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SPECTROPHOTOMETRIC ESTIMATION OF ACEBROPHYLLINE IN BULK AND CAPSULE FORMULATION

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ABSTRACT

A simple and precise UV spectrophotometric method (I) and first derivative spectrophotometric method (II) were developed for the estimation of acebrophylline in pharmaceutical dosage form. The λ_{max} of acebrophylline was found to be 273 nm and it shows zero crossing at 273 nm in the first derivative spectrum with $\Delta\lambda$. Linearity for these methods lies in the range of 10-80 µg/mL. The proposed methods are sensitive, accurate, reproducible and useful for the routine determination of acebrophylline in capsule dosage form.

Key words: Acebrophylline (ACE), UV spectrophotometry, First derivative spectrophotometry.

INTRODUCTION

Acebrophylline is chemically 4-[(2-amino-3, 5-dibromophenyl) methyl amino] cyclohexan-1-ol, compd. with 2-(1, 3-dimethyl-2, 6-dioxopurin-7-yl) acetic acid and is used in the treatment of chronic obstructive pulmonary disease and bronchial asthma. No method of estimation for acebrophylline in bulk and formulation has been reported so far. All the measurements were made using Shimadzu UV Visible Spectrophotometer with 1 cm matched quartz cells. All the solutions were freshly prepared with distilled water.

EXPERIMENTAL

Preparation of standard stock solution

An accurately weighed amount of 100 mg of ACE was taken in 100 mL volumetric flask and dissolved in 25 mL of distilled water. Then it was made up to volume with distilled

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water.

Preparation of sample solution

Twenty capsules were weighed accurately and then emptied. The empty shells were reweighed and the powder was mixed uniformly. The powder equivalent to 100 mg of acebrophylline was taken in 100 mL volumetric flask and dissolved in 25 mL of distilled water and then it was made up to volume with the same distilled water. The solution was then filtered. The first few mL of the filtrate was discarded and remaining solution was used for the analysis.

Assay procedure

Method I: Aliquots of the standard stock solution were transferred to a series of 100 mL volumetric flask and suitably diluted to give a varying concentrations ranging between 10-80 µg/mL. The solutions were scanned in the spectrum mode from 400-200 nm using distilled water as blank[5]. The λ_{max} was found to be 273 nm. A calibration graph was obtained by plotting concentration versus absorbance. It obeyed Beer's law in the range of 10-80 µg/mL. The sample solution was suitably diluted to get a concentration between 10-80 µg/mL and the procedure adopted for standard solutions was followed. The absorbance obtained for the sample was then interpolated on the calibration graph and the concentration of ACE in the sample was then determined.

Method II: Aliquots of the standard stock solution were transferred to a series of 100 mL volumetric flask and suitably diluted to give a varying concentrations ranging between 10-80 µg/mL. The solutions were scanned in the spectrum mode from 400-200 nm using distilled water as blank. The normal spectrum obtained was derivatized to the first order using derivative mode[5]. The amplitudes of the derivative spectra between 266.60-287.60 nm were noted**.** A calibration graph was obtained by plotting concentration versus amplitude. The sample solution was suitably diluted to get a concentration between 10-80 µg/mL and the procedure adopted for standard solutions was followed. The amplitude obtained for the sample was then interpolated on the calibration graph and the concentration of acebrophylline in the sample was then determined.

RESULTS AND DISCUSSION

The optical characteristics such as RSD, regression equation, correlation coefficient, slope and intercept for the two methods were calculated and the results are summarized in Table 1. To evaluate the validity and reproducibility of the methods, recovery studies were carried out by adding a known amount of pure drug to previously analyzed capsules powder

sample and reanalyzed. The results obtained are presented in Table 2. Interference studies revealed that the excipients and additives did not interfere. Hence, these methods are most economic, simple, sensitive and accurate and can be used for the routine determination of ACE in pharmaceutical preparations.

Table 1: Optical characterestics for acebrophylline

Parameters	Method I	Method II
λ_{max} (nm)	273	266.60-287.60
Beer's law limits (µg/mL)	10-80	10-80
Molar absorptivity ($Lmol^{-1}$ cm^{-1})	1.0538×10^4	-
Sandell's sensitivity (µg cm^{-2}/0.001 abs unit)	0.00584	-
Slope (m)	0.017367	1.468333
Intercept (c)	-0.00689	0.155556
Regression equation (y = mx + c)	0.017367 x -0.00689	1.468333 x +0.155556
Correlation coefficient (r)	0.9999	0.9998
Relative standard deviation	0.00586	0.012436

Table 2: Assay and recovery of acebrophylline and its formulations

Formulation	Label claim (mg)	Amount found by proposed method*(mg)		% Recovery by the proposed method	
		Method I	Method II	Method I	Method II
Capsule	100	100.75	101.86	100.34	100.96

*Each average of three determinations

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