NOTE

Visible spectrophotometric Determination of Roxithromycin in Pharmaceutical Solid Dosage Form

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A new visible spectrophotometric method is developed for the estimation of roxithromycin (RXM) in pharmaceutical solid dosage form. The method is based on the reaction of RXM with marquis reagent which forms a brown coloured chromogen with absorption maximum at 495 nm. The chromogen formed is stable and beer's law is obeyed in the concentration range of 15–25 µg/mL.

Roxithromycin[1-3] (RXM) is a semisynthetic macrolide antibacterial, widely used for treatment of various bacterial, orodental, skin and soft tissue infections[4,5]. It is chemically erythromycin-9-[o-[(2 methoxy-ethoxy)methyl]oxime]. It is not official in any pharmacopoeia and the literature survey reveals a UV spectroscopic method[6], HPLC methods[7-16] and a bioassay method[17] for the determination of RXM in its formulation and biological fluids. No simple spectrophotometric method is reported so far in the literature for the estimation of RXM and hence in the present communication we describe a new, simple and rapid spectrophotometric method for the estimation of RXM using marquis reagent.

An Elico model SL 159 UV-VIS spectrophotometer having two matched glass cells with 1 cm length was used for absorbance measurements.

Marquis reagent[18]

Freshly prepared solution containing 10 volume of sulphuric acid and 1 volume of formaldehyde solution was used for the colour development.

Preparation of standard solution

Stock solution of RXM was prepared (1 mg/1 mL) in absolute ethanol.

Calibration curve

Aliquots of standard solutions representing 10–30 µg/mL of RXM were transferred into 500 mL serially numbered volumetric flask. 1 mL of freshly prepared marquis reagent was added and the volume was made upto 100 mL with distilled water. The absorbance of this solution were measured at 495 nm using reagent blank.

Estimation of roxithromycin tablets

Tablet powder equivalent to 50 mg of RXM was weighed accurately and transferred into a 50 mL volumetric flask. The contents were dissolved and made upto 50 mL with absolute ethanol. Filtered. 1 mL of the filtrate representing 20 μg/mL was pipetted out into a 50 mL of volumetric flask and 1 mL of the freshly prepared marquis reagent was added and the volume was made upto 50 mL with distilled water.

The absorbance was measured at 495 nm against reagent blank. The absorbance for 20 μg/mL concentration of pure RXM was also measured at 495 nm for the calculation of drug content in tablets. The tablets were also analysed by the reported HPLC method[14].

Recovery study

To study the accuracy, reproducibility and to check the interference of excipients in tablets recovery study was performed. The recovery of the added standard was studied at four different levels. Each level was repeated five times. From the amount of drug found the percentage recovery was calculated using the formula (Table-1).

$$\% \text{ recovery} = \frac{N \cdot \Sigma XY - \Sigma X \cdot \Sigma Y}{N \cdot \Sigma X^2 - (\Sigma X)^2} \times 100$$

where X = amount of standard drug added.

Y = amount of drug found by proposed method.

N = total number of observations

TABLE-1
ANALYSIS OF ROXITHROMYCIN TABLETS

Tablets	Amount found by		Percentage recovery[c]	Standard deviation	Coefficient of variation
	Proposed method[a]	Reported method[b]			
Sample 1	149.65	150.26			
Sample 2	150.37	150.94	99.89	0.7247	0.4830
Sample 3	150.08	150.46			

[a]Each result is the mean of five replicates
[b]HPLC method: RXM was chromatographed on an hypersil ODS(C_{18}) column (250 X 4.6 mm 5 μ) at ambient temp with 220 nm detector. Acetonitrile : water : triethylamine (60 : 40 : 0.1) was used as a mobile phase at a flow rate of 1 mL/min.
[c]Recovery of 0 mg, 10 mg, 20 mg and 30 mg was added to pharmaceutical preparations.

The coloured solution exhibited maximum absorption at 495 nm and the colour was stable for more than 5 h. The optimum concentration for the estimation of RXM was established by varying one parameter at a time and keeping the others fixed and observing the effect of product on the absorbance of the coloured species and incroporated in the procedure. Beer's law is obeyed in the concentration range of 15–25 μg/mL (slope = 0.0177, Intercept = 0.698, r = 0.9998, molar

absorptivity = $1.4892 \times 10^4 \, mol^{-1} \, cm^{-1}$). The percentage recovery value (99.89%) indicates that there is no interference of the excipients present in the formulation. The low value of standard deviation and coefficient of variation indicates high precision of the proposed method and hence it can be used for routine analysis.

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