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Spectrophotometric Method For Estimation Of Erdosteine In Bulk And Capsule Dosage Form

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ABSTRACT

A simple, accurate, reproducible spectophotometric method for estimation erdosteine in bulk and capsule dosage formulation was developed. Beer's law is obeyed in the concentration range of 5 -90 µg/ml at the detection wavelength of 237.4 nm. Correlation coefficient, LOD, LOQ and COV were found to be 0.9998, 0.595, 1.798 and 0.899 respectively. Mean percent recoveries for commercial formulation found to be 98.772 ± 0.378. Results of analysis validated statistically and by recovery studies.

KEYWORDS

Erdosteine;
UV-Vis spectrophotometry

INTRODUCTION

Erdosteine chemically [[2-Oxo-2-[(tetrahydro-2-oxo-3-thienyl)amino]ethyl] thio] acetic acid having empirical formula $C_8H_{11}NO_4S_2$ is a thiol derivative developed for the treatment of chronic obstructive bronchitis, including acute infective exacerbation of chronic bronchitis[1]. It is yet not official in any Pharmacopiea. erdosteine modulates mucus production and viscosity and increases mucociliary transport, thereby improving expectoration. It also exhibits inhibitory activity against the effects of free radicals produced by cigarette smoke[2].

Literature survey revealed that; a method for quantitation of erdosteine in human plasma by use of 96-well solid-phase extraction (SPE) followed by liquid chromatography–electro spray ionization tandem mass spectrometry (LC–ESI/MS/MS) detection is reported[3]. Also HPLC determination of Erdosteine and its optical active metabolite is reported[4]. There is no spectrophotometric method reported for estimation of erdosteine. In the present investigation, an economical, precise and accurate spectrophotometric method has been developed for quantitative determination of Erdosteine in the bulk drug and capsule dosage form.

MATERIALS AND METHODS

Equipment

The instrument used in the present study was JASCO double beam UV/visible spectrophotometer

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TABLE 1. Optical characteristics of the proposed method.

Parameters	Values
λmax (nm)	237.4
Beer's law limit (µg/ml)	5-90
Molar absorptivity (l $Mol^{-1}cm^{-1}$)	5.068×10^3
Slope (m)	0.0194
Intercept (c)	0.0164
Correlation coefficient	0.9998
% COV (n=5)	0.899
Limit of Detection (µg/ml)	0.595
Limit of Quantitation (µg/ml)	1.798

(Model UV-530) with fixed slit width 2 nm connected to a computer with spectra manager software. All weighing were done on electronic balance (Model Shimdzu AY -120).

Chemicals and reagents

All chemicals used in spectrophotometric analysis were of analytical grade. Erdosteine sample was obtained from Glenmark Pharmaceuticals Ltd. (Nashik, India).

Procedure

Accurately weighed 25 mg of erdosteine was dissolved in 25 ml of methanol. 10 ml of this solution was diluted further to 100 ml with distilled water to get stock solution of 100 µg/ml. The aliquots of stock solution were transferred to 10 ml volumetric flasks and volume was made up to the mark with distilled water to get working standard solutions of erdosteine in concentration range of 5-90 µg/ml. Absorbance of the solutions were measured at 237.4 nm against blank and calibration curve was prepared.

For analysis of capsule dosage form (ERDOZET 300 mg, Glenmark Pharmaceuticals) powdered capsule contents equivalent to 25 mg of Erdosteine was weighed accurately and dissolved in 25 ml of methanol and filtered. 10 ml of this filtrate was diluted further to 100 ml with distilled water to get sample solution of 100 µg /ml. Two ml of sample solution was further diluted to 10 ml with distilled water to get final concentration of 20 µg/ml. Absorbance of this solution was recorded at 237.4 nm against blank and drug concentration in sample solution was determined from calibration curve.

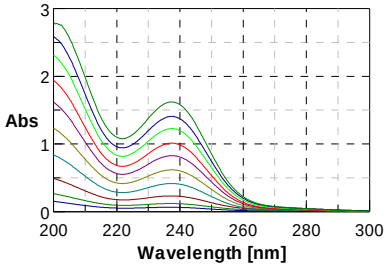

Figure 1. Overlain zero order spectrums of Erdosteine (a) 5; (b) 10.0; (c) 20.0; (d) 30.0; (e) 40.0 (f) 50 (g) 60 (h) 70 (i) 80 and (j) 90 µg/ml.

RESULTS AND DISCUSSION

The optical characteristics of the proposed method have been calculated and presented in TABLE 1. Mean percent recoveries for commercial formulation found to be 98.772 ± 0.378 with standard error of 0.218. To evaluate the accuracy and precision of the proposed method, recovery studies were carried out by addition of standard drug solution to preanalysed sample and determination was repeated at three-concentration levels[5]. The percent recovery data of the drug by this method is given in TABLE 2. Overlain zero order spectrums of erdosteine are shown in figure 1. The accuracy is evident from the data as results are closer to 100 % and low standard deviation values of determination indicate reproducibility of the method. The proposed method is simple, sensitive, precise and accurate. Hence it can be used for routine analysis of Erdosteine in bulk as well as in capsule formulation.

TABLE 2. Recovery study for erdosteine

Level of % Recovery	Amount present (µg/ml)	Amount of standard drug added(µg/ml)	Total Amount Recovered*	% Recovery*	Mean % Recovery (± SD)
80	20	10	29.817	99.39	99.551
100	20	20	39.88	99.70	± 0.156
120	20	30	49.78	99.56	

* Avg. of three determinations

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REFERENCES

[1] K.L.Dechant, S.Noble; Drugs, **52,** 875-81 **(1996).**
[2] M.Vagliasindi, G.B.Fregnan**;** Int.J.Clin.Pharmacol, Ther.Toxicol., **27**, 238-241 **(1989).**
[3] H.Kim, K.Y.Chang, H.J.Lee, S.B.Han, K.R.Lee; J.Pharm Biomed.Anal., **34**, 661-669 **(2004).**
[4] N.Muramatsu, T.Toyo'oka, K.Yamaguchi, S.Kobayashi; J.Choromatogr B.Biomed Sci.Appl., **719,** 177-189 **(1998).**
[5] Validation of Analytical procedures: Methodology, ICH Harmonized Tripartile guidelines, adoption on 6 November **(1996).**