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Development and Validation of a New UV Method for Analysis of Balofloxacin

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ABSTRACT

A new, rapid sensitive, simple and cost effective UV method was developed for the estimation of balofloxacin in bulk as well as in pharmaceutical formulations. The absorbance of balofloxacin was measured in 0.1N sodium hydroxide at new wave length (λ_{max} 290). The linearity range was found to be 1-9 µg/ml.The method was tested and validated for various parameters as per ICH specification. The result demonstrates that the developed procedure is accurate, precise and reproducible. Proposed method is applicable for the estimation of balofloxacin in different dosage forms and results are in good agreement with label claim.

Key words: Balofloxacin, 0.1N Sodium hydroxide, UV method.

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INTRODUCTION

Balofloxacin is the fourth generation of a new class of synthetic anti bacterial fluoroquinolone agents. Balofloxacin chemically (1-cyclopropyl-6-fluoro-1,4-dihydro -8-methoxy-7(3 methyl amino-piperidin-1-yl)-4-oxoquinolone-3-carboxylic acid. It has a broad anti bacterial Spectrum, ranging from gram positive bacteria to gram negative bacteria. Along with its poor water solubility it also has poor solubility in most of organic solvents, but it has pH dependent solubility. In literature, various analytical methods, such as RP-HPLC, UV have been developed for determination of balofloxacin. Though HPLC method is highly sensitive and accurate but it is time consuming (Processing time) and demands lot of expertise with higher cost. Developed methods needs costly solvents. Thus there is need to develop simple rapid and cost effective method for routine analysis. The objective of present study was to develop simple, sensitive, accurate rapid and cost effective method for estimation of balofloxacin. Analytical method was developed in sodium hydroxide 0.1N using UV spectrophotometer. The developed method was statistically validated as per ICH guidelines.

MATERIALS AND METHODS:

All Chemicals and reagents used were of analytical grade and purchased from merck Chemicals Corporation Ltd, Mumbai. A double beam Shimadzu UV Visible Spectrophotometer having two matched quartz cells, with1 cm light path, was employed for spectral measurement. Balofloxacin tablets (100 mg per tablet) were procured from local pharmacy store. 0.1N sodium hydroxide was used throughout the investigation.

Preparation of standard and sample solutions

A solution of balofloxacin of concentration 1000 µg/mL was prepared by dissolving 50mg of the pure drug in 50 mL of 0.1N sodium hydroxide. Standard stock solution was suitably diluted with 0.1N sodium hydroxide to give a concentration range of 1-9 µg/mL. The solutions were scanned in the UV range 200-400 (Figure 1), the absorbance was measured at 290 nm against blank. The above method was used to determine balofloxacin in tablets. Twenty tablets containing 100mg of balofloxacin were weighed and powdered. The powered drug equivalent to 50 mg of balofloxacin was weighed accurately and transferred into a suitable flask. The tablet powder was dissolved in 0.1N sodium hydroxide and filtered through a whatman filter no: 41.This filtrate was diluted to 50mL with 0.1N sodium hydroxide. Further dilution was done to get concentration of 1, 3, 5, 7, 9 µg/mL of balofloxacin solution in 0.1N sodium hydroxide. The absorbances of these solutions were measured at 290 nm .The drug content of the preparation was calculated

using the standard curve (Figure 2). The developed method was validated as per ICH guidelines. The results were reported in table 1. The recovery studies were conducted by the addition of different amounts of pure drug to a known concentration of pre analyzed tablet solution. To reveal that Percentage recovery was calculated by using formula given below

$$\% \text{ Recovery} = \frac{N \Sigma x\, y - \Sigma y\, \Sigma x}{N (\Sigma x2) - (\Sigma x)\, 2}$$

x- Amount of standard drug added

y- Amount of drug found by proposed method

N- Number of observations

RESULTS AND DISCUSSION

The proposed method shows absorption maxima at 290 nm and obeyed Beer's law in concentration range of 1-9 µg/ml. The percentage recovery value indicate that there is no interference of the excipients in the formulation the low value of standard deviation and coefficient of variation indicate that the proposed method is precise table 2.All statistical data prove validity of proposed method, which can be applied in industries for routine analysis of this drug from tablet.

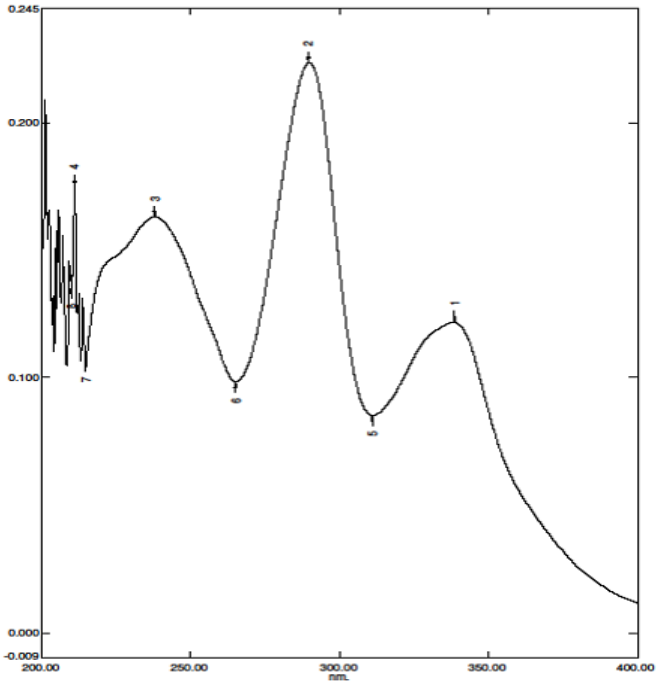

Figure 1. Determination of maximum wavelength of Balofloxacin

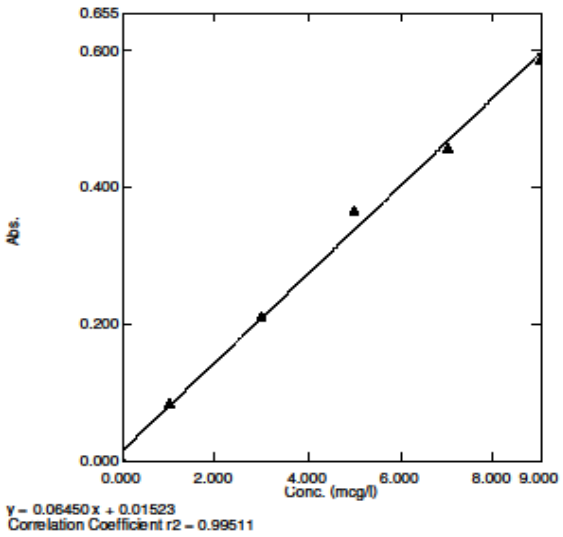

Figure 2. Calibration curve of Balofloxacin

Table 1: Validation Parameters

S.No	Parameters	Values
1	Maximum wavelength	290
2	Beer's law limit (µg/ml)	1-9%
3	Recovery	97.6
4	Regression equation	y = 0.06452 x + 0.01523
5	Slope(m)	0.06452
6	Intercept(c)	0.01523
7	Correlation coefficient	0.9951

Table 2: Assay of tablet formulations

Labeled claim (mg)	Amount	%Assay (mg)	%RSD
100	99.87	99.87	0.73

***Mean of six determinations

REFERENCES:

1) Nakagawa T, Ishigai M, Hiramatsu Y,Kinoshita H, Ishitani Y, Ohkubo K, Okazaki A. Determination of the new fluoroquinolone balofloxacin and its metabolites in biological fluids by high performance liquid chromatography. Arzneimittel for schung Jun-1995;45(6):716-8.

2) Mi Yaxian, WuYan, Li Hualong, Li Lijian.Study on determination of related - substances in balofloxacin by RP HPLC, Available from:http://eng.hi138.com, Updated 2010 March 29.

3) Yin S., et al. Determination of balofloxacin in human urine by RP-HPLC with fluorescence detection. Journal of Shenyang Pharmaceutical University 2007; 11:691-4.

4) Bian Z, Tian Y, Zhang Z, Xu F, Li J, Cao X. High performance liquid chromatography electrospray ionization mass spectrometric determination of balofloxacin in human plasma and its pharmacokinetics. J Chromatogr B Analyt Technol Biomed Life Sci. May- 2007;850(1-2):68-73.

5) Ponam M.Thumar, vandana B.patel, Development and validation of analytical Method for estimation of balofloxacin in bulk and pharmaceutical dosage form, International J Pharm Tech Res 2011; 3:1938-1941.

6) International conference on harmonization, guidance for industry, In Q2B validation on Analytical procedures, methodology, 1992, 2.