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Research Article

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UV Visible Spectrophotometric Estimation of Roxithromycin

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ABSTRACT

Selective and New spectrophotometric method has been developed for the estimation of Roxithromycin in bulk and tablet dosage form. Roxithromycin shows maximum absorbance at 420nm in presence of solvent Deionised Water and phosphate buffer of pH 7.4. The Beer's law is obeyed in the concentration range of 20-70 µg/ mL for this drug. The graph of the drug shows a straight line with correlation coefficient of 0 .9840. The assay method of the drug was validated by accuracy and precision of the proposed method. The results are validated as per the directions of International conference on Harmonization.

Keywords: Roxithromycin; Deionised water; Phosphate buffer of pH 7.4; UV spectrophotometry

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INTRODUCTION

It is a New generation Erythromycin,semi synthetic macrolide antibiotic , nullifies growth of bacteria and their synthesis of proteins. The molecular formula of the drug is $C_{41}H_{76}N_2O_{15}$ and molecular mass of 837.047 g/mol .It is a Semi synthetic White solid and freely soluble in Methanol, Ethanol, DMF, DMSO and Deionised Water. The molecular structure of the drug is shown in the figure 1 . Literature survey of Roxithromycin reveals that Different spectrophotometric methods have been reported [2-5].Therefore, an attempt was made to develop a low cost precise and accurate spectrophotometric method for the estimation of Roxithromycin in bulk and tablet dosage form.

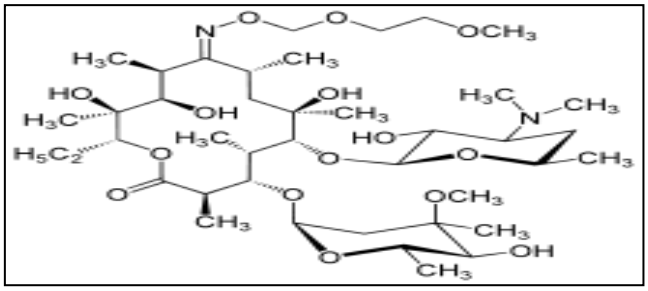


Figure 1: Structure of Roxithromycin

EXPERIMENTAL SECTION

Instruments and materials

A Shimadzu UV-1700 UV/VIS Spectrophotometer was used with 1 cm matched quartz cell. All the chemicals used were of analytical grade and procured from Merck India Ltd, Hyderabad. Pharmaceutical formulation of Roxithromycin was procured from Cipla PharmaceuticalsLtd, Hyderabad. Commercially available tablets namely Rotip (75mg) and Roxyfin (75mg) procured from Medwin pharmacy, Hyderabad,

Selection of solvent
Deionised Water and phosphate buffer of pH 7.4**[7]** are used throughout the analysis.

Selection of method and wave length
UV scan range of 380 nm to 500 nm was selected for the proposed method of Roxithromycin . The wavelength corresponding to maximum absorbance was found at 420 nm and calibration curve was taken at 420 nm. The intercept of calibration line of the drug was determined by linear regression analysis.

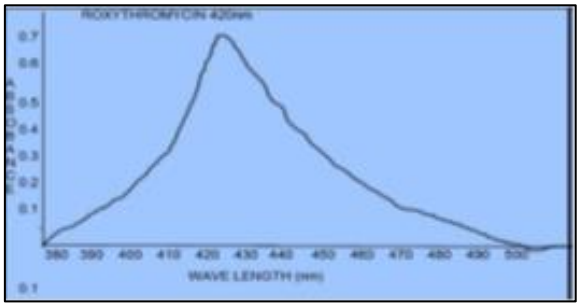
Preparation of standard stock solution and calibration curve
The 10 mg of standard (pure) drug of Roxithromycin is weighed accurately and dissolved in 100 ml Deionised water then transferred into 100 ml volumetric flasks to prepare 1000 µg/ mL**[6]**stock solution of Roxithromycin. Then to get different aliquots of of 2 to7 ml of standard stock solution were transferred into series of six 10 ml volumetric flasks and made upto mark by adding Deionised water to get the given concentration range .To each flask 2mL of phosphate buffer of pH 7.4 solution is added, then all stock solutions of the drug were scanned in the UV scan range of lambda max (λmax) 380 nm to 500 nm to determine maximum absorbance of this method. The calibration curve was plotted in the concentration range of 20-70 µg/ mL. The wavelength corresponding to maximum absorbance of Roxithromycin measured at 420nm against Deionised water as blank.

Preparation of sample solution
For the analysis of Roxithromycin two commercial brands namely Rotip (75mg) and Roxyfin (75mg) tablets were purchased from Medwin pharmacy, Hyderabad .Twenty tablets of the drug was weighed accurately and powdered, then 10 mg of the drug in powdered form dissolved in 100 ml of Deionised water and sonicated for few minutes and filtered by using whatmann filter paper No.42. The filtrate of 10µg/mL concentration is taken in a six 10 ml volumetric flasks. To each 10 ml flask 2mL of phosphate buffer of pH 7.4 solution is added. Then absorbance of Roxithromycin measured at 420nm against Deionised water as blank

Validation of method [8]
The spectrophotometric estimation of Roxithromycin is validated as per the directions of International conference on Harmonization to determine linearity, precision, accuracy, LOD and LOQ of the proposed method.

Linearity and range
Standard stock solution of Roxithromycin in appropriate dilution were assayed as per the proposed method According to Beer's –Lambert's law the concentration range of Roxithromycin was found to be 20-70 µg/ mL, So that the calibration curve in the figure 2 is linear in the given concentration range.

Figure 2: UV spectrum of Roxithromycin in water



Precision
The precision of the proposed method of Roxithromycin was estimated by using drug concentration of Roxithromycin were analyzed six times in a day (intra-day precision) and six continuous days (inter-day precision). Data is given in the table 2

Accuracy
The Accuracy of the proposed method of Roxithromycin was estimated by using standard addition method .This process is carried out by adding different amounts namely 80% ,100% and 120% of the pure sample of the drug to the pre-analysed formulation. Accuracy data of the drug is shown in the table 2

LOD and LOQ
LOD is Limit of Detection and LOQ is Limit of Quantitation. The LOD and LOQ of Roxithromycin were determined (Table 1) by using standard deviation of the response and slope approach as per the directions of

International Conference on Harmonization (ICH) guidelines. The limits of detection (LOD) is calculated by using the equation LOD $= \frac{3s}{k}$ Where, S = intercept of the standard deviation K = The slope of the calibration curve (mean) The limits of quantitation (LOQ), is calculated by using the equation LOQ $= \frac{10\,S}{K}$ Where, S = intercept of the standard deviation K = The slope of the calibration curve (mean).

Recovery studies of roxithromycin

Recovery analyses of Roxithromycin were performed to know the accuracy of the proposed method. This process is done by adding a known quantity of pure drug to a pre-analysed sample. The result of analysis of the drug is notified in the table 3

Table 1: Optical parameters of Roxithromycin

S No	Parameter	Roxythromycin
1	λMax (nm)	420nm
2	Beer's Law Limit (µg/mL)	20-70
3	Correlation Coefficient (r2)	0.984
4	Regression Equation (Y=a+bc)	0.017×0.0860
5	Intercept (a)	0.086
6	Slope ©	0.017
7	SD	18.7082
8	Mean	45
9	Variance	350
10	LOD (%)	1.313
11	LOQ (%)	3.98

Table 2: Precision and accuracy of Roxithromycin

S No	Name of the sample	Labeled amount (mg/capsule)	% Level	Amount found* (mg)	% Recovery
1	Rotip	75	74.23	0.0061	0.0068
2	Roxyfin	75	74.01	0.0075	0.0082

*average of 6 determinations

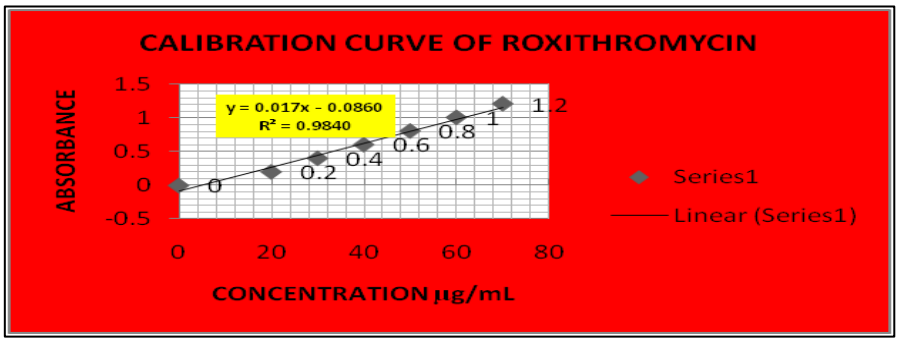
Table 3: Recovery studies of marketed formulations of Roxithromycin

S No	Name of the sample	Labeled amount (mg/capsule)	% Level	Amount found* (mg)	% Recovery
1	Rotip	75	120	74.23	98.9733
2	Roxyfin	75	80	74.01	98.68

RESULTS AND DISCUSSION

The U.V Spectrum of standard stock solutions of Roxithromycin shows absorption maximum at 420 nm, then the calibration curve is obtained by plotting a graph of absorbance verses concentration, the Beer –lamberts' law was verified from the data of calibration curve of the drug under investigation. The calibration curve of the drug is shown in the figure 3. The linearity was observed between 20-70 µg/mL for Roxithromycin. The graph of this drug shows a straight line with correlation coefficient of 0 .9840. The assay method of the drug was validated by the accuracy and precision of the proposed method shown in table 2. The % recovery of 98.97-98.68 shows accuracy of the proposed method. The validated optical, statistical parameters, LOD and LOQ data of Roxithromycin is given in table 1.

Figure 3: Calibration curve of Roxithromycin



CONCLUSION

The developed method was found to be simple, sensitive, accurate, precise, economic and can be used for routine quality control analysis of Roxithromycin in bulk as well as in pharmaceutical dosage form.

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