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AREA UNDER CURVE AND SECOND ORDER DERIVATIVE SPECTROSCOPY OF METAXALONE IN BULK DRUG AND TABLET FORMULATION

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ABSTRACT

Two simple, accurate, and precise spectrophotometric methods have been developed for metaxalone in pharmaceutical dosage form. Metaxalone has absorbance maxima at 278 nm. Method-A is area under curve (AUC) method, which involves the calculation of integrated value of absorbance with respect to wavelength between 246-288 nm Method-B involves the derivatisation of the primary absorption spectra for the second order. The amplitude (D_L) of the long wave peak satellite of the second order curve was measured in mm. Beer's law is obeyed in the concentration range of 40-240 μg/mL in these two methods. The results of analysis were validated statistically and the recovery studies were found to be satisfactory. The additives and common excipients did not interfere in their determinations.

Key words: Metaxalone, Area under curve, Second order derivative spectroscopy, Ethanol.

INTRODUCTION

Metaxalone is a muscle relaxant used to relax muscles and relieve pain caused by strains, sprains, and other musculoskeletal conditions. It may impair mental and/or physical abilities required for performance of hazardous tasks, such as operating machinery or driving a motor vehicle, especially when used with alcohol or other CNS depressants. It is chemically 5-(3,5-dimethyl phenoxy) methyl) oxazolidin-2-one.

Literature survey has indicated that, no spectroscopy method has been developed for the determination of metaxalone in tablets. Area under curve (AUC) and second order derivative spectroscopy provide greater selectivity than common spectroscopy and offer powerful approach for resolution of band overlapping. The aim of the present study is the

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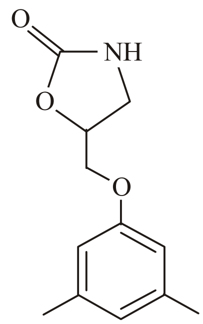
development of a simple, accurate and sensitive area under curve (AUC) and second derivative spectroscopic method for the determination of metaxalone.



EXPERIMENTAL

Instrumentation

Spectroscopic analysis was carried out on a double beam Shimadzu UV/Visible spectrophotometer. The zero order absorption spectra were recorded over the wavelength range of 200 -400 nm, against solvent blank, in quartz cuvettes with 1 cm matched cell. For all solutions, the second order derivative spectra were also obtained over 200-400 nm. All the measurements were made using Shimadzhu UV visible spectrophotometer with 1 cm matched quartz cells. All the solutions were freshly prepared in distilled water.

Preparation of standard stock solution

Standard and calbration solutions

Standard stock solutions of metaxalone were prepared using ethanol. Appropriate volume of standard stock solution was diluted with ethanol to get a concentration of 100 μg/mL of metaxalone. Further dilutions were made from these solutions in distilled water to get standard linearity concentrations in the range of 40-240 μg/mL for metaxalone.

Sample preparation

A total number of twenty tablets were accurately weighed and powdered in a mortar. Quantities of the powdered tablets equivalent to 50 mg were accurately weighed and transferred in a 50 mL volumetric flask. Weighed powder was dissolved in 30 mL of ethanol and the volume made upto 50 mL with ethanol, mixed thoroughly and shaken for 10 minutes. Solution obtained was filtered through Whatman filter paper No. 42 and few mL of the filtrate were discarded and diluted with the distilled water (solvent) to get the required concentrations.

Method A: Area under (AUC) method involves measurement of the area between two wavelengths at the point of maximum absorbance. The integrated value of absorbance with respect to the wavelength was selected for calculation. Two wavelengths selected are 246-288 nm. Standard dilutions of stock solution were prepared and scanned in spectrum mode from 400-200 nm and calibration curve was plotted.

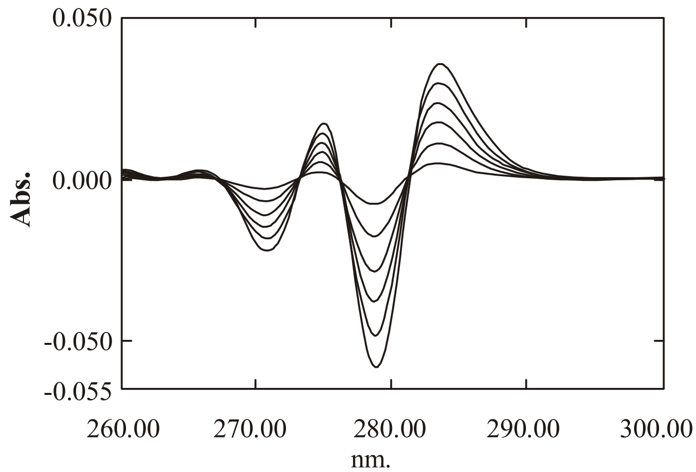


Fig. 1: Standard overlay spectrum

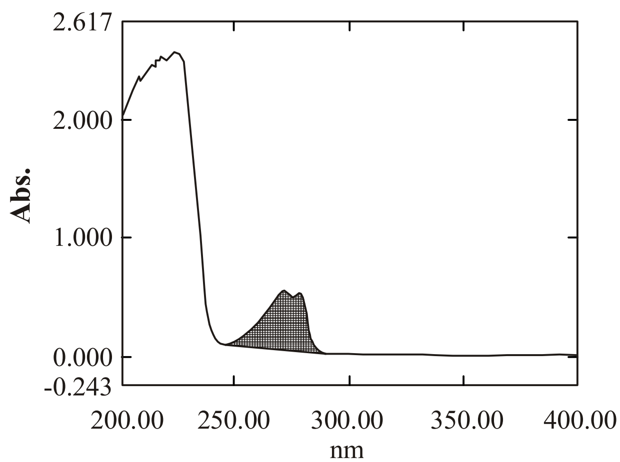


Fig. 2: Area under curve

Method B: Calibration curves were constructed by analysis of working standard solutions of metaxalone. Each concentration was analysed in triplicate. UV absorption spectra and second derivative amplitude values (D_2) of metaxalone were measured. Calibration curve was plotted by taking second derivative values (D_2) on Y-axis and concentrations on X-axis. The relation between drug concentration (x) and its corresponding D_2 value (y) is expressed by the equation (Y = mx + b), where m is slope and b is intercept.

Sample analysis

Applicability of the proposed methods for the AUC and second order derivative estimation of metaxalone was studied by assay of commercial tablets.

RESULTS AND DISCUSSION

The optical characteristics such as absorption maxima, Beer's law limits, and regression characteristics like slope (b), intercept (a), correlation coefficient (r), and standard error were calculated and the results are summarised in Table 1.

Table 1: Optical characteristics

Parameters	UV spectroscopy	Derivative spetroscopy
Wave length (nm)	278	278
Beer's law limits (µg/mL)	40-240	40-240
Slope (m)	0.0874	0.3669
Intercept (c)	- 0.42954	- 2.6071
Regression (y = mx + c)	0.08743X + (-0.042954)	0.2928X + 02.6071
Correlation coefficient (r)	0.9997	0.9997
Standard error	0.01822	0.7302

*Average of three determinations

To study the accuracy and reproducibility of the proposed method, recovery experiments were carried out by adding a known amount of drug to pre-analysed sample and the percentage recovery was calculated. The results are furnished in Table 2. The results obtained are in good agreement with the lable claim.

Rapid, simple and specific area under curve and second order derivative spectroscopic methods have been developed for estimation of metaxalone. These two methods are successfully applied for determination of drug in tablet dosage forms. This can be useful for the routine drug analysis in quality control laboratories.

Table 2: Assay and recovery

Tablet Metaxalone	Label claim	Amount found by proposed method	%Amount by the proposed method	%Recovered by the proposed method
Method A	400 mg	404.28	102.69	95.10
Method B	400 mg	397.76	99.30	98.14

*Average of three determinations

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