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ESTIMATION OF ACEBROPHYLLINE IN PHARMACEUTICAL ORAL SOLID DOSAGE FORM BY RP-HPLC

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ABSTRACT

A simple, specific and accurate reverse phase high performance liquid chromatographic method was developed for the estimation of acebrophylline in capsule dosage form. A phenomenex Gemini $C_{18,}$ 5µm column having 250x4.6mm i.d. in isocratic mode with mobile phase containing diammonium phosphate buffer (pH 4):methanol (60:40) was used. The flow rate was 1mL/minute and effluents were monitored at 273nm. The retention time was found to be 4.54minutes. The linearity was in the range of 80-120 µg/mL. The proposed method was validated and successfully applied for the estimation of acebrophylline in capsule dosage form.

Keywords: *Acebrophylline(ACE); RP-HPLC.*

INTRODUCTION

Acebrophylline is chemically, 4-[(2-amino-3,5-dibromophenyl)methylamino]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[1-4]. No method of estimation for acebrophylline in bulk and formulation has been reported so far. The objective of the present work was to develop an accurate, specific and reproducible method for the estimation of acebrophylline in pharmaceutical oral dosage forms. Parameters are established for standardisation of the methods including statistical analysis of data.

EXPERIMENTAL

Instruments

Shimadzu prominence LC 20AT, UV-Visible detector SPD-20A, Phenomenex column Gemini 5µ C_{18} – spherical size 250X4.60mm.

Reagents

Methanol HPLC grade, Diammonium phosphate buffer HPLC grade.

Preparation of standard solution

The standard solution was prepared by dissolving adequate quantity of drug, accurately weighed and transferred into 100mL volumetric flask with the mobile phase. The stock solution was further diluted with mobile phase in the concentration range of 80-120µg/mL.

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 100mg of ACE was taken in 100mL volumetric flask and dissolved in mobile phase and sonicated for 10 minutes. The solution was made up to the mark with the mobile phase. The resulting solution was filtered through a nylon 0.45µ membrane filter. The first few mL of the filtrate was discarded. Aliquot from stock solution was further diluted with mobile phase to get samples in the concentration range of 80-120ìg/mL.

ASSAY PROCEDURE

Pharmaceutical formulation of ACE was successfully analyzed by applying 20µL of filtered final solution to HPLC system to obtain the chromatogram. The content of the drug was calculated by comparing the peak area of sample and standard[5-6]. The method was validated by establishing linearity, accuracy and precision of sample application.

RESULTS AND DISCUSSION

The mobile phase consisting of diammonium phosphate buffer (pH 4):methanol (60:40) with flow rate of 1ml/min was found to give R_t 4.54minutes. Statistical parameters such as regression characteristic, slope, intercept, correlation co-efficient, % RSD and standard error obtained from different concentrations were calculated and the results are summarized in Table 1. The chromatographic parameters were also validated by system suitability studies(Table 2). 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 3. The results indicate that there is no interference from other ingredients present in the formulation. Thus, the proposed method is cost effective, faster, and can be used for routine analysis.

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Table 1. *Statistical Parameters*

Parameters	Results obtained
Wavelength(nm)	273
Linearity Range (µg/ml)	80-120
Slope (m)	10.079
Intercept (c)	0.2508
Regression equation (y = mx + c)	10.079x+0.2508
Correlation co-efficient (r)	0.9999
Standard Error (SE)	0.2430

Table 2. *System Suitability Parameters*

Parameters	Results obtained
Asymmetric factor	1.32
Retention time	4.54minutes
Theoretical plates	8851
% RSD	0.5391

Table 3. *Assay and recovery of acebrophylline in dosage forms*

FORMULATION	LABEL CLAIM (mg)	AMOUNT FOUND(mg)*	AMOUNT OF DRUG ADDED(mg)	AMOUNT OF DRUG RECOVERED(mg)	% RECOVERY
CAPSULE	100	100.79	50	49.58	99.16%

** Each average of three determinations*

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