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NOTE

Visible Spectrophotometric Determination of Clarithromycin in Pharmaceutical Solid Dosage Forms

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A new simple visible spectrophotometric method is developed for the estimation of clarithromycin in pure and pharmaceutical dosage forms. The method is based on the reaction of the drug with marquis reagent which forms a brown coloured chromogen with absorption maximum at 495 nm. The chromogen formed is stable and obeys Beer's law in the concentration range of 10–70 μg/mL.

Key Words: Spectrophotometric determination, Clarithromycin.

Clarithromycin (CMN) is designated chemically as 6-methoxy erythromycin[1]. It is employed in the treatment of streptococcal pharyngitis, community-acquired respiratory tract infections, skin and soft tissue infections and acute sinusitis. It is currently being evaluated for the treatment of some refractory infections in AIDS patients. The drug is official in USP[2]. Some methods to determine the drug in biological fluids like gastric juice, plasma, serum and urine by ion-pair HPLC[3], capillary electrophoresis[4], RP-HPLC[5,6] have been reported. HPLC[7,8] and colorimetric[9] methods have been developed for the assay of CMN in bulk and various dosage forms.

Marquis reagent[10]: Freshly prepared solution containing ten volumes of sulphuric acid and one volume of formaldehyde solution was used for colour development

Preparation of standard solution:

Stock solution of CMN was prepared (1 mg/mL) in absolute methanol.

Calibration curve: Aliquots of standard solution representing 0.1–0.7 mL of CMN were transferred into 10-mL serially graduated tubes. Then 1.5 mL of freshly prepared marquis reagent was added and the volume made up to 10 mL with distilled water. The absorbance of this solution was measured at 495 nm using a reagent blank.

Estimation of clarithromycin in tablets

Tablet powder equivalent to 100 mg of CMN was weighed accurately and

transferred into a 100 mL volumetric flask. The contents were dissolved and made up to 100 mL with absolute methanol and filtered. 0.5 mL of the filtrate representing 50 μg/mL was pipetted out into a 10 mL graduated tube and 1.5 mL of freshly prepared marquis reagent was added and the volume was made up to 10 mL with distilled water.

The absorbance was measured at 495 nm against reagent blank. The absorbance for 50 μg/mL concentration of pure CMN was also measured at 495 nm for the calculation of drug content in tablets. The tablets were also analysed by the reported colorimetric method.[9]

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)

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

where X = amount of standard drug added
Y = amount of drug found by proposed method
N = total number of observations

TABLE-1
ANALYSIS OF CLARITHROMYCIN TABLETS

Tablets	Amount found by		Recovery[c] (%)	Standard deviation	Coefficient of variation
	Proposed Method[a]	Reported Method[b]			
Sample 1	249.65	250.26			
Sample 2	250.37	250.94	99.98	0.7147	0.4843
Sample 3	250.08	250.46			

[a]Each result is the mean of six replicates.
[b]**Colorimetric method:** CMN was estimated by extractive spectrophotometry by using bromophenol blue dye.
[c]Recovery of 0 mg, 10 mg, 20 mg, 30 mg, 40 mg and 50 mg was added to pharmaceutical preparations.

The coloured solution exhibited maximum absorption at 495 nm and the colour was stable for more than 2 h.The optimum concentration for the estimation of CMN 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 incorporated in the producer. Beer's law is obeyed in the concentration range of 10–70 μg/mL (slope = 0.0089, intercept = 0.0012, r = 0.9999, molar absorptivity = 7.5045×10^3/mol cm). The percentage recovery value (99.98%)

indicates that there is no interference of the excipients present in the formulation. The low value of standard deviation and coeffcient of variation indicates high precision of the proposed method and hence it can be used for routine analysis.

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