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SPECTROPHOTOMETRIC METHODS FOR QUANTITATIVE ESTIMATION OF SPARFLOXACIN IN BULK AND PHARMACEUTICAL DOSAGE FORMS

Srikar A*, Channabasavaraj K.P, Dharmamoorty G, Nataraj Valmiki, Chinnappa C and Venu Babu T.

Department of Pharmaceutical Analysis, Bharathi College of Pharmacy,
Bharathinagara, Mandya (Dist), Karnataka-571422

ABSTRACT
Two simple and sensitive Spectrophotometric methods [A and B] have been developed for the quantitative estimation of Sparfloxacin in bulk and Pharmaceutical dosage forms. Method-A was based on condensation of Sparfloxacin with p-dimethylamino cinnamaldehyde to form Schiff's base, which was yellow colored chromogen and showed the maximum absorption at 465.0 nm. The Beer's Law range, regression equation and % recovery studies were found to be 10-50 µg/ml, Y = 0.0193X – 0.0038 and 99.73 respectively. Method-B was based on the oxidation of Sparfloxacin with ferric chloride followed by complex formation with 1, 10-phenathroline that was a red colored chromogen which showed the maximum absorption at 515.0 nm. The Beer's Law range, regression equation and % recovery studies were found to be 5-25 µg/ml, Y = 0.0245X – 0.0124and 99.13 respectively. Both the methods were validated and found to be satisfactory.

Key words: Spectrophotometric method, Beer's law, Sparfloxacin, Schiff's base.

INTRODUCTION

Sparfloxacin is chemically 5- amino-1-cycloproyl -7- [(3R, 5S) 3, 5- Dimethyl piperazine-1-yl] -6, 8-difluro-4-oxo- quinoline-3-carboxylic acid[1]. The structure of Sparfloxacin is shown in 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.

Few analytical methods for the estimation of Sparfloxacin from plasma[2-3], and metabolites including HPTLC[4-5], HPLC[6-7], and GC[8] are reported. To the best of our knowledge, a very few Spectrophotometric methods have been reported. 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

Chemicals

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's labs, Hyderabad and tablets of Sparfloxacin were procured from market (Sparflox from Dr. Reddy's labs).

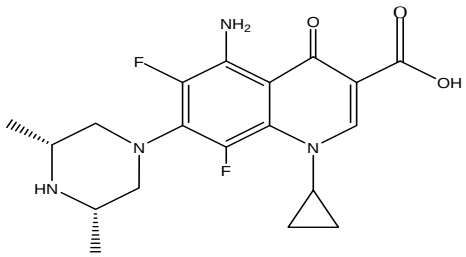

Fig. 1. Structure of Sparfloxacin

Preparation of Standard Solutions

The 10 mg of standard Sparfloxacin was weighed accurately and transferred into 100 ml volumetric flask. It was dissolved in ethanol and diluted up to the mark by using the same solvent to obtain a final concentration of 100µg/ml. The resulting solution was used as a working standard solution.

*Corresponding author:
Tel. +91 9849663738
E-mail address: srikar_043@yahoo.co.in

Method-A

Series of standard solution of Sparfloxacin were prepared using working standard solution in the range of 10-50µg/ml. To each standard solution, 1.0ml of p-dimethylamino cinnamaldehyde (0.1%w/v) and 0.5 ml of concentrated hydrochloric acid were added and heated on boiling water bath for 15 min at 60^0C. The flask was cooled and the volume in each flask was made up to 10ml with ethanol. The absorbance of yellow colored chromogen was measured at 515.0nm against the reagent blank. Calibration curve was prepared by plotting concentration versus absorbance and found to be linear over the concentration range 10-50µg/ml. Similarly, absorbance of sample solution was measured and the amount of Sparfloxacin was determined from standard calibration curve. The color was stable up to 2hrs.

Method-B

Series of standard solution of Sparfloxacin were prepared working standard solution in the range of 5-25µg/ml. To each standard solution, 0.5ml of ferric chloride solution (0.3%w/v) and 0.1ml of 1, 10-phenathroline (0.3%w/v) were added and heated on boiling water bath for 15min at 70^0C, then flasks were cooled and volume in each flask were made up to 10ml with ethanol. The absorbance of red colored chromogen was measured at 465.0nm 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 color was stable more than 1hr.

Preparation of Sample Solutions

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.

RESULTS AND 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 first method A is based on condensation of Sparfloxacin with p-dimethylamino cinnamaldehyde to form Schiff's base that is yellow colored chromogen which shows maximum absorbance at 465.0nm and obeys beer's law in the concentration range of 10-50µg/ml. The second method B based on the principle using oxidizing agent 1, 10-phenathroline produced red colored chromogen at 550.0nm. It was found that 20minutes is required to form stable colored chromogen. The chromogen was stable up to 2hrs in method A and more than 1hr in method B.

The regression equation for method A was found to be Y = 0.0193X – 0.0038 and for method B was found to be Y = 0.0245X – 0.0124. From the calibration curve yielded correlation coefficient (r^2) for method A was 0.9962, for method B was 0.9987. The molar

Table 1. Results of analysis of marketed tablets

Method	Formulation	Label claim(mg/tablet)	% of label claim estimated [a)]	% Recovery [b)]	Relative Standard Deviation
Method (A)	Tablet	200	199.46±0.72	99.73	0.190
Method (B)	Tablet	200	199.30±0.93	99.13	0.160

[a)] Average of five determinations
[b)] Average of recovery studies at three different concentrations levels

absorptivity (lit/mol.cm) for method A was found to be 2.7302 x 10^4 and for method B was found to be 2.0192 x 10^4. The results of analysis of marketed formulation are shown in Table 1. The quantitative results obtained were subjected to statistical analysis to find out relative standard deviation values. The relative standard deviation values are below 2%, indicating the precision of the method. The validation of the proposed method was further confirmed by recovery studies. The %recovery values vary from 98-101%, indicating good accuracy of the method. The high % recovery value indicates non interference from excipients used in formulations.

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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