Research Article

Development of UV Spectrophotometric Method for Estimation of Clarithromycin in Pharmaceutical Dosage Forms by using Folin-Ciocalteu Reagent

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ABSTRAT

A simple and sensitive Spectrophotometric method has been described for the assay of clarithromycin either in pure form or in pharmaceutical solid dosage form. Absorption maxima of clarithromycin in 0.1 N Hydrochloric acid and folin catechu reagent were found to be at 760.5 nm. Beer's law is obeyed in the range 20-120µg/mL. Result of percentage recovery and placebo interference shows that the method was not affected by the presence of common excipients. The percentages assay of clarithromycin in tablet was more than 99%. The method was validated by determining its sensitivity, accuracy and precision which proves suitability of the developed method for the routine estimation of clarithromycin in bulk and solid dosage form.

Keywords: Clarithromycin, UV spectrophotometer, Folin-Catechu Reagent.

INTRODUCTION

Clarithromycin is a semi-synthetic macrolid used as an antibacterial. Its structure is similar to that of erythromycin, except that the o-methyl group has been substituted for a hydroxyl group at positions six of the lactones[1].It exhibits greater potency against Myc. Pneumonia, Legionella Spp., H. influenza and Mor. Catarrhalis than erythromycin. It is also used for the treatment and prevention of disseminated M. avium infection in patients with AIDS[2, 3].

As most of the methods reported for determination of clarithromycin are HPLC with electrochemical[4,5] or mass spectrometric detection[6-8]. The Spectrophotometric detection with HPLC is based on pre-column derivatization[9-10] because the molecule lacks suitable chromospheres. Clarithromycin is relatively weak UV absorbing compound and therefore, the direct UV absorbance measurements at low concentration will be unreliable.

Hence, the authors have made an attempt to develop a simple and rapid UV Spectrophotometric method for the estimation of clarithromycin in the bulk drugs and in pharmaceutical formulations taking water as solvent.

EXPERIMENTAL SECTION

Instrument and Apparatus

A Shimadzu UV-Visible Spectrophotometer (UV-1800 Pharmaspec, Japan) with 1-cm matched quartz cells was used for absorbance measurement. Glassware used in each procedure were washed with double distilled water and dried in hot air oven.

Reagents and Materials

All chemicals were of analytical reagent grade and double distilled water was used to prepare solutions.

Pharmaceutical grade clarithromycin was kindly provided by Ajanta Pharmaceutical Ltd., India.

Standard Drug Solution

A stock standard solution of 1mg/mL clarithromycin was prepared by dissolving 25 mg of pure drug in 25 mL of 0.1N hydrochloric acid in 25 mL in calibrated flask. 10 ml of this solution was diluted to 25 ml with 0.1 N HCl to prepare stock solution having concentration of 400 mcg/ml. From the stock solution 1.5 ml was transferred to 10 ml volumetric flask, to this solution 2 ml of dilute F. C. reagent (one part of F. C reagent + two part of distilled water) and 2 ml of 20 % sodium bicarbonate solution was added and volume was made to 10 ml with 0.1 N HCl to prepare solution

having concentration of 60 mcg/ml. This solution was then transfered to test tube and allows completing reaction for 15-20 minutes. The solution was then scanned in the range of wavelength 200 to 800 nm against blank (2 ml of 0.1 N HCl + 2 ml of dilute F. C reagent + 2 ml 20 % sodium carbonate solution). The UV spectrum showing λmax was recorded using double beam UV-Visible spectrophotometer. (Fig. 1). The same λ max was used for further measurement of drug.

Method

Different aliquots of (0.5, 1, 1.5, 2, 2.5, 3 mL) 0f 0.4 mg/mL were transferred to the series of 10 ml volumetric flask. To each of this solutions 2 ml of dilute F. C. reagent (one part of F. C reagent + two part of distilled water) and 2 ml of 20 % sodium bicarbonate solution were added and volume was made to 10 ml with 0.1 N HCl. These solutions were then transferred to test tubes and allow completing reaction for 15-20 minutes. Absorbance values of these solutions were measured against blank (2 ml of 0.1 N HCl + 2 ml of dilute F. C reagent + 2 ml 20 % sodium carbonate solution and volume was made to 10 ml with 0.1 N HCl) at 760.5 nm using double beam UV Spectrophotometer.

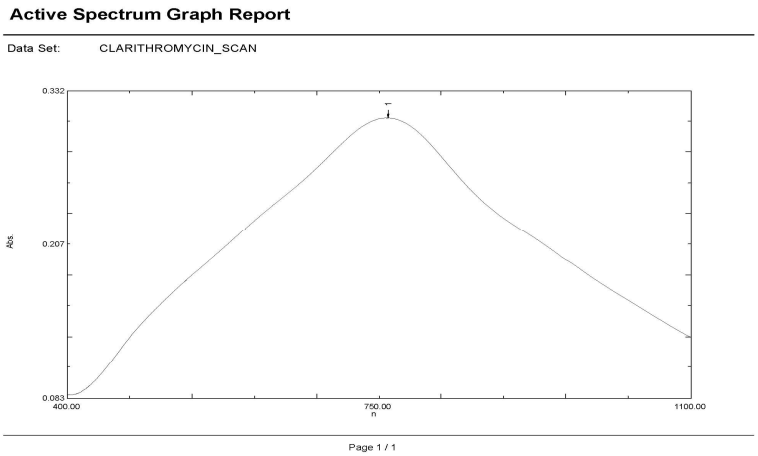

Fig. 1: Standard Chromatograph for Clarithromycin

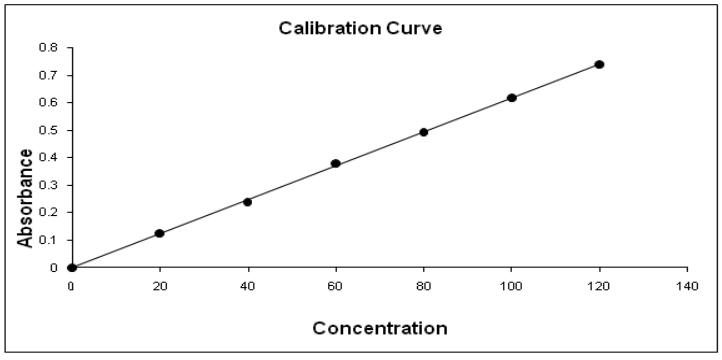

Fig. 2: Standard plot for Clarithromycin

Assay of Pharmaceutical Formulation

Twenty tablets were weighed accurately and ground into a fine powder. Powder equivalent To 500mg of Clarithromycin was weighed accurately and transferred into a 50 mL volumetric flask with 20 mL 0.1N hydrochloric acid, dissolved the powder and made up volume with 0.1N hydrochloric acid. 4 ml of this solution was diluted to 100 ml with 0.1 N HCl to prepare a solution having concentration of 400 mcg/ml. From the solution 1.5 ml was

transferred to 10 ml volumetric flask, to this solution 2 ml of dilute F. C. reagent (one part of F. C reagent + two part of distilled water) and 2 ml of 20 % sodium bicarbonate solution was added and volume was made to 10 ml with 0.1 N HCl to prepare solution having concentration of 60 mcg/ml. This solution was then transferred to test tube and allowed to complete reaction for 15-20 minutes. Absorbance of this solution was measured against blank (2 ml of 0.1 N HCl + 2 ml of dilute F. C reagent + 2 ml 20 % sodium carbonate solution) at 760.5 nm using double beam UV Spectrophotometer.

RESULTS AND DISCUSSION

The absorption spectrum of Clarithromycin was measured in the range 400–1100 nm against the blank solution. The standard solution show maximum absorbance at λ max as recorded in Table 1. And the method was validated by studying the following parameters.

Table 1: Parameters for determination of Clarithromycin

Parameters	Values
λ max(nm)	760.5
Beer's law limit (µg/ml)	20-120
Regression equation	
Slop(m)	0.012
Intercept (c)	0.0124
Correlation coefficient	0.9997

The assay of the above method in the case of formulation was presented in Table 2.

As an additional check on the accuracy of these methods, recovery experiments were performed by adding known amounts of pure drug to pre-analyzed formulation and percent recovery experiments were also done. Recovery experiments indicated the absence of interferences from the commonly encountered pharmaceutical additives and excipients.

Table 2: Assay of Clarithromycin in Pharmaceutical Formulations

Formulation	Label Claim (mg)	Amount Found(mg) FFFoundFound(mg)	% Assay*
A	500	502.52	100.50
B	500	501.35	100.27

A and B are tablets from different batches (Biaxin, Abbott aboratories)
*Assay amount was the average of six determinants.

CONCLUSION

It could be concluded that the developed method for estimation of Clarithromycin in pharmaceutical dosage forms and in bulk is simple, sensitive, relatively precise and economical. The proposed methods are used for the routine analysis of the drugs in the quality control.

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