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Spectrophotometric method for determination of Bambuterol hydrochloride in bulk and tablets

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ABSTRACT

A simple, rapid, precise and accurate spectrophotometric method has been developed for estimation of Bambuterol hydrochloride from tablet formulation. In methanol, Bambuterol showed absorbance in the visible range at 265 nm. Linearity was observed in the concentration range of 40-240 µgmL^{-1} (r^2= 0.9990). The assay results were found to be in good agreement with label claim. The recovery studies were carried out at three different levels i.e. at 80%, 100%, 120%. The method was validated statistically and by recovery studies.

Key words: Bambuterol, Spectrophotometry.

INTRODUCTION

Bambuterol hydrochloride, [3(dimethylcarbamoyloxy) -5-[1-hydroxy-2-(tert-butyl amino) ethyl]phenyl] N,N-dimethylcarbamate is used as β_2 adrenergic agonist. Literature survey reveals potentiometric[1] method for estimation of bambuterol from pharmaceutical formulations. The present study describes a simple rapid and economical UV-visible spectrophotometric estimation of bambuterol from tablets. The method was validated as per ICH method validation guidelines.

MATERIAL AND METHODS

Preparation of standard stock solution

Standard stock solution was prepared by dissolving 10 mg of bambuterol in 10 ml methanol. Different aliquots were taken from the stock solution to obtain series of concentrations. The solutions were scanned on Shimadzu UV-1601 Spectrophotometer, in the visible range and absorbance was recorded at the λ_{max} 265 nm against methanol as blank. The calibration curve was found to be linear in the concentration range 40 to 240 mcg/ml. The linear regression was found to be y = 0.001x + 0.004 with r^2 = 0.999.

Preparation of sample solution

Twenty tablets were accurately weighed, their average weight determined and crushed in to fine powder. An accurately weighed quantity of tablet powder equivalent to 10 mg of bambuterol was transferred to 10 mL volumetric flask containing 6 mL methanol, sonicated for 5 min and filtered. Volume of filtrate was made up to 10 ml with methanol. After appropriate dilution, absorbance of solution was recorded at 265 nm. The concentration of the drug was determined by linear regression equation; the results are shown in Table 1.

Table 1: Results of Assay

Label Claim (mg/tablet)	Amount found*	% Amount found	%RSD
Bambuterol (10 mg)	9.865	98.65	0.243

*Average of six determinations

Recovery studies

To check the accuracy of the proposed method, recovery studies were carried out at three different levels i.e. 80%, 100% and 120%. To the preanalysed sample solution, the amount of bulk drug was added at three different levels; it was then reanalyzed. The results from the recovery studies are shown in Table 2.

Table 2: Summary of validation parameters

Parameters	Visible spectro-photometric method
E (1%,1cm)	10.68
Linearity (µg/ml)	40 -240
LOD	5.54
LOQ	16.79
Accuracy (%Recovery)	95 -98 %
%RSD	0.9656
Precision (%RSD)	0.0816
Intra-day (n = 3)	1.704
Inter-day (n = 3)	1.93
Repeatability (n =6)	1.99
Sandell Sensitivitymcg/cm^3/AU	0.009441

RESULTS AND DISCUSSION

Bambuterol is β_2 adrenergic receptor blocker used in the management of asthma. It showed absorbance in the visible range at 265 nm. Linearity was obeyed in the concentration range of 40-240 µgmL^{-1} (r^2= 0.9990). The % label claim was found to be in the good agreement of label claim. The percentage recovery was found to be in the range of 95 – 98 %w/w; the %RSD value less than 2 indicate the method was accurate. The precision of the method was studied as an intra-day, inter-day and repeatability. The %RSD value less than 2 indicate that the method was précised. The method was found sensitive with respect to Sandells Sensitivity. The results from validations are shown in Table 2.

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