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UV- SPECTROPHOTOMETRIC METHOD DEVELOPMENT AND VALIDATION OF BENFOTIAMINE IN BULK AND PHARMACEUTICAL DOSAGE FORMS

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ABSTACT

A simple, sensitive, accurate and precise Area under curve spectroscopy method was developed for the estimation of Benfotiamine in bulk and tablet dosage form. This method, involves the measurement of absorbances of Benfotiamine at the wavelength of 239-249 nm. 0.1 M HCl was used as solvent. Linearity was observed in the concentration range of 3-18 µg/ml with correlation coefficient 0.999. The method was validated for linearity, precision, accuracy, limit of detection, limit of quantitation and ruggedness. The accuracy of the method was confirmed by recovery studies of tablet dosage forms and was found to be 99.30%-100.51% for Benfotiamine. The method showed good reproducibility and recovery with % RSD less than 2.0. The limit of detection and limit of quantitation for estimation of Benfotiamine was found to be 0.122 µg/ml and 0.372 µg/ml. Thus the developed method was successfully applied for the estimation of Benfotiamine in pure and pharmaceutical dosage form.

KEYWORDS: Benfotiamine, Area under curve Spectroscopy, 0.1MHCl, accuracy.

INTRODUCTION

Benfotiamine[1,2] (S-benzoylthiamine O-monophosphate) is a synthetic S-acyl derivative of thiamine (vitamin B1). It is a lipid-soluble form of the Vitamin B-1. It may ease pain from neuropathy, retinopathy, nephropathy, by blocking AGEs (advanced glycation end products),

it prevents some complication due to diabetes. It is Chemically {[(4-Amino-2-methylpyrimidin-5-yl) methyl](formyl)amino}-5-(phosphonooxy) pent-2-en-3-yl] benzenecarbothioate.

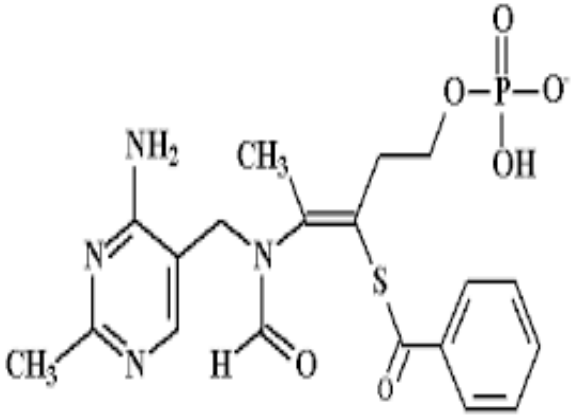

Figure 1: Chemical structure of Benfotiamine.

Literature Survey revealed that the drug has been estimated by few UV spectrophotometric[3,4,5], HPLC methods[6,7,8,9], and Liquid Chromatography[10] has been reported so far.

The aim of present work was to develop and validate a novel, rapid, simple, precise, and specific Area under curve spectroscopic method for estimation of Benfotiamine in its bulk and pharmaceutical dosage form.

MATERIALS AND METHOD

Instrument

UV-Visible double beam spectrophotometer, SHIMADZU (model UV-1800) with UV probe software. All weights were taken on analytical balance.

Chemicals

Benfotiamine pure form was obtained as gifted sample from pharma industry and its pharmaceutical dosage form Benfotiamine Tablets labelled claim 10 mg were purchased from local pharmacy.

Solvent

0.1M HCl (prepared by dissolving 8.5ml in 1000ml of distilled water).

Selection of analytical wavelength

Appropriate dilutions were prepared for drug from the standard stock solution and the solution were scanned in the wavelength range of 200-400 nm. The absorption spectra thus obtained were derivatized from AUC method which illustrated in Fig.2.

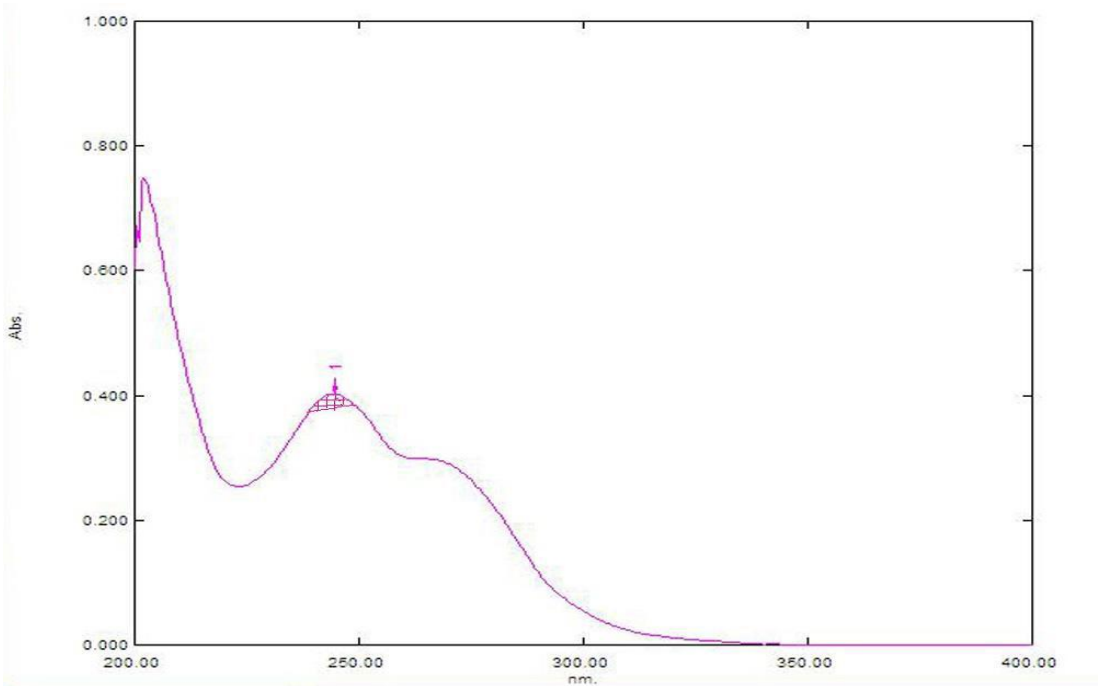

Fig. 2: Typical Zero order spectra of Benfotiamine showing Area Under Curve [AUC] from 239nm to 249 nm.

Preparation of Standard stock solution

Accurately weigh 100mg of Benfotiamine was transferred into 100ml volumetric flask and dilated with 0.1M HCl up to the mark. From this pipette out 10ml into 100ml volumetric flask and diluted with 0.1M HCl up to the mark, from this solution pipette out 0.3, 0.6, 0.9, 1.2, 1.5, and 1.8 ml into 10ml individual volumetric flask and add 0.1M HCl up to the mark, this gives 3,6,9,12,15 and 18 µg/ml concentrations.

Preparation of Sample solution

The Commercially available BenFORCE contains 150 mg of Benfotiamine. The powder equivalent to 100 mg of Benfotiamine was accurately weighed and transferred to volumetric flask of 100 ml capacity then it was diluted with the 0.1 M HCl and made up to the mark and the solution was filtered through whatman filter paper NO. 41. From the above solution 10 ml was pipetted out into 100 ml volumetric flask and the volume was made up to the mark with 0.1 M HCl solution then 20 ml of this solution is pipetted out into 100 ml standard volumetric

flask and diluting with 0.1 M HCl solutionto produce 20 µg/ml. Aliquots of Benfotiamine ranging from 1.5-9.0 ml of standard solution were transferred into series of 10 ml volumetric flasks and used for estimation of Benfotiamine.

Method validation: The method is validated according to the ICH guidelines.[11,12,13]

RESULTS AND DISCUSSION

Method: Area under curve Spectroscopy

Linearity

The working standard solution were diluted serially with 0.1MHCl to obtain the range of 3-18 µg/ml. a calibration curve for Benfotiamine was obtained by measuring the absorbance between 239 - 249 nm and absorbance values are shown in Table.1 and Calibration graph were presented in Fig.3. Statistical parameters like slope, intercept, coefficient of correlation, and Sandel sensitivity were determined and presented in Table.2.

Table 1: Results of calibration curve by Area under curve Spectroscopy.

Sl. no	Concentration in (µg/ml)	Absorbance between 239-249 nm
1	3	0.109
2	6	0.201
3	9	0.286
4	12	0.381
5	15	0.481
6	18	0.562

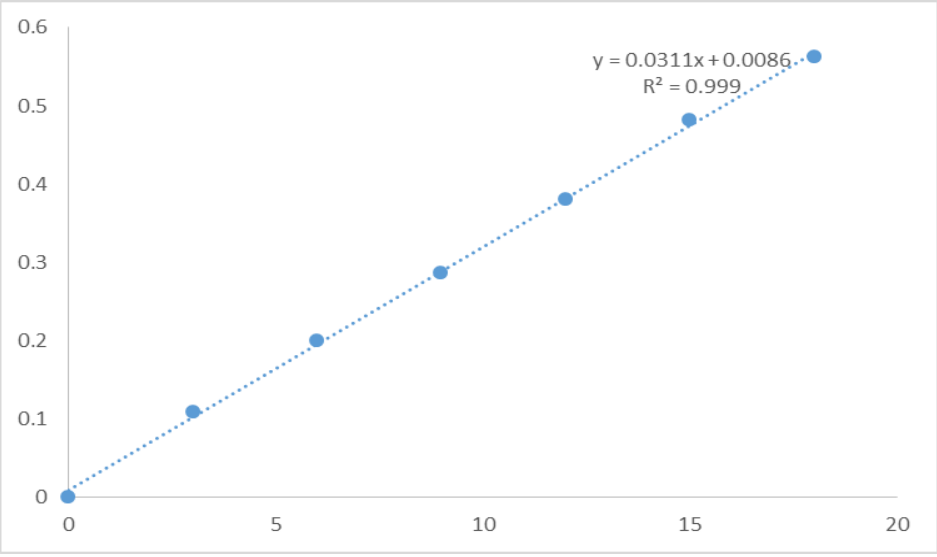

Fig. 3: Linearity curves for Benfotiamine by Area under curve Spectroscopy.

Table no. 2: Regression parameters for Benfotiamine by Area under curve Spectroscopy.

Regression parameters	Benfotiamine
Range	3-18 µg/ml
Range to measure AUC nm	239-249 nm
Regression equation	Y=0.031x+ 0.0086
Slope (b)	0.031
Intercept(a)	0.0086
Correlation coefficient (r^2)	0.999

Precision

Precision of the method was studied as intra-day and inter-day precision. Intra-day precision was determined by analyzing the 3, 6, 9, 12, 15 and 18µg/ml concentration for three times in same day. Inter-day precision was determined by analyzing the same concentration of solution daily for three days. Precision results are shown in Table.3.

Table 3: Determination of precision results for Benfotiamine by Area under curve Spectroscopy.

Concentration (µg/ml)	Intra-day Absorbance ±SD**	%RSD	Inter-day Absorbance ±SD**	%RSD
3	0.1083 ± 0.00057	0.53	0.1076 ± 0.00152	1.42
6	0.1993 ± 0.00208	1.04	0.2026 ± 0.00251	1.24
9	0.2866 ± 0.00115	0.40	0.2893 ± 0.00305	1.05
12	0.381 ± 0.00360	0.94	0.3826 ± 0.00251	0.65
15	0.4833 ± 0.00585	1.21	0.483 ± 0.002	0.41
18	0.566 ± 0.00871	1.54	0.5666 ± 0.00416	0.73

** Average of six determinations, SD and RSD indicates standard deviation and relative standard deviation.

Accuracy

To assess the accuracy of the proposed method, recovery studies were carried out at three different levels i. e, 50%, 100% and 150%. In which the formulation concentration was kept constant and varied pure drug concentration. Accuracy results were shown in Table.4.

Table 4: Determination of accuracy results for Benfotiamine by Area under curve Spectroscopy.

Spiked levels	Amount of sample (µg/ml)	Amount of standard (µg/ml)	Amount recovered(µg/ml)	% Recovery ±SD**	%RSD
50	9	3	11.946	99.31 ± 0.617	0.61
100	9	6	14.968	100.5 ±1.040	1.03
150	9	9	17.924	99.85 ± 0.544	0.54

**Average of six determinations.

Ruggedness

Ruggedness was determined between different analysts Label claim 150 mg concentration. The value of %RSD was found to be less than 2 and the results were shown in Table.5.

Sample	Label claim (mg)	Analysts	Amount found (mg)	% Recovery ± Standard deviation*	% RSD
BenFORCE	150	Analyst I	149.29	99.52 ± 0.720	0.72
		Analyst II	149.64	99.76 ± 0.531	0.53

* Average of six determinations, RSD indicates relative standard deviation.

Limit of detection and Limit of Quantitation

The LOD and LOQ of the present method were calculated based on standard deviation of the Response and slope of linearity curve. LOD and LOQ values of Benfotiamine were found to be 0.122 µg/ml and 0.372µg/ml.

CONCLUSION

Thus, the developed method was found easy, simple, accurate, precise, selective and economical for the routine estimation of Benfotiamine in bulk and pharmaceutical dosage form.

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