Journal of Pharmaceutical and Scientific Innovation
www.jpsionline.com
Research Article

DEVELOPMENT AND VALIDATION OF A NEW SPECTROPHOTOMETRIC METHOD FOR THE DETERMINATION OF BALOFLOXACIN IN PHARMACEUTICAL TABLET DOSAGE FORMS

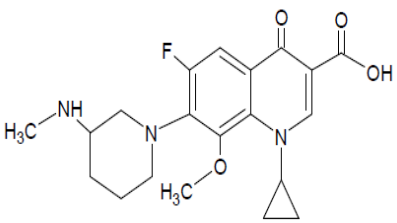
Nayak Shreya and Sanjay Pai P. N.*
Goa College of Pharmacy, Panaji, Goa, India
*Corresponding Author Email: pnsanjaypai@gmail.com
DOI: 10.7897/2277-4572.02455
Published by Moksha Publishing House. Website www.mokshaph.com

Received on: 26/07/13 Revised on: 28/08/13 Accepted on: 31/08/13

ABSTRACT
A rapid, reliable, sensitive UV-spectrophotometric method has been developed for the determination of Balofloxacin in bulk and marketed tablet dosage form using 1 % w/v of ferrous sulphate as a chromagenic / complexing agent. The yellow colour complex formed by complexation of iron (II) with balofloxacinwas stable and was measured for absorbance at its λ max of 357 nm. The Beers law was obeyed at the concentration range of 10-100 µg / ml with good correlation coefficient of 0.9992. The method was optimized and validated for linearity, accuracy and precision. The proposed method is simple and can be routinely used for the estimation of balofloxacin in its tablet formulations.
Keywords: Balofloxacin, Spectrophotometric, Analytical method validation, Ferrous sulphate

INTRODUCTION

Balofloxacin(BLFX),1-cyclopropyl-6-fluoro-8methoxy-7-(3-methylaminopiperidin-1-yl)-4-oxoquinoline-3-carboxylic acid[1], is a broad spectrum fourth generation fluoroquinolone antibacterial, having a formula as $C_{20}H_{24}FN_3O_4$ and molecular mass 389.42 g / mol. It exhibits excellent antibacterial activity against gram-positive bacteria such as multiple-drug-resistant *staphylococci* and *pneumococci.* It acts by binding to and inhibiting topoisomerase II (DNA-gyrase) and topoisomerase IV enzymes, which are responsible for the coiling and uncoiling of DNA, which is needed for bacterial cell repair and replication[2]. Several analytical methods such as UV spectrophotometric method[1,3], HPLC determination in biological fluids[4], HPLC determination in human plasma with solid extraction[5], RP-HPLC[6], RP-HPLC with fluorescence detection[7], HPLC-Electropray ionization mass spectroscopy[8], have been developed for determination of Balofloxacin. In the current study a simple, rapid and reliable visible spectrophotometric method was developed and validated for linearity, accuracy, precision and specificity. The method was extended for determination of balofloxacin in the marketed tablet formulation (Baloforce™ Tablet manufactured by Mankind, New Delhi, India).



Balofloxacin

Method

Perkin Elmer Lambda 25 uv / vis spectrophotometer was used for recording the absorbance. Reference standard of Balofloxacin was kindly received from Cirex Pharmaceuticals (P) Ltd, Hyderabad, India. All the solvents used were of analytical grade.

Preparation of standard drug solution

A 1 mg / ml of stock solution was prepared in a 10 ml volumetric flask by dissolving 10 mg of balofloxacin in 0.1N hydrochloric acid, diluting to the mark with the same acid.

Preparation of 1 % w/v of ferrous sulphate (Reagent)

A 1 % w/v of ferrous sulphate reagent was prepared by weighing 100 mg of the solid ferrous sulphate and acidifying in 1 ml of 0.1N hydrochloric acid in 10 ml volumetric flask and diluting up to the mark with water.

Standard Calibration Plot

Aliquots of the stock solution ranging from 0.1 ml to 1 ml were taken in separate 10 ml volumetric flasks and 3.5 ml each of reagent was added, further diluted to the mark with water to get the working standard solution of concentrations 10 – 100 µg / ml. The absorbance of each solutions was measured at 357 nm against reagent blank (Figure 1). A standard calibration curve was prepared by plotting absorbance versus concentration of balofloxacin (Figure 2). Further, with optimized conditions, the proposed method was validated for linearity, accuracy, precision, sensitivity, reproducibility and stability of colour. Recovery studies were carried out by mixing standard solutions of the drug at 3 different levels (75 %, 100 % and 125 %) with previously analyzed tablet samples of balofloxacin. The results of the validation study and recovery study is presented in Table 1 and Table 2 respectively.

Estimation of Balofloxacin from tablets

10 tablets of (Baloforce) containing 100 mg of the active ingredient in each tablet was weighed and powdered. Tablet powder, equivalent to 25 mg of balofloxacin was transferred to 25 ml of volumetric flask and sonicated using 5 ml of 0.1N hydrochloric acid at ambient temperature for 15 minutes. The resulting solution was filtered using whatman filter paper no. 42 and volume of solution diluted up to the mark with 0.1N

hydrochloric acid. Different aliquot volumes of this solution was taken in 10 ml volumetric flasks to which 3.5 ml of 1 % w/v of ferrous sulphate was added and diluted to mark with water. The absorbance of the sample solutions was recorded against reagent blank prepared in a similar manner, but excluding the sample. The amount of balofloxacin was calculated from the calibration curve (Figure 2).

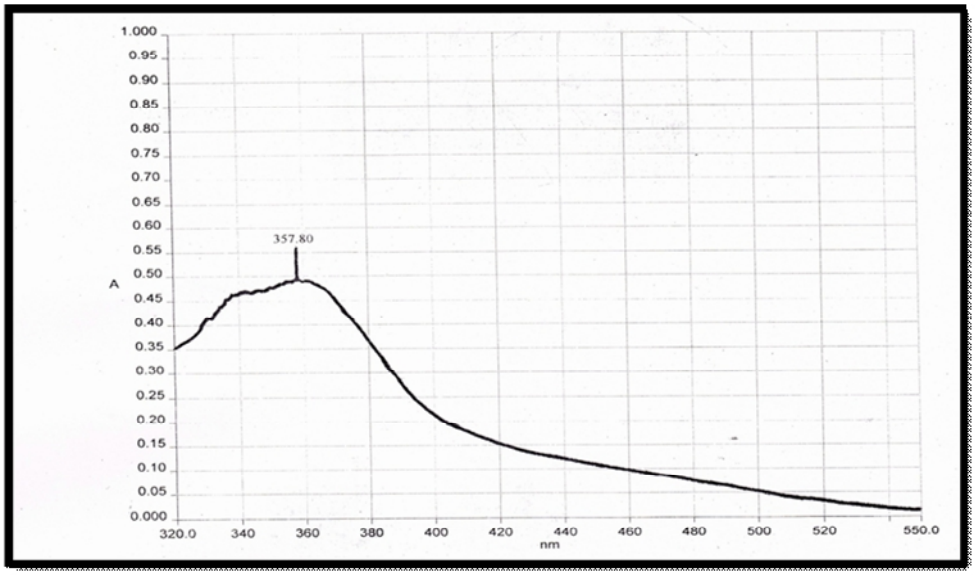


Figure 1: Absorbance Maxima Spectra

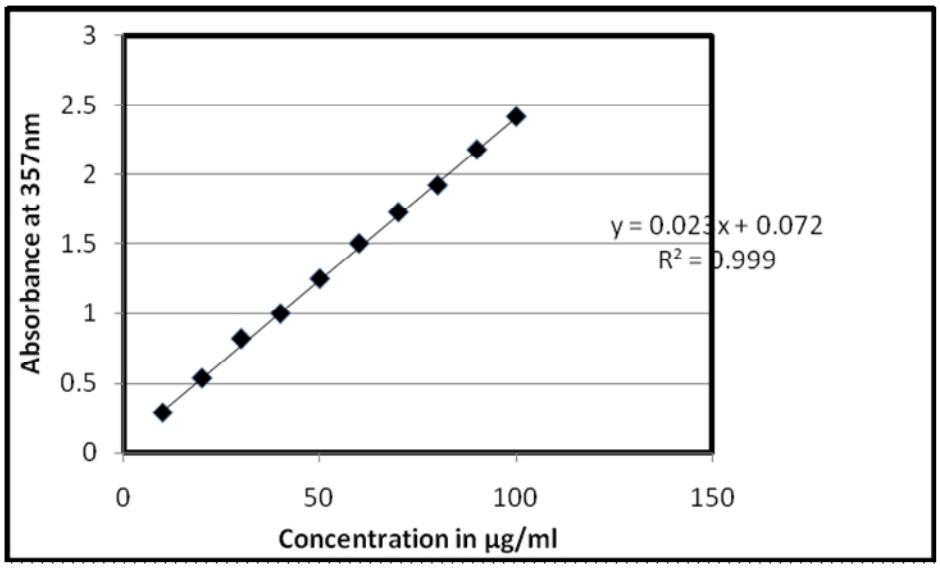


Figure 2: Standard Calibration Plot

Table 1: Validation Parameters

Parameters	Observations
Linearity	10 – 100 µg / ml
Precision	0.039 % RSD
Sandell's sensitivity	3.512 x 10^{-2} µg / cm^2
Equation of linearity graph Slope: Intercept:	0.023x + 0.072 0.023 0.072
Stability of Colour	2 h

Table 2: Results of Recovery Study

Standard concentration (in µg / ml)	Sample concentration (µg / ml)	Absorbance at 357 nm	Total concentration as calculated from linearity graph	% Std Recovery
7.5	10	0.4781	17.33	99.02 %
10.0	10	0.5483	20.33	101.65 %
12.5	10	0.6025	22.66	100.70 %

RESULTS AND DISCUSSION

Balofloxacin, forms a yellow coloured solution after complexing with the iron (II) in 1 % w/v ferrous sulphate. The developed method was linear over the concentration range of 10 – 100 µg / ml. Accuracy was determined from recovery study at 3 different levels of 75 %, 100 % and 125 %, by adding standard solution of balofloxacin to previously analysed tablet samples of balofloxacin. Average recovery of 99.02 % to 101.65 % indicated accuracy of the method. Sandell's sensitivity was determined and found to be 3.512 X 10^{-2} µg / cm^2. The colour was found to be stable. The results of assay showed that the amount of drug determined by new method was in good agreement with the label claim of formulation. From the above results it can be concluded that the developed visible spectrophotometric method is simple, rapid, accurate, precise and economical. Hence the method can be applied for quantitative analysis of balofloxacin in bulk and pharmaceutical formulation like tablet dosage form.

REFERENCES

1. MT Punam, BP Vandana. Development and Validation of Analytical Methods for Estimation of Balofloxacin in Bulk and Pharmaceutical Dosage Forms. Int. J. PharmTech Res 2011; 3(4): 1938-41.
2. Ross DL, Elkinton S, Riley CM. Physiological properties of fluoroquinolone anti bacterials IV 1-octanol / water partition coefficient and their relationship to structure. Int. J. Pharm 1992; 88: 379-89. http://dx.doi.org/10.1016/0378-5173(92)90336-Z
3. RS Ashok, KB Chandra Sekhar. Development and Validation of Analytical Method for Estimation of Balofloxacin in Bulk and Pharmaceutical Dosage Form. J. Glo. Tre. Pharm. Sci 2012; 3(2): 647-55.
4. Nakagawa T, Ishigai M, Hiramatsu Y, Kinoshita H, Ishitani Y, Ohkubo K *et al*. Determination of New Fluoroquinolone Balofloxacin and its Metabolites in the Biological Fluids by High Performance Liquid Chromatography. Arzneimittel forschung 1995; 45(6): 716-8. PMid:7646578
5. Deng J, Xiao Z, Zhang H, Zhang M, Tang T. Determination of Balofloxacin in Human Plasma by HPLC with Solid Phase Extraction. Se Pu 2007; 25(6): 942-3. PMid:18257322
6. M Yaxian, W Yan, L Hualong and L Lijian. (cited 2013 Jan 13, Available from: URL: http://eng.hi138.com, Updated 2010 March 29).
7. Yin S, Tao G, Jing Wang Z, Yun Biao T, Long Shan Z. Determination of Balofloxacin in Human Plasma by HPLC with Fluorescence Detection. Journal of Shenyang Pharmaceutical University 2007; 11: 691-4.
8. Bian Z, Tian Y, Zhang Z, Xu F, Li J, Cao X. High Performance Liquid Chromatography – Electrospray Ionisation Mass Spectrometric Determination of Balofloxacin in Human Plasma and its Pharmaceutics. J. ChromatogrBAnalyt. Technol. Biomed. Life Sci 2007; 850(1-2): 68-73. http://dx.doi.org/10.1016/j.jchromb.2006.11.001 PMid:17161665

Source of support: Nil, Conflict of interest: None Declared

QUICK RESPONSE CODE	ISSN (Online) : 2277 –4572
	Website http://www.jpsionline.com

How to cite this article:
Nayak Shreya and Sanjay Pai P. N. Development and validation of a new spectrophotometric method for the determination of balofloxacin in pharmaceutical tablet dosage forms. *J Pharm Sci Innov*. 2013; 2(4): 59-61.