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RESEARCH ARTICLE

VALIDATED SPECTROPHOTOMETRIC METHOD FOR THE ESTIMATION OF CLARITHROMYCIN IN MARKETED FORMULATION USING DYE DRUG REACTION

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ABSTRACT:

Quality is important in every product or service, but it is vital in medicine, as it involves life, so there should not be any compromises to quality of drug product. In Present work a simple method developed for the estimation of clarithromycin in marketed formulation by spectrophotometer. The developed methods were found to be linear up to 10-50µg/ml**.** The values of mean percent recoveries were found to 99.12 to 99.44%**.** The mean percent label claims of tablets by the proposed methods were close to 100, indicating the accuracy of the proposed method and low values of standard deviation and percentage relative standard deviation was found to less than 2. The proposed Spectrophotometric methods were accurate, precise and reliable for the measurement of clarithromycin in dosage form.

Keywords: Spectrophotometric, Clarithromycin, Validation

INTRODUCTION:

Modern medicines for human use are required to comply with specific standards and regulation set forth by the concerned authorities. The efficacy and safety of medicinal products can only be assured by analytical monitoring of its quality. Pharmaceutical analysis is an art and science of determining the concentration of drug constituents present in marketed formulation.[1] It is

considered as an application of procedures necessary to determine and estimate the identity, strength, quality and purity of drug. Therefore, the quality control laboratory is considered as the backbone of the Pharma industries with ever-increasing need for the development of analytical techniques for drug formulation.[2]

Clarithromycin is a novel macrolide antibiotic with a methoxy group (-OCH3) attached to the C-6 position of erythromycin, which makes it more acid stable than erythromycin. Clarithromycin is a broad spectrum antibiotic it is active against both gram positive and gram negative micro bacteria like *Staphylococcus aureus, E. coli, Klebsiella, proteus*[3]. Clarithromycin is used to treat soft tissue and skin infections, Clarithromycin is also used to treat both upper and lower respiratory tract infection, *Helicobacter pylori* infections.[4]

MATERIALS AND METHODS

Apparatus

The present work was carried out on UV visible spectrophotometer (Labindia 3000+). The absorption spectra of reference and test solution were carried out in a 1 cm quartz cell over the range of 200-800nm.

Chemicals and reagents

All chemicals of analytical grade were used.

Methyl orange (Narang Laboratory Reagent) dye solution: 2% dye solution was prepared by dissolving 2g of Methyl orange in100ml of distilled water.

Methods

Preparation of calibration curve

The absorption maxima of clarithromycin were determined by running the spectrum of drug solution in double beam ultraviolet spectrophotometer. Accurately weighed 10 mg of Clarithromycin separately and dissolved in 10 ml of 0.1N HCL in 10 ml of volumetric flask and prepared suitable dilution to make different concentration of standard with concentration range of 10-50µg/ml clarithromycin. From this take 2, 2…….ml of each conc. of 10 µg/ml, 20 µg/ml…….50 µg/ml and add 1 ml of methyl orange dye solution and 3 ml of chloroform pipette out the coloured layer and calculate the absorbance at 416.nm. (LABINDIA UV 3000 +)

Table No. 1 Readings for Calibration curve of clarithromycin

Replicate	10	20	30	40	50
1	0.112	0.285	0.398	0.553	0.765
2	0.111	0.283	0.394	0.551	0.763
3	0.114	0.286	0.396	0.551	0.767
Mean	0.112	0.285	0.396	0.552	0.765
S.D.	0.002	0.002	0.002	0.001	0.002
% RSD	1.360	0.537	0.505	0.209	0.261

Table No. 2 Stastical Data For Linearty

S.No.	Parameter	Remark
1	Linearty Range	10-50 µg/ml
2	Regression Equation	0.015x+0.023
3	Correlation Cofficient	0.990

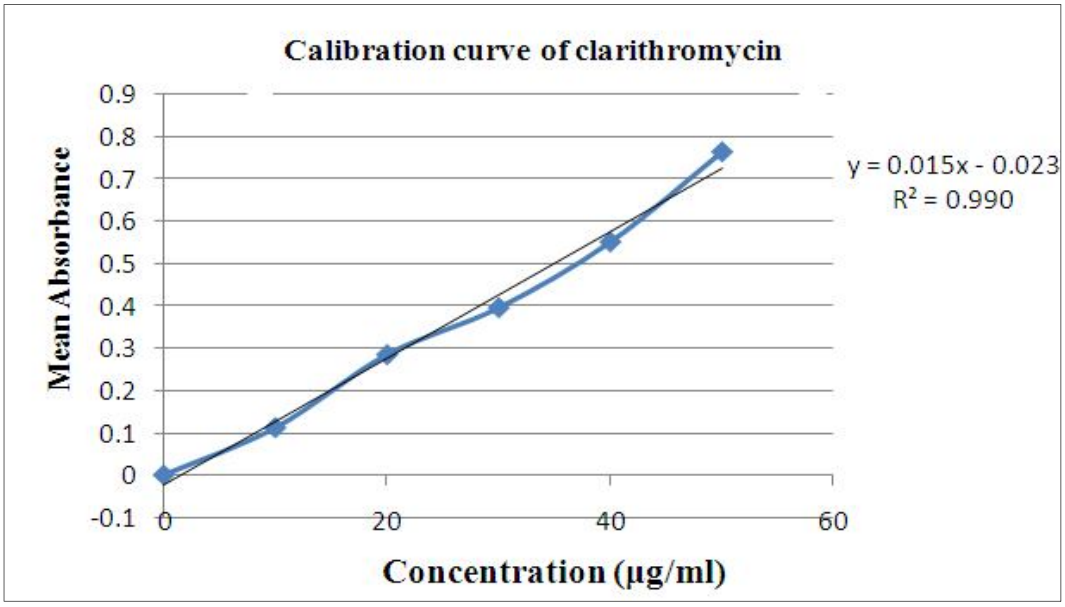

Fig. 1: Calibration Curve of Clarithromycin at 416nm

Assay of tablet formulation

Twenty tablets were taken and average weight of tablet was determined. The tablets were crushed in a mortar and the powder equivalent to 100mg of drug was transferred to 100ml standard flask. The powder was dissolved in 50 ml of 0.1 N HCl and made up to volume with of 0.1 N HCL. The sample was mixed thoroughly and filtered through a 0.45µ membrane filter. The filtered solution was diluted suitably and add 1 ml of methyl orange dye solution and 3 ml of chloroform pipette out the coloured layer and analyzed for drug content by UV spectrophotometer at a λmax of 416.0 nm using of 0.1 N HCl as blank.

Validation of developed method [5]

Linearity

Linearity of both drugs was established by response ratios of drugs. Response ratio of drug calculated by dividing the absorbance with respective concentration. Then a graph was plotted between concentration and response ratio.

Accuracy

The accuracy of the proposed methods was assessed by recovery studies at three different levels i.e. 80%, 100%, 120%. The recovery studies were carried out by adding known amount of standard solution of clarithromycin to preanalysed tablet solutions. The resulting solutions were then re-analysed by proposed methods. Whole analysis procedure was repeated to find out the recovery of the added drug sample. This recovery analysis was repeated at 3 replicate of 5 concentrations levels.

Precision

Precision of the methods was studied at three level as at repeatability, intermediate precision (Day to Day and analyst to analyst) and reproducibility. Repeatability was performed by analyzing same concentration of drugs for five times. Day to Day was performed by analyzing 5 different concentration of the drug for three days in a week. The results are shown in table 4.

Table No. 3: Results of recovery studies on marketed formulations

Recovery Level %	% Recovery (Mean±SD)*
80	99.44±0.158
100	99.55±0.258
120	99.12±0.145

*Average of five determination

Table No. 4: Results of validation (%R.S.D.)

	Parameters	Results
Precision (%R.S.D.)*	Repeatability	0.045
	Day to Day	0.052
	Analyst to Analyst	0.046
	Reproducibility	0.078

*Average of five determination

Conclusion

The proposed spectrophotometric methods were accurate, precise and reliable for the Measurement of clarithromycin in dosage form. The developed spectrophotometric method was validated for estimation of clarithromycin using linearity, range, accuracy and precision. The RSD for all parameters was found to be less than one, which indicates the validity of method and assay results obtained by this method are in fair agreement. The developed method can be used for routine quantitative estimation of clarithromycin in pharmaceutical Preparation.

Reference

1. Mehdhem J, Denney RC, Barnes JD and Thomsa MJK. Chemical analysis. Vogel's Text Book of quantitative Chemical Analysis. Pearson Education Limited; Delhi,6th Ed. 2002; 1-11.
2. Willard HH, Merritt Jr. LL, Dean JA and Settle Jr. FA. Introduction to Instrumental Methods of Analysis. CBS Publishers and Distributors: Delhi. 7th Ed 2001;112.
3. Khan NW, Hassan Fouzia, Naqvi BS and Hasan MF. Antimicrobial activity of Erythromycin and Clarithromycin against clinical isolates of *E. coli, Staphylococcus aureus, Klebsiella* and *Proteus* by disc diffusion method. Pak J Pharm Sci. 2011; 24(1):25-29.
4. Parish LC. Clarithromycin in the treatment of skin and skin structure infections: two multicentre clinical studies. Clarithromycin study group. Int J Dermatol. 1993; 32: 528-32.
5. Guidance for Industry Q2B Validation of Analytical Procedures: Methodology.