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Spectrophotometric Estimation of Sparfloxacin in Bulk and Tablet Dosage Form

Sujitha Parimala S*, Asha Jyothi P, Tejaswi K
Sri Padmavathi School of Pharmacy, Tiruchanoor (Po), Tirupathi, Andhra Pradesh, India.

ABSTRACT

A simple, accurate, precise, sensitive and a highly selective spectrophotometric method was developed for the sparfloxacin in bulk and tablet dosage form. The estimation of sparfloxacin was carried out at 610nm. The method was found to be linear in the range of 10-60 µg/ml (Table.1) with recovery of 99.99%. The developed method was validated according to ICH guidelines and it found to be accurate and precise. Thus the proposed method can be successfully applied for determination of sparfloxacin in routine analysis work.

Keywords: Sparfloxacin, Bulk drug, Tablet dosage form, ICH, Validation.

INTRODUCTION

Sparfloxacin 5-amino-1-cyclopropyl-7-[(3R, 5S)-3,5-dimethylpiperazin-1-yl]-6,8-difluoro-4-oxo-1,4-dihydroquinoline-3-carboxylic acid is a synthetic fluoroquinolone broad-spectrum antimicrobial agent in the same class as ofloxacin and norfloxacin and exerts its antibacterial activity by inhibiting DNA gyrase, a bacterial topoisomerase. Literature review explores the complexation of bromothymol blue 0.5% and sparfloxacin to form a compound of yellow colour with maximum absorption at 385 nm. The Lambert-Beer law was obeyed in the concentration range of 2-12 mg/ml. (Marona HR and Schapoval EE, 2001). A selective and sensitive spectrophotometric method for simultaneous determination of Sparfloxacin has been validated by three simple, precise and economical UV methods have been developed for the estimation of Sparfloxacin in tablet dosage form. Sparfloxacin has the absorbance maxima at 280 nm (Method A), and in the first order derivative spectra, showed sharp peak at 267 nm (Method B). Method C applied was in the wavelength range of 296-298 nm. Linearity for detector response was observed in the concentration range of 5-40µg/mL for Method A, Method B and Method C (Anonymous 1-4; MC Sharma and smita sharmaa, 2010).

EXPERIMENT

Instrumentation

The present work was carried out on Shimadzu UV- 1700 series spectrophotometer having double beam detector configuration. The absorption spectra of reference and test solution were carried out in a 1 cm quartz cell over the range of 610nm.

Reagent and chemicals

Sparfloxacin obtained as gift sample from Mylon laboratories, Hyderabad. 0.1N sodium hydroxide was obtained from Merck chemicals, Mumbai, India.

Experimental conditions

According to the solubility characteristics of drug 0.1N sodium hydroxide was selected as solvent for analysis. From the overlay spectra wavelength was selected for the estimation of sparfloxacin at 610nm**.**

Standard stock and sub stock solution

UV analysis was done by using the standard stock solution of 1000 µg/ml of Sparfloxacin. 25mg of standard drug dissolved in 0.1N sodium hydroxide. Aliquots of 10, 20, 30, 40, 50, 60 µg/ml were prepared by using this stock solution and diluted with distilled water, for the preparation of calibration curve.

Table.1 Calibration curve of standard Sparfloxacin bulk drug

S. No	Concentration (µg/ml)	Absorbance at 610nm
1	10	0.129
2	20	0.336
3	30	0.532
4	40	0.726
5	50	0.957

***Corrosponding author**

Sujitha Parimala S
Email id: sujithanissie7@gmail.com

Table.2 Intra day precision

S. No	Concentration (µg/ml)	Absorbance at 610nm	%RSD
1	20 µg	0.182 0.187 0.183 0.182 0.189 0.181	1.7526
2	30 µg	0.244 0.248 0.243 0.242 0.241 0.245	1.0843
3	40 µg	0.307 0.311 0.309 0.313 0.315 0.305	1.2069

Table 3 Interday precision

S. No	Concentration(µg/ml)	Absorbance at 610nm	% RSD
1	30 µg	DAY 1 0.241 0.246 0.240 0.239 0.243 0.244	1.0899
		DAY 2 0.248 0.249 0.241 0.239 0.244 0.247	1.6484
		DAY 3 0.248 0.247 0.244 0.240 0.238 0.244	1.6326

Table.4 Recovery studies

Recovery Range	Test Concentration (µg/ml)	Amount Of Concentration Spiked (µg/ml)	Amount Of Sample Recovered (µg/ml)	Avg. amount of sample from calibration graph	% Recovery
75%	20	15	20.16	35.16	100.83
		15	19.83	34.83	99.166
		15	20.33	35.53	101.65
100%	20	20	20.16	40.16	100.83
		20	19.83	39.83	99.16
		20	20.00	40.0	100.00
125%	20	25	19.83	44.83	99.15
		25	20.00	45.00	100.00
		25	20.33	45.33	101.65

Table.5 Optimised Validation Parameters for Sparfloxacin

S. No.	Validation Parameters	Results
1	Linearity	10-50µg/ml
2	Correlation coefficient	0.999
3	Precision	(%RSD)< 2
	Intra-day precision (n = 6) 20µg/ml 30µg/ml 40µg/ml	 1.75 1.08 1.20
	Inter-day precision (n = 6) 1st day 2nd day 3rd day	 1.08 1.64 1.63
4	LOD(µg/ml)	0.143
5	LOQ(µg/ml)	0.429
6	% Recovery	99.99%

Fig.1 Spectrum of Sparfloxacin Bulk Drug

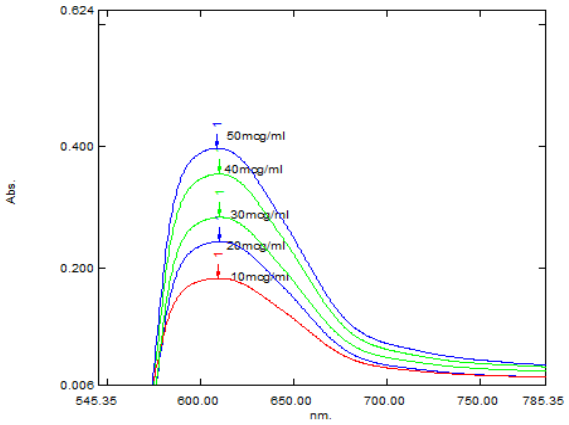
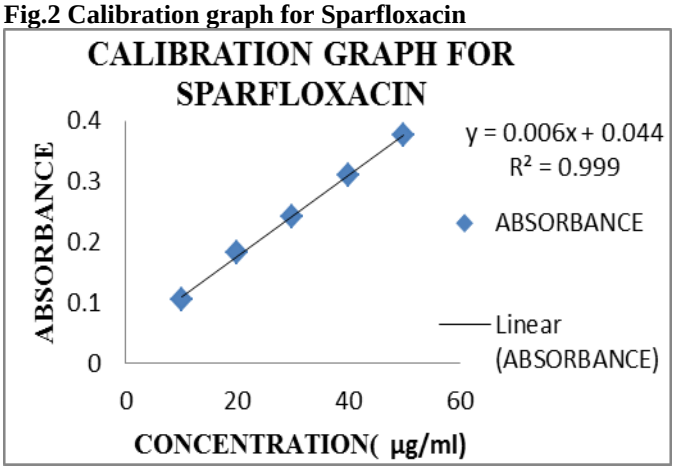


Fig.2 Calibration graph for Sparfloxacin



Method validation studies

Linearity

The linearity of the method is its ability to elicit test results that are directly proportional to the concentration of the analyte in samples. The calibration curve was taken in the range of 10-60µg/ml for Sparfloxacin at the respective λmax i.e;610nm. The correlation coefficient of the linearity was found to be 0.999.

Precision

The precision of an analytical method is determined by assaying a sufficient number of aliquots of a homogeneous sample to be able to calculate statistically valid estimate of % Relative Standard Deviation (%RSD). Intermediate precision was done to express within laboratory variation, on different days. Five replicates of 30µg/mL concentration of the working standard mixture and sample solution were analysed. %RSD was found to be less than 2%.

RECOVERY STUDIES

In order to ensure the reliability and suitability of the proposed method, recovery studies were carried out. It was done by mixing known quantity of standard drug with formulation sample and the content were reanalysed by the proposed method. To a quantity of formulation equivalent to 10 mg of Sparfloxacin, standard drugs of Sparfloxacin added at 75%, 100% and 125% levels. This was extracted diluted and reanalysed as per the formulation procedure. Absorbance was noted at respective wavelength. Recovery studies were repeated for six times and shown in table.4.

RESULTS AND DISCUSSION

The proposed methods for simultaneous estimation of Sparfloxacin in tablet dosage form were found to be simple, accurate, economical and rapid. The % RSD was found to be less than 2% in the developed method. Hence proposed method may be used for routine analysis of the drug.

CONCLUSION

Although the various spectrophotometric methods have been reported for the estimation of Sparfloxacin it was found that the reagents used for the study were not much investigated. An attempt has been made to develop simple method for the estimation of sparfloxacin by spectrophotometric method. The work deals with spectrophotometric method i.e., oxidation reaction with potassium permanganate reagent & found that the proposed method is advantageous, economic, accurate, precise and sensitive.

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