharmaceuticals and biological fluids. Pharm Acta Helv 2000 (Apr); 74(4): 371-7.
5. Efthimiadou EK, Sanakis Y, Raptopoulo CP, Karaliota A, Katsaros N, Psomas G. Crystal structure, spectroscopic, and biological study of the copper (II) complex with third-generation quinolone antibiotic Sparfloxacin. Bioory Med Chem Lett 2006 (Jul); 16(14): 3864-7.
6. Alaa S Amin, Ayman Abou El-Fetouh Gouda, Ragaa El-Sheikh, Faten Zahran. Spectrophotometric determination of gatifloxacin in pure form and in pharmaceutical formulation. Spectrochim Acta A Mol Biomol Spectrosc 2006 Oct 14:171-9.
7. Shekha M Al-Ghannam. Atomic absorption spectroscopic, conductometric and colorimetric methods for determination of some fluoroquinolone antibacterials using ammonium reineckate. Farmaco 2004 Nov; 59(11):907-11.

8. Higuchi T, Brochman-Hausen E. Pharmaceutical Analysis, 6th Edn.London: Interscience; 1961, p. 433-40.
9. Vogel AJ. Elementary Practical Organic Chemistry and Quantitative organic Analysis. 2nd Edn. New Delhi: CBS publishers; 1987.

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