UPI Journal of Pharmaceutical Medical, and Health Sciences

Content Available at www.uniquepubinternational.com ISSN: 2581-4532

Open Access **Research Article**

Development of Simple VU Spectrophotometric Method for the Estimation of Bambuterol Hydrochloride in Bulk and Its Formulations

M Ramakrishna[1*], Dr J NSuresh kumar[2], R. Rajeswari[3], T. Nagajyothi[3], M. Jhansi rani[3], CH. Aparna[3], N. Pushpak[3]

1. Associate Professor, 2. Principal & Professor, 3. Research Students

1,2,3. Narasaraopeta Institute of Pharmaceutical Sciences, Narasaraopet, Palnadu-A.P

Article History

Received: 12-02-2023
Revised: 19-03-2023
Accepted: 27-04-2023

Keywords: Bambuterol hydrochloride, UV Spectrophotometry, Method validation Distilled water, λmax

***Corresponding Author**
M Ramakrishna

DOI: https://doi.org/10.37022/jpmhs.v6i2.89

Abstract

A simple, rapid and highly sensitive spectrophotometric method has developed for the estimation of Bambuterol hydrochloride in bulk and marketed tablet dosage form. In distilled water, Bambuterol showed absorbance at 264nm. Linearity was observed in the conc range of 200-1000 µg/ml (r^2 = 0.9990). The assay results were found to be in a good agreement with label claim. The recovery studies were carried at 3 different levels i.e, at 100%, 150%, 200%. The accuracy of the method was conformed by recovery studies of tablet dosage forms and was found to be 96.43% for bambuterol hydrochloride. The method was validated stastically and by good recovery with % RSD is less than 2Thus the proposed method was found to be rapid, specific, precise, accurate and cost-effective quality control tool for the routine analysis of bambuterol hydrochloride in bulk and combined dosage form.

Introduction

BAMBUTEROL is a respiratory medication primarily used to treat and prevent asthma and chronic obstructive pulmonary diseases (COPD) like bronchitis (inflammation of the lining of your bronchial tubes). Asthma is a chronic (long-term) respiratory condition in which airways narrow, swell and produce extra mucus, leading to difficulty breathing. COPD is a group of lung diseases that causes obstructed airflow from the lungs.

BAMBUTEROL contains 'Bambuterol' and belongs to the class of bronchodilators. It is a long-acting beta-agonist that relaxes the muscles in the airways and increases airflow to the lungs. bambuterolmakes breathing easier by widening the airways. It helps to prevent asthma attacks in adults.If you use bambuterol for asthma, you must use it together with an inhaled steroid medicine for long-term asthma control.

Take bambuterol as prescribed by your doctor. You are advised to take bambuterol for as long as your doctor has prescribed it for you, depending on your medical conditions. You may experience restlessness, headache, palpitations, insomnia (difficulty in sleeping), trembling (shaking as a result of anxiety), and muscle cramps. Most of these side effects of bambuterol do not require medical attention and gradually resolve over time. However, if the side effects persist or worsen, please consult your doctor.

BAMBUTEROL should not be taken if you are allergic to bambuterol or other ingredients. bambuterol should not be taken in conditions like liver or kidney disease, heart disease, and diabetes. If pregnant or breastfeeding, please inform your doctor before using bambuterol. bambuterol is not recommended for children. bambuterol may not affect your ability to drive or use machines. However, if you notice any side effects like dizziness, avoid driving and operating machinery until you feel better. Avoid drinking alcohol while taking this medicine, as it can worsen your side effects.

Uses of BAMBUTEROL

Asthma, Chronic Obstructive Pulmonary Disease (COPD), Bronchitis

Medicinal Benefits

BAMBUTEROL is a bronchodilator used to treat and prevent respiratory disorders like asthma or exercise-induced bronchospasm and chronic obstructive pulmonary diseases (COPD). bambuterol relaxes your airways which helps reduce wheezing and chest tightness caused by asthma and other airways-related problems. It relaxes the muscles in the airways and increases airflow to the lungs. It makes breathing easier by widening the

airways. If you use bambuterol for asthma, you must use it with an inhaled steroid medicine for long-term asthma control.

Directions for Use

Take bambuterol with or without food as advised by your doctor and swallow whole with a glass of water. Do not crush, chew or break it.

Storage

Store in a cool and dry place away from sunlight

MATERIALS AND METHODS

Determination of λmax:

The wavelength at which the sample/drug shows higher absorption is known as λmax=264nm. 10mg of drug [0.010g] dissolved in 100ml of water.

Take 1ml and dilute to 10ml. For the selected drug sample, maximum absorbance was determined. It was found to be 264nm.

Preparation of standard stock solution:

Bambuterol Hydrochloride standard stock solution was prepared by taking transferring precisely weighed 100mg of standard Bambuterol hydrochloride raw material into 100ml volumetric flask and dissolved in few ml of distilled water. The solution is sonicated for 15 minutes, and the solution was made up to 100ml by using distilled water and thus a solution of 1000µg/ml concentration was obtained.

The solutions were scanned on Shimadzu UV Spectrophotometer, in the UV range and absorbance was recorded at the **λmax 264 nm** against distilled water as blank. The calibration curve was found to be linear in the concentration range 200to1000 µg /ml. The linear regression was found to be y = 0.0011x + 0.0164with r^2 = 0.9993

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 50 mg of Bambuterol was transferred to 50mL volumetric flask containing 3/4th of distilled water, sonicated for 15 min and filtered. Volume of filtrate was made up to 50 ml with distilled water. After appropriate dilution, absorbance of solution was recorded at 264 nm. The concentration of the drug was determined by linear regression was found to be Y=0.001+0.0048with r^2= 0.9998.

Limit of detection (LOD):

LOD, which is the lowest amount of analyte in the sample, which can be detected but not necessarily quantitated under stated experimental conditions, was determined by the formula:

LOD=3.3*σ/S

Where σ = the SD of response and S is the slope of the calibration plot.

limit of quantification (LOQ):

Limit of quantification (LOQ), which is the lowest amount of analyte in a sample, which can be quantitatively determined with suitable precision and accuracy, was calculated from the formula:

LOD=10*σ/S

Stability:

For determining the stability of the dug in the selected solvent absorbance of the sample solution (200µg/ml) was measured every 15min for 4hrs. It shows constant stable observed values up to4hrs, so we selected the distilled water as solvent for method development.

Recovery studies:

To check the accuracy of the proposed method, recovery studies were carried out at three different levels i.e 20%, 40% and 60%. To the pre analyzed sample solution, the amount of bulk drug was added at three different levels; it was then reanalyzed. The results from the recovery studies.

S.NO	Parameter	Results
1	Detection of wavelength	264λmax
2	Beer- Lambert law (µg/ml)	200-1000 µg/ml
3	Regression equation (y= mx+c)	Y= 0.0011
4	Slope	0.0011
5	Accuracy (%mean recovery)	100.14
6	LOD	0.6 µg/ml
7	LOQ	1.8181 µg/ml
8	Intra- day (%RSD)	0.586
9	Inter- day(%RSD)	0.5783

Table 1.1 The results of validation are summarized

Accuracy:

To check the accuracy of the developed method and to study interference of formulation excipients, analytical recovery studies were conducted by taking 6µg/ml solution of formulation in each of three 10ml volumetric flask and then adding 200,400,600µg/ml of raw material the solution were prepared in triplicate the accuracy was indicated by percentage recovery.

Precision:

To check the precision of the proposed method the recovery studies performed three times in same day (intra-day) and recovery studies between days (inter-day) were analyzed. The relative standard deviation of intra-day and inter-day values were calculated and given in table. The precision is expressed in the form of percent relative standard deviation.

RESULTS

Determination of λ max:

The wavelength at which the sample/drug shows higher absorption is known as λmax. 10mg of drug [0.010g] dissolved in 100ml of water. Take 1ml and dilute to 10ml. For the selected drug sample, maximum absorbance was determined. It was found to be 264nm.

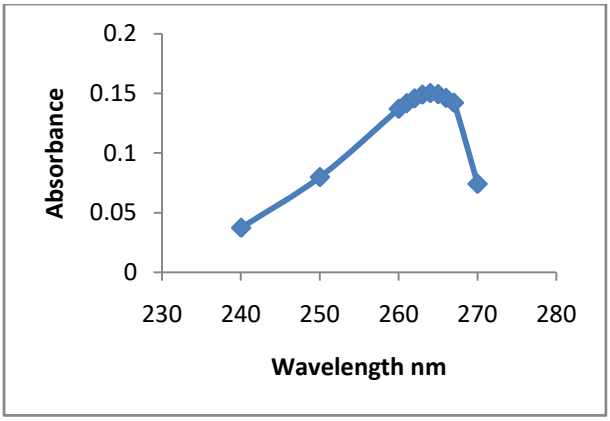

Fig 1.1 Determination of λmax

Determination of stability:

The absorbance of 200µg/ml of Bambuterol hydrochloride was measured every 15min for 2hrs the values are consistence throughout the experiment can be seen in table 7.1.

Table 1.3 calibration curve

Sl. No	Time	Absorbance
1	0min	0.2146
2	15min	0.2156
3	30min	0.2142
4	45min	0.2168
5	60min	0.2141
6	1hr15min	0.2152
7	1hr30min	0.2164
8	1hr45min	0.2168
9	2hrs	0.2157

Table 1.2 Stability study

Preparation of calibration curve:

From the absorbance values a calibration curve was plotted in the desired concentration range. The curve obtained was linear with co-relation coefficient 0.9958.

S.NO	Concentration (µg/ml)	Absorbance
1	200	0.2155
2	400	0.4674
3	600	0.6713
4	800	0.8636
5	1000	1.0089
Slope	**0.001**	

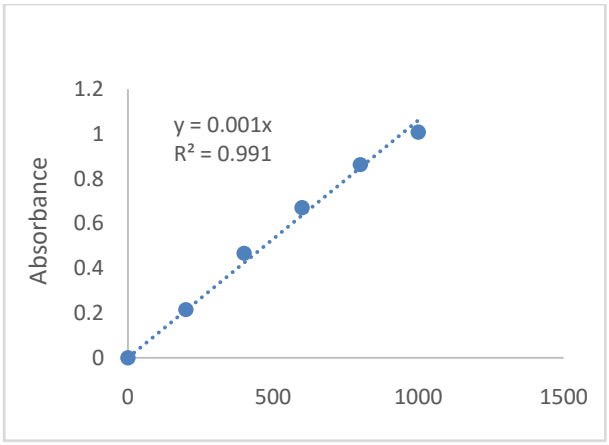

Fig1.2 Calibration curve of Bambuterol hydrochloride

LOD and LOQ:

The limit of detection and limit of quantification were determined by taking 6 linearity and average slope. The values of LOD and LOQ for the proposed method were found to be 0.6µg/ml and1.8181µg/ml respectively.

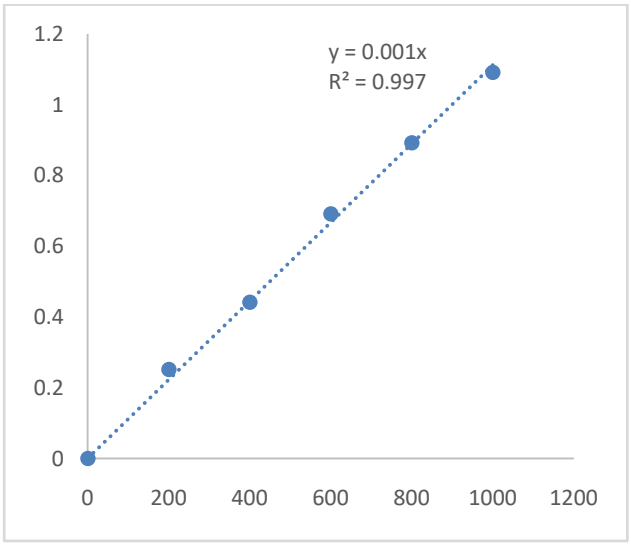

Fig1.3 Linearity of Bambuterol hydrochloride standard

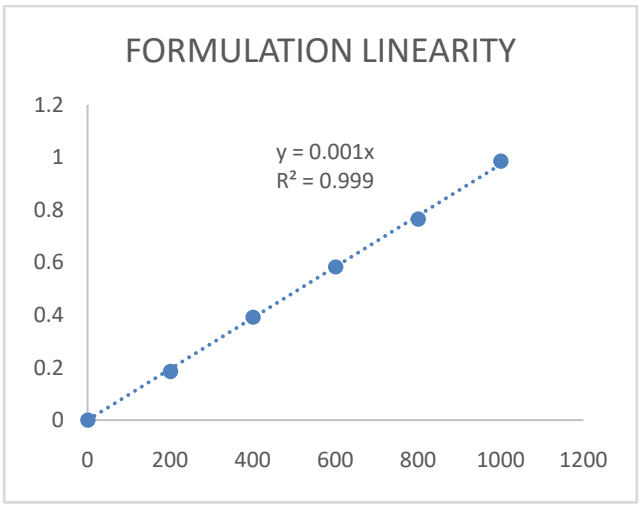

Fig1.4 Formulation linearity of Bambuterol hydrochloride

S. No	Slope	LOD(µg/ml)	LOQ(µg/ml)	SD
1	0.0011	0.600	1.8181	0.0002
2	0.001			
3	0.0012			
4	0.0011			
5	0.0011			
6	0.0011			
7	0.0011			

Table1.4 LOD and LOQ

ACCURACY:

The accuracy of the method was proved by performing recovery studies for commercially available.

Formulations of Bambuterol hydrochloride the standard deviation values and percentage recovery values of intraday and interday recovery of Bambuterol hydrochloride in formulations was found to be with in the accepted limits and is represented.

PRECISION:

It was found that the %RSD values of intraday and interday precision were0.5783 and 0.586. Respectively pertaining to Bambuterol hydrochloride and the values of RSD %(<2.0) clearly show that the method is fairly precise.

Sl.NO	Amount of drug present (µg/ml)	Amount Added (µg/ml)	Amount Recovery (µg/ml)	Percentage	SD	RSD
1	400	200	200.36	100.18	0.5835	0.5783
2	400	200	200.72	100.36		
3	400	200	200.27	100.135		
4	400	400	406.90	101.72		
5	400	400	405.70	101.42		
6	400	400	405.81	101.45		
7	400	600	606.90	101.15		
8	400	600	605.09	100.84		
9	400	600	604.81	100.80		

Table 1.5 Recovery Study of Bambuterol hydrochloride (Intra- Day recovery) (Mean of three observations)

Sl.NO	Amount of drug present (µg/ml)	Amount Added (µg/ml)	Amount Recovery (µg/ml)	Percentage	SD	RSD
1	400	200	200.18	100.09	0.5911	0.586
2	400	200	200.27	100.13		
3	400	200	200.45	100.22		
4	400	400	406.54	101.63		
5	400	400	405.63	101.40		
6	400	400	406.09	101.52		
7	400	600	606.54	101.09		
8	400	600	606.72	101.12		
9	400	600	604.27	100.71		

Table 1.6 (Inter day recovery study) (Mean of three observations)

SUMMARY AND CONCLUSION

Summary:

A UV spectrophotometric method has been developed and validated for determination of Bambuterol hydrochloride in pure form and its pharmaceutical dosage forms.

The process was done by using distilled water as a solvent with the detection wavelength set at 264nm. Bambuterol hydrochloride was checked for its stability in the chosen solvent and found to be stable. The method was linear with correlation coefficient 0.999 in the concentration range of 1000µg/ml. The limit detection and limit quantification were 1.8181µg/ml and 0.6 µg/ml, respectively. The intra and inter-day precisions were satisfactory; the relative standard deviations did not exceed 2%. The accuracy of the method is high as can be seen from the mean recovery values of Bambuterol hydrochloride. The method met the ICH regulatory requirements. The results of validation are summarized.

CONCLUSION:

A simple, economical, rapid, precise, and accurate UV spectrophotometric method was developed for the estimation of Bambuterol hydrochloride in bulk and pharmaceutical formulations.

The method was developed by using distilled water as solvent. The developed method was validated for parameters viz accuracy, precision, linearity, limit of detection and limit of quantification as per ICH guidelines.

All the parameters were found to be within the acceptance limits. The results indicated that the proposed method for the estimation of Bambuterol hydrochloride is very accurate and cost effective and can be employed in routine sample analysis of Bambuterol hydrochloride in bulk and pharmaceutical formulation.

REFERENCES

1. Beckette AH, Stenlake JB. Practical Pharmaceutical Chemistry. 4thed. The Anthlone Press; London, 157: 281-307 (1988).
2. Juniper IR. Method Validation: An Essential Element in Quality Assurance In: Parkany M. Quality assurance and TQM for Analytical
1. Laboratories. The Royal society of chemistry, Thomas Graham House, Cambridge. 114-120 (1995).
2. SOP:Validation studies. Indian Pharma Guidance Academy; Nagpur. 1-3 1996.
3. British Pharmacopoeia. vol I. The Stationary Office, London, 222-223 (2008).
4. Beckette AH, Stenlake JB. Practical Pharmaceutical Chemistry, 4 ed. The Anthlone Press; London, 1988, P. 157, 281-307.
5. Pauwels R, O'Byrne PM. Beta - Agonists in Asthma Treatment. Vol. 106. New York: Marcel Dekker; 1997. p. 115-6.
6. Nyberg L, Rosenborg J, Weibull E, Nilsson M, Jönsson S, Kennedy B. Pharmacokinetics of bambuterol in healthy subjects. Br J Clin Pharmacol 1998;45:471-8
7. Latha EP, Abiram L. Simultaneous determination of montelukast sodium and bambuterol hydrochloride in tablet dosage form by ultraviolet spectrophotometry. Int Res J Pharm Appl Sci 2011;1:1-8.
8. Satish AP, Dhara JP, Natavarlal JP. Simultaneous spectrophotometric determination of montelukast sodium and bambuterol hydrochloride in tablets. Int Res J Pharm 2011;2:154-8.
9. Pawar V, Lalitha N, Puranik SB, Pai PN, Rao GK. Spectrophotometric method for determination of Bambuterol hydrochloride in bulk and tablets. Orient J Chem 2008;24:769-70.
10. Kalyan P, Srikanth M, Prasadarao M. Method development and validation of bambuterol in pharmaceutical formulation by RP-HPLC method. World J Pharm Sci 2015;4:759-68.
11. Gohil DY, Savaliya RP, Desai SD, Patel DJ. Formulation and characterization of bambuterol hydrochloride fast dissolving tablet using various superdisintegrants. Int J Pharm Sci Res 2011;2:84-9.
12. Behera S, Ghanty S, Ahmad F, Santra S, Banerjee S. UV-visible spectrophotometric method development and validation of assay of paracetamol tablet formulation. J Anal Bioanal Tech 2012;3:6.
13. Sweetman SC. Martindale: The complete drug reference. 33 rd edition. London: Pharmaceutical Press,2002:761.
14. Budavari S. The Merck Index 12th edition. White house station, NJ: Merck and Co. Inc. 1996:163. 3. The British Pharmacopoeia. 3 rd edition. London: stationary office books. 2010; 1:174-175.
15. Svensson LA: Bambuterol, a bronchodilator prodrug with sustained action, enhances delivery of active drug to the lung. Agents Actions Suppl. 1988;23:271-6.
16. Waldeck B: Beta-adrenoceptor agonists and asthma--100 years of development. Eur J Pharmacol. 2002 Jun 7;445(1-2):1-12.
17. Coleman RA, Johnson M, Nials AT, Vardey CJ: Exosites: their current status, and their relevance to the duration of action of long-acting beta 2-adrenoceptor agonists. Trends Pharmacol Sci. 1996 Sep;17(9):324-30.
18. Zhang D, Cheng M, Hyun MH, Xiong Z, Pan L, Li F: Enantiomeric separation of beta2-agonists on macrocyclic antibiotic chiral stationary phases in high performance liquid chromatography. Pharmazie. 2007 Nov;62(11):836-40.
19. Chou YL, Wu CC, Wang HW: Effects of bambuterol and terbutaline on isolated rat's tracheal smooth muscle. Eur Arch Otorhinolaryngol. 2010 Aug;267(8):1305-11. doi: 10.1007/s00405-009-1173-7. Epub 2009 Dec 12.
20. Chen X, Ji ZL, Chen YZ: TTD: Therapeutic Target Database. Nucleic Acids Res. 2002 Jan 1;30(1):412-5.
21. Willed 10H, Men L Dean JA, Settle FA. Instrumental methods of analysis edition CBS Publishers and Distributors: New Delhi 1906, 1-15.
22. Kirkbright G. Development and publication of new Spectrophotomic method of analysis 4dition, John Wiley & Sons Inc. Talm , 1966, p. 1-14 19. Douglas A.Skoog, Principles of instrumental analysis, and stition. Thomson brook ColdPublications, 2007, p. 3.