INTERNATIONAL RESEARCH JOURNAL OF PHARMACY
www.irjponline.com ISSN 2230 – 8407
Research Article

VALIDATED SPECTROPHOTMETRIC METHOD FOR THE DETERMINATION OF SALBUTAMOL SULPHATE IN BULK AND PHARMACEUTICAL DOSAGE FORMS

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Article Received on: 08/02/12 Revised on: 22/03/12 Approved for publication: 10/04/12

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ABSTRACT
A new, simple, accurate and sensitive spectrophotometric method has been developed for the estimation of Salbutamol sulphate in bulk and in pharmaceutical formulations. Salbutamol sulphate shows ʎ max at 292 nm. The drug follows the beer's lambert's law in the concentration range of 20-100µ ml. the method was validated by following the analytical performance parameters as suggested by the international conference on harmonization which included accuracy, precision, linearity. All validation parameters were with in the acceptable range. The developed method was successfully applied to estimate the amount of Salbutamol sulphate in bulk and pharmaceutical dosage forms.
Keywords: Salbutamol sulphate, UV spectrophotometry, capsules.

INTRODUCTION

Salbutamol is a sympathomimetic amine has chemical name [RS]-4-(2-tertbutylamino)-1-hydroxyethyl)-2-(hydroxymethyl) phenol[1]. The plasma half life of Salbutamol is 2-7 hrs. Its usual dose is 2-4mg, 3-4 times daily. Racemic (+,-) Salbutamol is used commonly. It is β2 receptor agonist . It is used in treatment of bronchial asthma[2]. It has more β2 activity and less β1 activity on cardiac muscle. Salbutamol increases intracellular cAMP levels which results in relaxation of smooth muscles of bronchi (bronchodilation) and uterus, dilation of smooth muscles of peripheral blood vessels increased heart rate, opens ATPase channels that increases intracellular potassium and decreases extracellular potassium[3]. Salbutamol is available in tablets, capsules, aerosol inhalers. The aim of the present work is to develop and validate new spectrophotmetric method for the estimation of Salbutamol sulphate in bulk and pharmaceutical formulations[4].

MATERIALS AND METHODS

Chemicals and reagents

Analytically pure Salbutamol sample was obtained as gift sample from Aurobindo pharma Ltd, Hyderabad. Commercial capsule formulations were purchased from the local market. All chemicals and reagents used were of analytical grade.

Instrument

Micro-processor, U-V visible spectrophotometer (model-1371), digital balance (shimadzu)-b1220H were used during the analysis.

Standard stock solutions and working standard solutions

100mg of pure Salbutamol sulphate drug sample was accurately weighed and transferred to a 100ml standard flask,to this a small amount of 0.1N sodium hydroxide solution was added to dissolve the drug. The volume was made up to 100ml with the same. The concentration of stock solution was 1mg/ml. from this, 100µg/ml working standard solution were prepared.

Method

The solution of concentration 100µg/ml was scanned in the wave length range of 200-400nm maximum absorbance was seen at the wave length of 292nm[5]. From the 100µg/ml solution aliquots of 2, 4, 6, 8, 10 ml were taken in a 10ml standard flask and volume was adjusted to 10ml with 0.1 N NaOH to give the concentration range of 20, 40, 60, 80, 100µ/ml. absorbance of each solution was measured at 292nm against 0.1N NaOH as blank[6]. The graph was plotted by taking the concentration (µg/ml) vs absorbance. The calibration curve results were shown in figure 1.

Estimation of Salbutamol sulphate in capsules

20 capsules of Salbutamol sulphate are weighed; the average weight of each capsule was calculated. Then the drug was removed from the capsules and the weight of empty capsules was taken. Amount of drug present in one capsule was calculated[7, 8]. Then the amount of drug powder equivalent to 10mg was weighed accurately and dissolved in NaOH to give a concentration of 1mg/ml from this 100µg/ml was prepared. The solution was filtered through whatmann filter paper 42. The sample solution was analyzed.

METHOD VALIDATION

The developed method was validated in terms of linearity, accuracy, precision, LOD, LOQ, correlation co-efficient[9-12].

Linearity

Salbutamol sulphate was found to be linear in a concentration range of 20-100µg/ml. the absorbance of the solution was measured at 292nm and a calibration graph was plotted using concentration on X-axis and absorbance on Y-axis.

Precision

Repeatability

Inter day precision

This is done by analyzing formulation by same analyst and instrument for six days subsequently. The %RSD values are shown in table 3.

Intra day precision

This was done by analyzing formulation in same day for 6 times of individual preparation and observation. The % RSD and data are shown in table 4.

Accuracy

Accuracy of the method was determined by the recovery studies in the capsule formulation of Salbutamol sulphate. Recovery studies were carried out by addition of known

quantities of standard drug solution to pre analyzed sample at three different concentrations.

RESULTS AND DISCUSSION

The proposed method is simple, sensitive and more reproducible UV spectrophotmetric method has been developed for the determination of Salbutamol sulphate inn bulk and capsules. The maximum absorbance of Salbutamol sulphate in 0.1N NaOH was found at 292nm. Beer's law was found to be obeyed in the concentration range of 20-100µg/ml with linear regression of 1.The proposed method of determination of salbutamol sulphate showed molar absorptivity is 2700.8783 $L.mol^{-1}.cm^{-1}$. Linear regression of absorbance on concentration with the equation y=0.0934c-0.0927 with a correlation co-efficient of 0.9999. The applicability to propose method for the assay of Salbutamol sulphate in capsule was examined by analyzing commercial formulations and the results were tabulated in Table 1.

Accuracy was performed by recovery studies. The % recovery value indicates that there is no interference form the excipients present in the formulation. The recovery studies are presented in Table 2. The precision of method was checked in terms of interday and intraday where method was repeated on six different days and also on six different time periods in the same day. The results are presented in Table 3 and 4. Summary of optical and regression parameters were shown in Table 5. The results were in good agreement with label claim. The result of analysis of commercial formulation and the recovery study of drug suggested that there is no interference forms any excipients.

ACKNOWLEDGEMENT

The authors are thankful to Anurag pharmacy college in Ananthagiri, Kodad for providing necessary facilities. Authors are also thankful to Aurobindo Pharma Ltd, Hyderabad for providing gift sample of drug.

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Table 1: Assay results of the marketed formulations of Salbutamol sulphate

Marketed formulation	Label claim(µg)	Amount obtained(µg)	Percentage purity
Rotacaps	200	198.6	99.3%

Table 2: Recovery of salbutamol sulphate using the proposed U.V.method

S.NO	Amount of drug added(mg)	Amount present	Mean(±)amount found(mg)	Mean(±)amount %of recovery
1	8mg	18mg	17.90±0.05	99.44
2	10mg	20mg	19.88±0.07	99.40
3	12mg	22mg	21.85±0.09	99.31

Table 3: Precision –Interday

SI.No	Concentration	Absorbance	Mean	Standard Deviation	%RSD
1	100µg/ml	0.468	0.468	0.00141	0.3012
2		0.467			
3		0.468			
4		0.469			
5		0.470			
6		0.466			

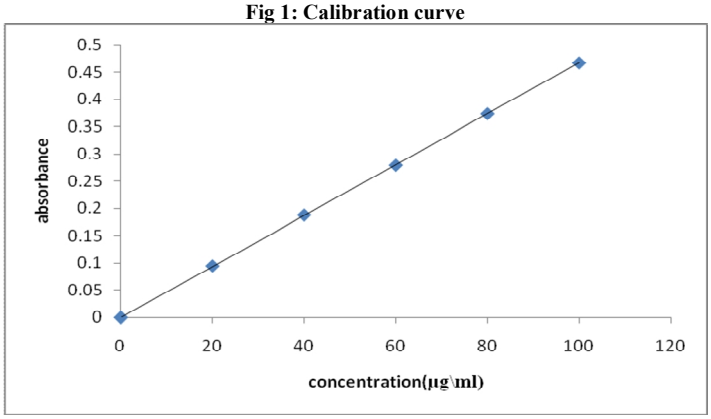
Table 4: Precision-Intraday

SI.No	Concentration	Absorbance	Mean	Standard Deviation	%RSD
1	100µg/ml	0.466	0.4678	0.00116	0.25
2		0.467			
3		0.468			
4		0.468			
5		0.469			
6		0.469			

Table 5: Optical characteristics of Salbutamol sulphate

S.NO	Parameter	Value
1.	λ max	292
2.	Beer´s law limit	20-100µg\ml
3.	Molar extinction coefficient	2700.8783 $L.mol^{-1}.cm^{-1}$
4.	Correlation coefficient	0.9999
5.	Regression equation	0.0934x-0.0927
6.	LOD	0.0409
7.	LOQ	0.1241
8.	Sandell´s sensitivity	0.213µg\ml

Fig 1: Calibration curve



Source of support: Nil, Conflict of interest: None Declared