

## A NEW SPECTROPHOTOMETRIC METHOD FOR DETERMINATION OF CLARITHROMYCIN IN TABLETS

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### ABSTRACT

A new spectrophotometric method for determination of clarithromycin in tablets has been proposed. The drug forms a green chromogen with *p*-dimethylamino benzaldehyde in sulphuric acid, which can be estimated in the concentration range of 10–70 µg/mL at 600 nm.

**Key words:** Clarithromycin, Spectrophotometric method

### INTRODUCTION

*Clarithromycin* (CMN), designated chemically as 6-methoxy erythromycin<sup>1,2</sup> is currently being evaluated for the treatment of some refractory infections in AIDS patients. So far, some HPLC<sup>3,4</sup> and colorimetric<sup>5–9</sup> methods have been developed for the assay of this drug. The authors now propose a new spectrophotometric method for determination of CMN in which the drug forms a green chromogen with *p*-dimethyl amino benzaldehyde and sulphuric acid. The absorbance measurements are made at 600 nm.

### EXPERIMENTAL

**Standard and sample solution :** About 100 mg of pure clarithromycin was accurately weighed and dissolved in 100 mL of methanol in a volumetric flask to make a 1 mg/mL standard solution. Two commercial samples of the drug tablets (Crixan of Croslands and Clarithro of Alembic) were chosen for determining the drug in tablets by the proposed method. Twenty tablets were finely ground and the powder equivalent to 100 mg was accurately weighed. The powder was mixed thoroughly with 100 mL of methanol in a volumetric flask and filtered to make the sample solution.

**Reagent.** A 2% solution of *p*-dimethylamino benzaldehyde (PDAB) was prepared by dissolving appropriate quantity of a Loba sample of the compound in conc. sulphuric acid.

Spectral measurements were made on a Systronics UV-Vis. spectrophotometer (Model 117) with 10 mm matched quartz cells.

**Method :** To each of a series of 10 mL graduated test tubes, the standard drug solution ranging from 0.1–0.7 mL and 1.5 mL of PDAB reagent were added and the volume of the

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contents was brought to 10 mL with conc.  $\text{H}_2\text{SO}_4$ . The absorbance of the green coloured species formed was measured at 600 nm against a reagent blank. A calibration curve of the absorbances obtained for different concentrations of the drug was plotted. The sample solutions from the tablets were also treated in a similar manner and the corresponding absorbances were measured. The amount of CMN present in each of the sample solutions was computed from the above standard plot.

## RESULTS AND DISCUSSION

The optical characteristics of the method are: Beer's law limits (10–70  $\mu\text{g}/\text{mL}$ ), Sandell's sensitivity (0.10948  $\mu\text{g}/\text{cm}^2/0.001$  A.U.), molar extinction coefficient ( $6.8313 \times 10^3$  lit/mol/cm), percent relative standard deviation (0.8954) and percent range of error (0.7486 and 0.9999 at 0.05 to 0.01 confidence limits, respectively). Values for slope (0.0089), intercept (0.00125) and correlation coefficient (0.9999) were obtained by regression analysis. The proposed method has been extended to two commercial brands Crixan and Clarithro and the percent recoveries were found to be 100.4 and 99.8, respectively. Studies indicated that the usual diluents and additives employed in tablets did not interfere in determination of the drug accurately by the proposed method. Hence, the authors conclude that the proposed spectrophotometric method for the estimation of CMN is simple, sensitive and accurate and can be applied for routine quality control analysis of the drug in tablets.

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