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DEVELOPMENT OF VALIDATED UV SPECTROPHOTOMETRIC METHOD FOR ESTIMATION OF BAMIFYLLINE IN THE BULK DRUG AND MARKETED FORMULATION

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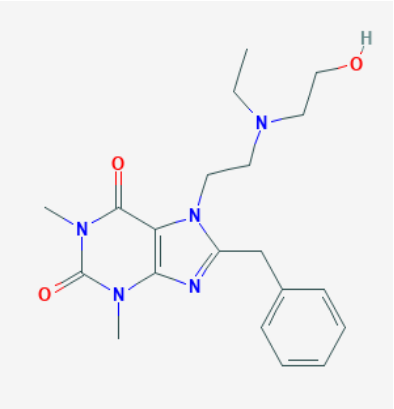
ABSTRACT

A simple, sensitive, accurate, precise, and economic UV spectrophotometric method has been developed and validated for the estimation of bamifylline in tablet dosage form. Bamifylline showed maximum absorption at 221, 257 and 273 nm respectively using a UV–Visible spectrophotometer (Jasco, model V-630). Beer's law was obeyed in the concentration range of 1-10 µg/ml. with a correlation coefficient was found to be 0.999 for drug. The method was validated for various parameters according to ICH guidelines. The low relative standard deviation values indicate good precision and high recovery values indicate accuracy of the proposed method. Assay results were in good agreement with label claim.

KEYWORDS: Bamifylline, UV spectrophotometric method.

INTRODUCTION

The chemical name for Bamifylline hydrochloride is 8-benzyl-7-[2-[ethyl (2-hydroxyethyl) amino] ethyl] -1,3- dimethylpurine-2,6-dione hydrochloride. Bamifylline is a stimulant drug of the xanthine chemical class which acts as a selective adenosine A1 receptor antagonist.[1] It is used as a bronchodilator and cardiac asthama.[2,3] It dilates the bronchi and also used in the treatment of reversible airways obstruction. Bamifylline hydrochloride is extensively absorbed from the GI tract, Distribution volume is 3 to 10 folds more rapidly than theophylline.



Structure Of Bamifylline.

MATERIALS AND METHODS[4-6]

The instruments used were an Shimadzu UV-1800 Double Beam Spectrophotometer equipped with 1cm matched quartz cells were used for the present study. A SHIMADZU AX200 single pan balance was used for weighing purpose. All the apparatus and instruments were calibrated and validated before starting the experimental work. Authentic drug sample of was given **Bamifylline hydrochloride** as a gift sample by Torrent Pharmaceuticals Ltd., Sikkim. All chemicals and reagents used were of analytical grade. Tablets of Bamifylline hydrochloride were procured from laboratory.

Chemicals and reagents

Analytically pure drug of bamifylline hydrochloride was procured from Hetero Drugs Ltd., Hyderabad, Telangana, India. The Bamifix tablets containing 600 mg labelled claim of bamifylline hydrochloride procured from local market. Water, methanol was procured from E. Merck specialties, private Ltd., Mumbai, India.

Selection of solvent

Copious trials were performed to find out the suitable solvent system for dissolving the bamifylline hydrochloride. The solvents such as acetonitrile, dimethyl sulfoxide [DMSO] methanol and triple distilled water were tried based on the solubility of the drug. Bamifylline hydrochloride is soluble in solvents such as triple distilled water, methanol so triple distilled water were selected right through the experiment.

Selection of detection wavelength

To estimate the optimum λmax, bamifylline hydrochloride 10 mg /ml of the working standard solution was prepared and scanned in the UV wavelength range of 200 - 400 nm. It was

observed that the drug showed maximum absorbance at 263 nm, which was chosen as the detection wavelength for the estimation of bamifylline hydrochloride. Preparation of stock and working standard solution: Bamifylline hydrochloride 10 µg/ ml standard stock solution was done by transferring precisely weighed 10 milligrams of standard bamifylline hydrochloride to ten milliliters calibrated flask and dissolved in water. The volume was filled up to the mark with triple distilled water (1000 µg/ml standard stock solution). From this solution one milliliter was precisely transferred into a hundred milliliter volumetric flask and volume was filled up to the mark with triple distilled water to get a concentration of 10 µg/ml which was treated as the working standard solution.

Preparation of Calibration curve

From the above prepared bamifylline hydrochloride stock solution, appropriate dilutions were prepared to get the eventual concentration of 2, 4, 6, 8, and 10 µg/ ml and absorbance was taken at λmax 263 nm. Average of such five sets of values were taken for standard calibration plot, and the calibration curve was plotted. Calibration curve was done by plotting bamifylline hydrochloride concentration on X-axis and their respective absorbance's on Y-axis. Calibration data are shown in **Table 1**. The calibration curve is exhibited in **Figure 2**.

DEVELOPMENT AND VALIDATION

Method Validation is a process of establishing documented evidence, which provides a high degree assurance that a specific activity will consistently produce a desired result, or a product meeting its predetermined specifications and quality characteristics. The method was validated for different parameters like Linearity, Accuracy, Precision, Ruggedness and Limit of Detection (LOD) and Limit of Quantification (LOQ).

Linearity

Various aliquots were prepared from the working stock solution-II (100 µg/ml) ranging from 2-10µg/ml. The absorbances were measured at 273.5 nm against methanolic Hcl as blank with the help of a UV-VIS Spectrophotometer. The correlation coefficient of the linearity was found to be 0.9999. In order to check the linearity, calibration curve was plotted by using absorbance values on Y axis, concentration on X-axis (**Table 1 & Fig 1)**. The method exhibits good linearity with a correlation coefficient 0.9999 which indicates that the method obeys Beers law.

Accuracy

The accuracy is the closeness of the results obtained by the method to the true value. Recovery studies were carried out by addition of standard drug solution to sample. Accuracy may often express as percent recovery by the assay of known amount of analyte added. To study the accuracy of the proposed method, recovery studies were carried out at three different levels 80%, 100% and 120% by addition of known amount of pure drug to a known concentration of the pre-analyzed solution. The accuracy of the method was confirmed by the recovery studies, by adding known amount of pure drug to the Pharmaceutical formulation previously analyzed by this method and the analytical data was presented in **Table 2.**

Precision

The precision of an analytical method is degree of agreement among individual test results when the method is applied repeatedly to multiple samplings of homogenous samples. It provides an indication of random error and was expressed as coefficient of variation. The results were indicated by % RSD.

Precision was done under two parameters:

a) Repeatability Precision
b) Intermediate Precision

Repeatability Precision

Repeatability expresses the precision under the same operating conditions. Repeatability was investigated by using concentration of Bamifylline hydrochloride (6 µg/ml) in 3 replicates of each.

Intermediate precision

Intermediate precision expresses precision within different days and different analysts. A variation of results within the same day (intra-day), variation of results between days (inter-day) was analyzed. Intra- day precision was determined by analyzing drug for three times in the same day at 273.5 nm. Inter-day precision was determined by analyzing the drug once for three days at 273.5 nm. The relative standard deviations of intra-day and inter-day values were calculated. The precision of the proposed method was checked in terms of inter-day and intra-day, where method was repeated on three different days and also repeated for three different time periods on the same day. The results were given in **Tables 3.** Summary of assay results was shown in **Table 3.**

Limit of Detection

The detection limit of an individual analytical procedure is the lowest amount of analyte in a sample, which can be detected, but not necessarily quantified by analytical method. Limit of detection is determined by the analysis of samples with known concentrations of analyte and by establishing the minimum level at which the analyte can be reliably detected.

Limit of quantification

The LOQ is the concentration that can be quantitated reliably with a specified level of accuracy and precision. Detection and quantification limit were calculated by the method based on the standard deviation (σ) and slope of the calibration curve, using the formula.

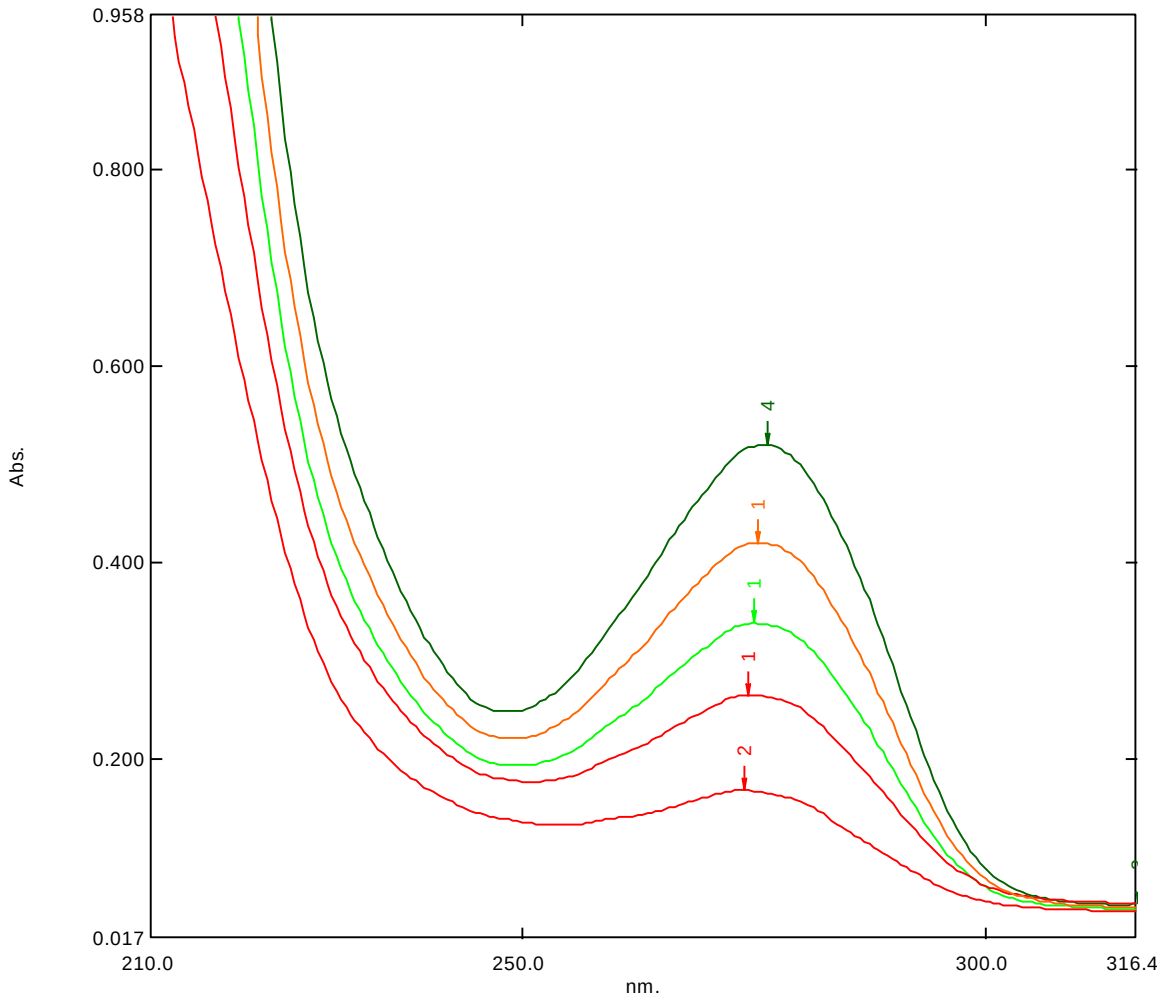


Fig. 1: Overlaid Spectrum of Bamifylline Hydrochloride.

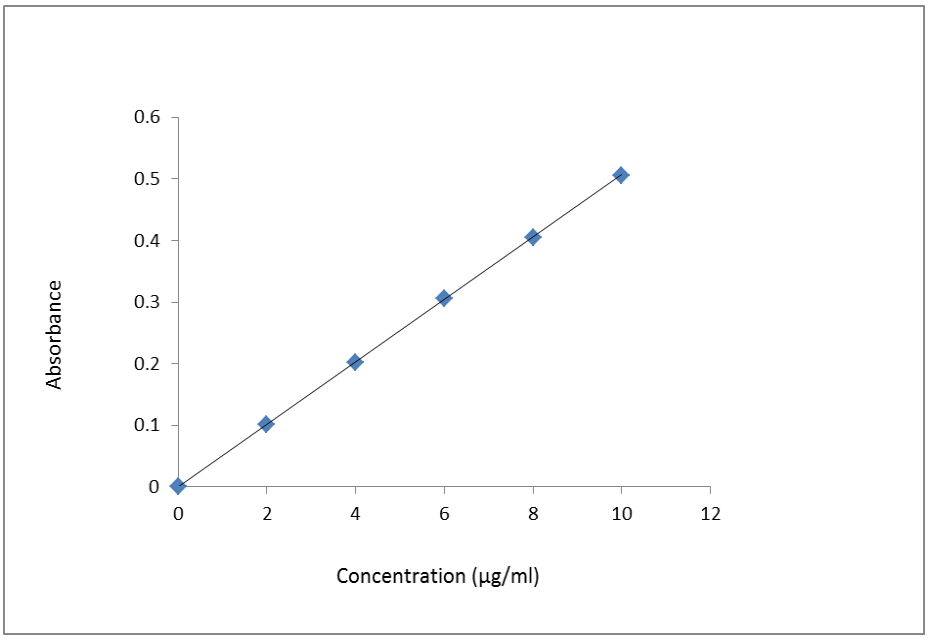


Fig. 2: Calibration curve.

Tab. 1: Calibration Curve of Bamifylline Hydrochloride by UV.

S.No.	Concentration (µg/ml)	Absorbance*
01	0	0
02	2	0.101
03	4	0.202
04	6	0.306
05	8	0.404
06	10	0.506

Tab. 2: Determination of Accuracy of Bamifylline hydrochloride.

Drug	Concentration of Sample (µg/ml)	Level of Addition (%)	Amount of drug added (µg/ml)	Amount* recovered (µg/ml)	% Recovery* ± S.D
Bamifylline	6	80	4.8	4.804	100.05±0.24
	6	100	6	5.998	99.98 ± 0.26
	6	120	7.2	7.202	100.01 ±0.04

Tab. 3: Results for Intermediate Precision of Bamifylline HCl.

Concentration of drug (µg/ml)	Average absorbance in intraday studies** (µg/ml)			Average absorbance in inter day studies** (µg/ml)		
6	Sess-I	Sess-II	Sess-III	1st day	3rd day	5th day
	0.3059	0.3062	0.3057	0.3061	0.3062	0.3058
	SD : 0.0008			SD : 0.0006		
	%RSD : 0.261			%RSD : 0.219		

Table 4: Summary of assay results.

S.no	Label claim	Amount Found (mg/tablet)	% Assay (n=3)
1	600mg	600.102mg	100.017
2	600mg	599.64mg	99.94
3	600mg	600.054mg	100.009

CONCLUSION

The UV Spectrophotometric method for the estimation of bamifylline hydrochloride in pharmaceutical dosage forms was found to be rapid, simple, accurate, sensitive and precise. Moreover, this UV method offers time saving, cost effective for an HPLC method of analysis for bamifylline hydrochloride from formulations. Hence the proposed method can be utilized for the routine analysis of bamifylline hydrochloride in its pharmaceutical dosage form.

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REFERENCES

1. https://en.wikipedia.org/wiki/Bamifylline
2. https://pubchem.ncbi.nlm.nih.gov/compound/bamifylline
3. https://ipfs.io/ipfs/QmXoypizjW3WknFiJnKLwHCnL72vedxjQkDDP1mXWo6uco/wiki/Bamifylline.html
4. https://innovareacademics.in/journals/index.php/ijap/article/viewFile/19438/11694
5. https://europepmc.org/abstract/med/552145
6. https://www.researchgate.net/publication/233267533_Simultaneous_Determination_of_Bamifylline_and_Its_Major_Metabolite_AC-119_by_RP-HPLC.