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# Validated Spectrophotometric Estimation of Benfotiamine in Pure and Tablet dosage form

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ABSTRACT

A new, simple and sensitive UV-spectrophotometric method was developed for the determination of Benfotiamine in bulk and tablet dosage form. This method, involves the measurement of absorbances of Benfotiamine at the wavelength of 244nm. 0.1M HCl was used as solvent. Linearity was observed in the concentration range of 3-18µg/ml with correlation coefficient 0.999. The accuracy of the method was confirmed by recovery studies of tablet dosage forms and was found to be 99.32%-100.42% for Benfotiamine. The method showed good reproducibility and recovery with %RSD lessthan 2.0. The LOD and LOQ of Benfotiamine was found to be 0.051µg/ml and 0.155µg/ml. Results of the analysis were validated for accuracy, precision, LOD, LOQ and were found to be satisfactory. Thus the developed method was found to be simple, sensitive, rapid, precise, accurate and cost effective quality control tool for the routine analysis of Benfotiamine in bulk and tablet dosage form.

**Keywords:** Benfotiamine, UV Spectrophotometry, BenFORCE, Tablet.

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## INTRODUCTION

Benfotiamine (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[1]. It may ease pain from neuropathy, retinopathy, nephropathy, by blocking AGEs (advanced glycation end products), it prevent some complication due to diabetes and it is used for treating sciatica and other painful nerve conditions [2].

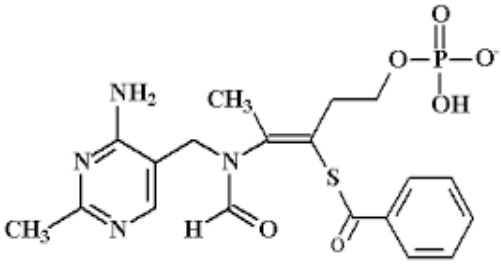

**Figure 1: Chemical structure of Benfotiamine**

The nomenclature of the Benfotiamineis{[(4-Amino-2-methylpyrimidin-5-yl)methyl] (formyl)amino}-5-(phosphonooxy)pent-2-en-3-yl] benzenecarbothioate and it has a molecular formula of $C_{19}H_{23}N_4O_6PS$ and a molecular weight is 466.448 g/mol. It is a white crystalline powder, soluble in 0.1M HCl, poorly soluble in water. Extensive literature survey reveals that UV-spectrophotometric[3-4] and HPLC[5-10] methods are reported for determination of Benfotiamine in bulk and tablet dosage form. Thus, a simple, rapid and cost effective analytical method is required for routine analysis of Benfotiamine in bulk and pharmaceutical dosage form.

The aim of present work was to develop and validate a simple, sensitive,accurate, rapid and precise, specific spectrophotometric method for Benfotiamine in its bulk and tablet dosage form.

## MATERIALS AND METHODS

Instrument: UV-Visible double beam spectrophotometer, SHIMADZU (model UV-1800) with UV probe software.

**Preparation of standard and sample Benfotiamine solution:**

The standard solution of Benfotiamine was prepared by dissolving 100mg in 100ml standard volumetric flask diluting with 0.1M HCl solution and made upto the mark then 10ml of this solution is pipetted out into 100ml standard volumetric flask and diluting with 0.1M HCl solution to produce 100µg/ml then 20ml of this solution is pipetted out into 100 ml standard volumetric flask and diluting with 0.1M HCl solution to produce 20µg/ml.

Ten tablets were weighed and powdered. The tablet powder equivalent to 100mg of Benfotiamine was transferred into 100ml volumetric flask it was diluted with the 0.1M HCl solution and made upto the mark and the solution was filtered through whatman filter paper NO.41. From the above

solution 10ml was pipette out into 100ml volumetric flask and the volume was made upto the mark with 0.1M HCl solution then 20ml of this solution is pipetted out into 100ml standard volumetric flask and diluting with 0.1M HCl solution to produce 20µg/ml. Aliquots of Benfotiamine ranging from 1.5-9.0ml of standard solution were transferred into series of 10ml volumetric flasks. Then all dilutions were measured at 244nm(Figure 2).The amount of Benfotiamine present in the sample was computed from the calibration curve. The same λmax was used for further measurement of drug. A calibration curve for absorbance v/s concentration was plotted(Figure:3).

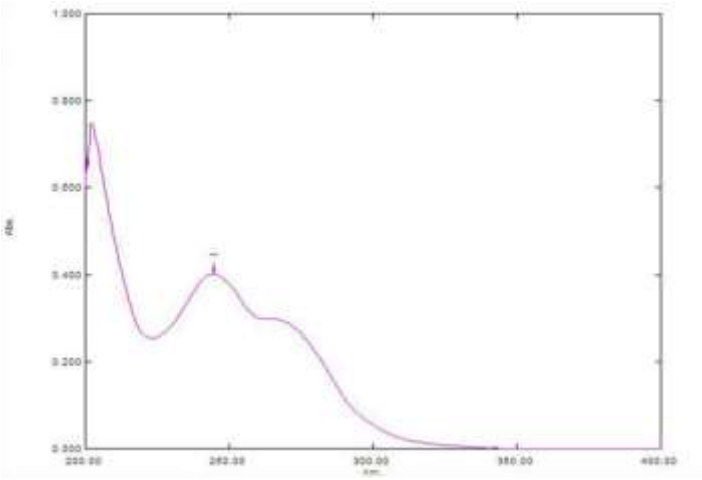

**Figure 2: Spectrum shows the λmax at 244nm**

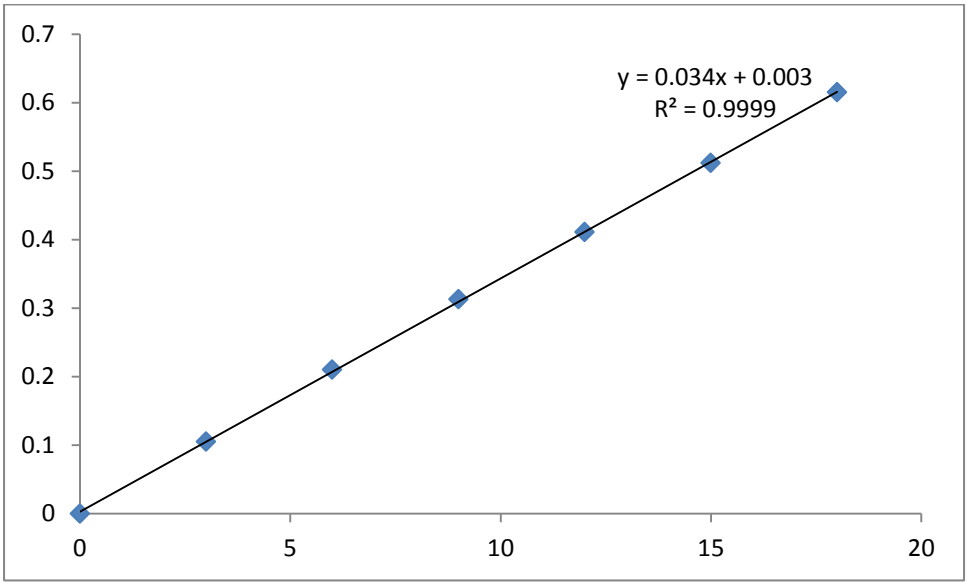


**Figure 3: Calibration curve at 244nm**

## RESULTS AND DISCUSSION:

The absorption spectral analysis shows the λmax at 244nm. The calibration curve was obtained for the series of concentration in the range of 3µg/ml-18µg/ml. They were found to be linear and hence suitable for the estimation of the drug. The slope, intercept, correlation coefficient and

optical characteristics are summarized in table 1. Regression analysis of Beer's law plot revealed a good correlation. The effects of various excipients generally present in tablet dosage form of Benfotiamine were investigated. The results indicated that they did not interfere in the assay in amounts far in excess of their normal occurrence in it. The developed method was validated as per ICH guidelines[11]. The recovery technique was performed to study the accuracy and reproducibility of the developed method. For this, known quantities of the Benfotiamine solution were mixed with definite amount of pre-analysed formulation and the mixture were analyzed. The total amount of Benfotiamine was determined by using the developed method and the amount of added drugs was calculated by the difference. The %RSD was less than ±2.0. This showed that the recovery of Benfotiamine by the developed method is satisfactory and the results are shown in table 2.The precision method was studied as intraday and interday. Intraday precision was determined by analyzing Benfotiamine (3, 6, 9µg/ml) for six times in the same day, interday precision was determined by analyzing the same concentration of the solution daily for six days and the results are shown in table 3. Limit of detection (LOD) and Limit of quantitation (LOQ) were determined by the developed method.

**Table 1: Values of Regression analysis.**

| Parameters | Values |
|---|---|
| Absorbance maximum (nm) | 244 |
| Linearity range (µg/ml) | 3-18 |
| Sandell's sensitivity (µg/ml-0.001 absorbance units) | 0.0289 |
| Regression equation | Y=0.034X+0.003 |
| Slope | 0.034 |
| Intercept | 0.003 |
| Correlation coefficient ($r^2$) | 0.999 |
| Standard deviation (SD) | 0.0054 |
| %RSD | 1.806 |
| Limit of detection (LOD) | 0.051 |
| Limit of quantitation (LOQ) | 0.155 |

**Table 2: Results of Accuracy Studies.**

| Drug | Sample drug µg/ml | Standard drug µg/ml | Amount recovered µg/ml | % Recovery* ± Standard deviation | %RSD |
|---|---|---|---|---|---|
| Benfotiamine (BenFORCE) 150mg | 9 | 3 | 11.950 | 99.32±0.554 | 0.55 |
| | 9 | 6 | 14.970 | 99.98±0.842 | 0.84 |
| | 9 | 9 | 18.009 | 100.42±0.677 | 0.67 |

* Average of six determinations, RSD indicates relative standard deviation

**Table 3: Results of precision Studies.**

| Concentration µg/ml | Intraday Precision* | %RSD | Interday Precision* | %RSD |
|---|---|---|---|---|
| 3 | 100.28 | 0.99 | 99.96 | 1.05 |
| 6 | 100.06 | 0.82 | 99.90 | 0.82 |
| 9 | 99.88 | 0.62 | 100.04 | 0.71 |

* Average of six determinations, RSD indicates relative standard deviation

## CONCLUSION

Thus it can be concluded that the method developed in the present investigation is simple, sensitive, accurate, rapid and precise. Hence, the above said method can be successfully applied for the routine estimation of Benfotiamine in pure and tablet dosage form.

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