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Determination of Albuterol in Bulk and Dosage Form by UV-Visible Spectroscopy using Buffer-Ethanol System

Prashant G Phanasekar*, Pushpendra Sharma

Department of Chemistry, University Teaching Department, Sri Satya Sai University of Technology & Medical Sciences, Sehore-466001

ABSTRACT

A novel, simple, accurate and precise UV-visible spectroscopic method for determination albuterol in buffer-ethanol (1:1) system has been developed and validated. The linearity is obeyed over a concentration range of 10-100 µg/ml with correlation coefficient of 0.9989 for drug. The proposed method was validated by determining accuracy, precision and stability parameters. The method was found to be robust. The method was used successfully for the determination of albuterol in aerosol dosage form.

Keywords: Albuterol, Stress, Accuracy, Oxidation, Degradation

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***Address for Correspondence:**

Prashant G Phanasekar, Department of Chemistry, University Teaching Department, Sri Satya Sai University of Technology & Medical Sciences, Sehore-466001

INTRODUCTION

Albuterol is a beta-adrenergic agonist used as an anti-asthmatic drug [1]. Albuterol is used for the treatment and prevention of bronchospasm (acute or severe) in patients with reversible obstructive airway disease [2-4]. It is also indicated for the prevention of exercise-induced bronchospasm. Albuterol acts on beta-2-receptors to relax the bronchial smooth muscle [5-7]. It also inhibits the release of immediate hypersensitivity mediators from cells, especially mast cells. Although albuterol affects beta-1-receptors, this is minimal and has little effect on the heart rate [8-10]. Albuterol comes in a variety of dosing forms and strengths. An aerosol metered-dose inhaler gives 90 mcg (base)/actuation, which is equivalent to 108 mcg of albuterol sulfate. The powder metered-dose inhaler form gives the same values as the aerosol metered-dose inhaler. Albuterol also is offered in 2 mg and 4 mg tablets [11-13]. There are several methods for estimation of albuterol. The present study deals with estimation of albuterol in ethanol-buffer system. It is official in Indian pharmacopoeia [14]. It is estimated by acid-base titration method as per Indian pharmacopoeia and British pharmacopoeia [14]. The literature review reveals that HPLC [15] and UV spectrophotometric methods [16] have been reported for estimation of albuterol in pharmaceutical dosage forms. But for routine analysis, no simple and accurate method is available for determination of albuterol in tablet dosage form. The aim of present work is to find out a simple, sensitive, specific, spectrophotometric method and its validation for estimation of albuterol from pharmaceutical formulation. The present study deals with estimation of albuterol in ethanol-buffer system.

MATERIAL AND METHOD

Instruments

UV-Visible double beam spectrophotometer (UV-1700, SHIMADZU Co, Japan) with 1cm matched quartz cells, Micropipette of Variable volume 10-1000 µL (Gene Pete Co.) and Digital balance (Citizen Co.) were used.

Chemicals

Albuterol was purchased from Sigma Eldrich, Germany. The formulation of albuterol Asthalin, Cipla) was purchased from local market. All other used in the present study were of analytical grade. Triple distilled water was used in the present study. All chemicals and reagents used were of analytical grade.

Preparation of Standard Stock Solution

The standard stock solution was prepared by dissolving albuterol in 0.1N HCl to make final concentration of 200µg/ml. Different aliquots were taken from stock solution and diluted with 0.1N HCl separately to prepare series of concentrations from 10-120 µg/ml. The λ_{max} was found by UV spectrum of albuterol in 0.1NHCl: ethanol (1:1), in the range of 200-400 nm and it was found to be 276 nm.

Absorbance was measured at 276 nm against 0.1N HCl as blank. The calibration curve was prepared by plotting absorbance versus concentration (µg/ml) of albuterol.

Determination of Albuterol in dosage form

The proposed method was applied in order to determine the albuterol in formulation. The marketed tablet formulation of albuterol was used for this. The powder equivalent to 100 mg of albuterol was transferred in 100 ml volumetric flask and dissolved in 0.1NHCl by shaking. The volume was made up to mark to get final concentration of 1mg/ml. Frequent shaking given and volume was made up to 100ml mark with 0.1N HCL. The solution was then filtered through Whattman filter paper #01.This filtrate was diluted suitably with 0.1NHCl: ethanol (1:1) to get the solution of 100µg/ml concentration. The working solution of drug (100µg/ml) was prepared from standard stock solution in 0.1NHCl: ethanol (1:1). The absorbance of this solution was measured and amount of albuterol was calculated from the calibration curve. The readings were taken in triplicate.

Method Validation

According to the ICH guidelines, accuracy, precision, LOD, LOQ and linearity of the calibration curve were determined(Guideline, 2005). For linear response measurement, the least squares method was applied. The statistical analysis was calculated by ANOVA. Amounts of 60 and 80µg/ml of albuterol standard solution were added into pre analysed 60 and 80µg/ml samples and absorbance were measured and the recovery was calculated.

RESULTS AND DISCUSSION

Under experimental conditions described, linearity, assay of tablet, accuracy studies and precision were performed. In this study, linearity was observed in the concentration range of 2-10µg/ml and 2-20 µg/ml for albuterol and correlation coefficient was found to be > 0.998. The results of commercial formulation are presented in Table 1and figure 1. Results of accuracy studies are presented in Table 2.

Table 1: results obtained after analysis of albuterol

Parameters	Results
Absorption maxima(nm)	276
Linearity Range (µg/ml)	10-100
Standard Regression Equation	Y = 0.002*x* +0.0823
Correlation Coefficient (r^2)	0.9989
Accuracy (% recovery ±SD)	98.57±0.239
Precision (%)	1.628±0.326(Intraday) 1.279±0.215(Interday)
LOD (µg/ml)	4.239
LOQ (µg/ml)	12.708
%Drug found in formulation	99.78

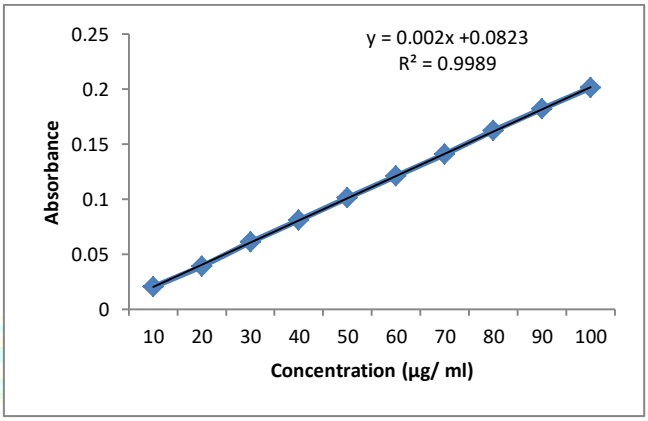

Figure 1: calibration curve of albuterol

Table 2: results of precision and recovery

S. No.	Amount of drug from formulation	% Addition	Amount added (µg/ml)	Amount recovered (µg/ml)	% Recovery	Precision (Intra day)*	Precision (Inter day)*
1.	Albuterol	60	100	60	59.19	1.55	1.26

Standard addition method was used to assess the accuracy. For evaluating precision, the selected concentration (60 µg/ml) were prepared in 0.1N HCL and analyzed to determine the intraday and inter day variability. The intra-day and inter day precision were determined. The precision and accuracy of the analysis are given in Tables 2, indicates high precision and accuracy.

Table 3: determination of albuterol in formulation

Formulation	Claimed amount	Amount found	Percent content
Albuterol	100 µg	98.235±0.358	98.23

Content of albuterol found in the marketed method from the proposed method is shown in Table 3. The % purity was 98.23%.

CONCLUSION

The two methods was developed and validated as per ICH guidelines. The standard deviation and % RSD calculated for the proposed methods are within limits, indicating high degree of precision of the methods. The results of the recovery studies performed indicate the methods to be accurate. Hence, it can be concluded that the developed spectrophotometric method is accurate, precise and can be employed successfully for the estimation of albuterol and ambroxol in bulk and formulation.

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