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DERIVATIVE SPECTROSCOPIC DETERMINATION OF MESALAMINE IN TABLET DOSAGE FORMS

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ABSTRACT

Mesalamine (5-Amino salicylic acid) is used because of its local effect in the treatment of inflammatory bowl disease. Mesalamine is a bowel-specific aminosalicylate drug that is metabolized in the gut and has its predominant actions there, thereby having less systemic side effects. There fore the aim of this work to estimate Mesalamine in tablet dosage forms. Mesalamine has absorption maxima at 325.4nm (method A) and in the first order derivative spectra showed sharp peak at 310 nm (method B) using 0.1 N sodium hydroxide as solvent. Calibration curve of drug was found to be in the concentration range of 5-25µg/ml for both methods. The proposed methods were successfully applied for determination of Mesalamine in commercial tablet dosage forms. The results of the analysis were validated statistically and by recovery studies and were found to be satisfactory.

Keywords: Mesalamine, Sodium hydroxide, Zero order derivative, First order derivative.

INTRODUCTION

Chemically Mesalamine is 5-amino salicylic acid[1-4]. It is an anti-inflammatory drug structurally related to salicylates and active in inflammatory bowel disease[5, 6].Tablet formulations containing 250, 400 and 500 mg are available in the market. Literature survey reveals that Mesalamine is estimated by HPLC[7],visible spectrophotometric method[8, 9]. Derivative spectroscopic methods have not been reported for estimation of Mesalamine in single component formulations. Hence, an attempt has been made to develop derivative spectroscopic methods for its estimation in pharmaceutical formulations with good accuracy, precision and economy.

MATERIALS AND METHODS

Instrument: A double-beam Shimadzu UV-Visible spectrophotometer 1700 and a pair of 1-cm matched quartz cells were used.

Materials: Standard gift sample of Mesalamine was provided by Cosmo Pharma Pvt. Ltd. Goa. Mesalamine tablets were purchased from Local market, 0.1N NaOH was used as a solvent.

Standard Stock solution: Standard stock solution of Mesalamine was prepared by dissolving 100mg in 100ml of 0.1N NaOH. Working standard solution of drug was prepared by further dilution with 0.1N NaOH.

Procedure[10-12]

Method A: Zero order derivative Spectroscopy

For the selection of analytical wavelength, 30µg/ml solution of was prepared by appropriate dilution of standard stock solution and scanned in the spectrum mode from 400nm to 200 nm. From the spectra of drug (Fig a), λ max of Mesalamine 325.4 nm was selected for the analysis. The calibration curve (Fig b) was found to be in the concentration range of 5-25 µg/ml. The amount of drug present in the sample was computed from its calibration curve.

Method B: First Order Derivative Spectroscopy

In this method, 30µg/ml solution of Mesalamine was prepared by appropriate dilution of standard stock solution and scanned in the spectrum mode from 400 nm to 200 nm. The absorption spectra thus obtained were derivatized from first to fourth order. First order derivative spectra were selected for analysis of drug (Fig c). First order derivative spectra of drug showed a sharp peak at 310 nm,which was selected for its quantification. The calibration curve (Fig d) for Mesalamine was plotted in the concentration range of 5-25µg /ml. The amount of drug present in the sample was computed from its calibration curve.

Assay of Mesalamine in Tablet Dosage forms:

Two brands of commercially available tablets were taken, twenty tablets each weighing 400mg were weighed and powered. A tablet powder equivalent to 100 mg was weighed accurately and transferred in to 100 ml volumetric flask containing 50 ml of 0.1N NaOH, the flask was sonicated for 5 min, the volume was made up to mark with 0.1N NaOH, and the solution was filtered through whatmann filter paper 41, from the above stock solution, working standard solution of 100mg/ml were prepared by further dilution with 0.1N NaOH, the above procedure was applied for analysis.

RESULTS AND DISCUSSION

The methods described in the present work provide a convenient and accurate way for analysis of Mesalamine in its pharmaceutical formulations. Absorbance maxima of Mesalamine at 325.4 nm (Method A) and in the first order derivative spectra at 310.0 nm (Method B) were selected for the analysis. Calibration curves in the concentration range of 5-25 µg/ml for Method A and B respectively.

TABLE NO 1: OPTICAL CHARACTERISTICS AND PRECISION

Parameters	Method A	Method B
λ max (nm)	325.4	310
Beer's law limits (µg/ml)	5-25	5-25
Molar absorptivity (L mol^{-1} cm^{-1})	3.4918 X 10^3	3.055X10^3
Regression equation (Y = a+bc)		
Slope (b)	0.0224	0.0210
Intercept (a)	0.008	-0.021
% R S D	0.2710	0.1159
Correlation coefficient (r)	0.9999	0.9998
Confidence limit with 0.05 level	9.7918 X 10^{-4}	4.8960 X 10^{-4}
Confidence limit with 0.01 level	1.4486 X 10^{-3}	7.2436 X 10^{-4}

Y=bC+a were C is the concentration of Mesalamine in µg/ml and Y is absorbance unit

TABLE NO 2: EVALUATION OF MESALAMINE IN PHARMACEUTICAL DOSAGE FORMS

	Label claim (mg)	Amount of drug obtained by proposed method (mg)	% Label claim ± S.D	% Recovery*
M_1	400	398.64	99.66 ± 0.2103	99.37
M_2	400	398.74	99.69 ± 0.1791	99.28

* mean of six determinations, M_1 = Mesacol (Uni pharma Pvt Ltd), M_2 = Walasa (Wallace Pvt Ltd)

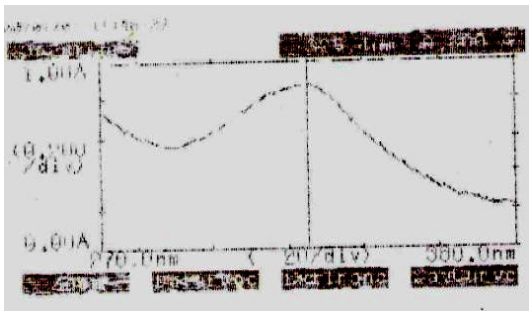

Figure a
UV Spectrum of Mesalamine

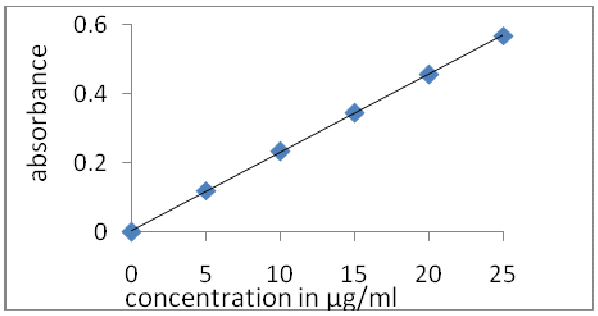

Figure b
UV Calibration Curve of Mesalamine

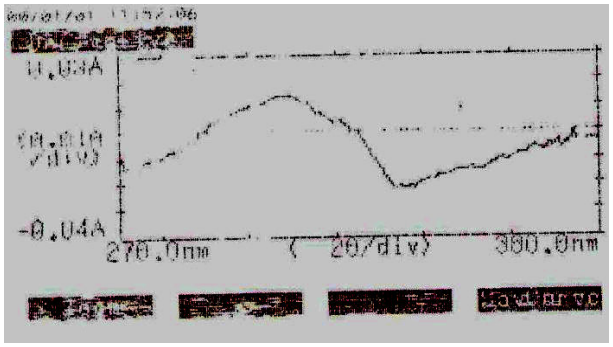

Figure c
First Order Spectrum of Mesalamine

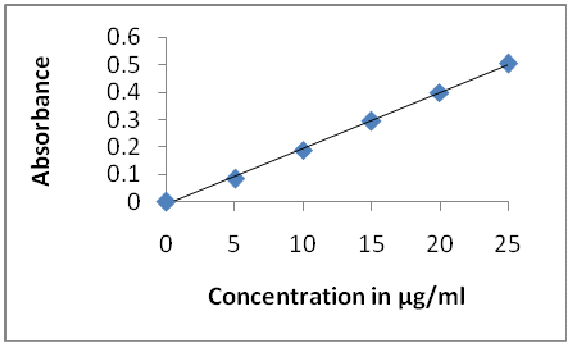

Figure d
First order Calibration Curve

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