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# QUANTIFICATION OF BENFOTIAMINE IN SOLID DOSAGE FORM BY IR SPECTROPHOTOMETRY

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## ABSTRACT

Simple, sensitive Infrared spectrophotometric method had been developed for the estimation of benfotiamine in tablet dosage form; the linearity concentration was found to be 2mg-10mg. The correlation coefficient for the method was found to be 0.99. The percentage purity of the sample was found to be between 99-101% and the percentage recovery was found to be between 99-100%. indicating that the method is accurate and reproducible.

**KEYWORDS:** benfotiamine, linearity, Infrared spectrophotometric method, accurate.

## INTRODUCTION

Benfotiamine is a molecule with the proper name of *S-benzoylthiamine O-monophosphate* and is a derivative of Vitamin B1.[1-3] After oral ingestion, it can be converted to thiamine and is thus considered a prodrug for thiamine. Benfotiamine is hydrophobic and is structurally stable unless dephosphorylated, in which case it may degrade into thiamine. Benfotiamine acts by blocking the biochemical pathways by which high blood sugar damages cells. It gives protection against polyneuropathy, diabetic peripheral vascular disease and diabetic retinopathy. Quantitative IR spectroscopic method was developed for the estimation of benfotiamine in bulk and solid dosage form.

### Quantitative infrared spectrophotometry method[4-10]

Quantitative infrared spectophtometry involves the measurement of amount of infrared radiation absorbed by substance in the pellet. The wavelength from 25 to 2.5 micron or wave numbers from 400cm$^{-1}$ to 4000cm$^{-1}$ is considered to be infrared region. The use of

quantitative infrared spectroscopy for quantitative analysis employs the method of comparing the absorbance/area of reference standards and samples at selected wave number. Various infrared quantitative methods include baseline method, compressed disc method, reflectance method and GC-FTIR.

## MATERIALS AND METHOD

**Method:** KBr Disc method.

### Instrumentation

All spectral measurements were made on Shimadzu FT-IR solutions with KBr press (model no: M 15).

All the chemicals used for the experiment were of IR grade.

- Potassium bromide(KBr)
- Benfotiamine standard was obtained as a gift sample from Franko Indianpharmaceuticals.
- Benfotiamine tablets were purchased from local market.

### Experimental work

### Calibration of the standard

Potassium bromide was dried, reground and stored over phosphorus pentoxide. Five different concentration of standard disc were obtained by mixing known weight of standard substance with KBr. The discs were prepared by grinding the standard known quantity of KBr in an agate mortar and pestle under IR lamp using KBr press. The infrared spectrum was recorded in transmittance mode; the calibration curve was obtained by plotting the area of the IR band at 2333cm$^{-1}$(prominent bond)against the concentration of the substance.

**Table 1: Concentration of KBr and standard in KBr discs**

| | | | | | | |
|---|---|---|---|---|---|---|
| KBr (in mg) | 50 | 50 | 50 | 50 | 50 | 50 |
| Standard (in mg) | 0.0 | 2 | 4 | 6 | 8 | 10 |

### Sample preparation

10 tablets of benfotiamine were weighed and ground to fine powder. Aliquot quantity of tablet powder was extracted using ethanol as solvent. The combined ethanol extracts were allowed to concentrate. The residue of benfotiamine so obtained was dried and used as sample which was mixed with KBr and then homogenized by using agate mortar & pestle. The fine powder was transferred into KBr press to form a disc and the infrared spectrum in

transmittance mode was recorded. The sample peak area was interpolated on the respective linearity chart and the concentration was determined. The amount of drug present in each tablet was calculated and the assay results are presented in the table.

**Recovery studies[11]**

The recovery studies were carried out on spiked samples by adding predetermined amount of standard drug to the respective sample. About 50 and 100% of standard drugs were added to the sample and the respective peak area at 2333cm$^{-1}$ was recorded. The percentage recovery was calculated.

## RESULTS AND DISCUSSION

Benfotiamine showed good linearity in the concentration range of 2-10 mg which is indicated by the correlation coefficient value(0.99). The results of the analysis showed that the amount of drug present in the formulation was in good agreement with the label claim of the formulation .The accuracy of the proposed method was studied by recovery studies. The percentage recovery was found to be between 99-100%.

**Table 2: Peak area at 2333 cm$^{-1}$wave number**

| Concentration | Area |
|---|---|
| 2 mg | 56.86 |
| 4mg | 113.3 |
| 6 mg | 167.5 |
| 8 mg | 217.52 |
| 10 mg | 265.07 |

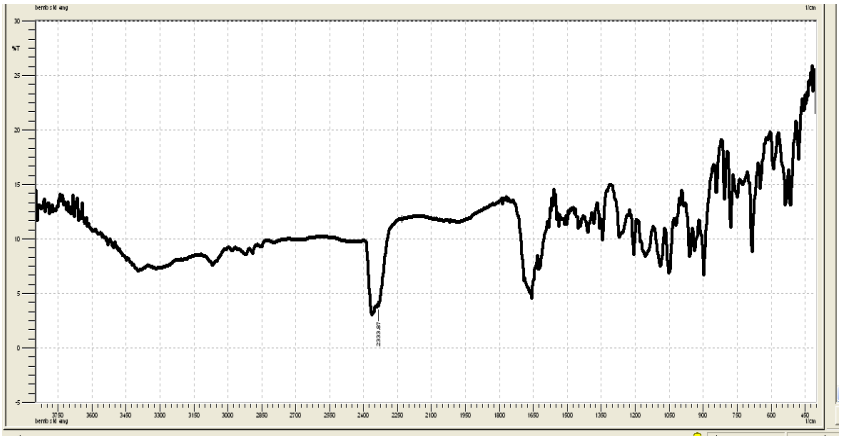
**Table 3: Assay and recovery study for benfotiamine by IR method**

| S.no | Label claim | Amount of drug in each tablet(mg) | Percentage purity of sample(%) | Amount of drug added(%) | Amount of drug recovered(%) | %Recovery |
|---|---|---|---|---|---|---|
| 1. | 100mg | 101.20 | 101.20* | 50<br>100 | 49.82*<br>100.24* | 99.64*<br>100.24* |

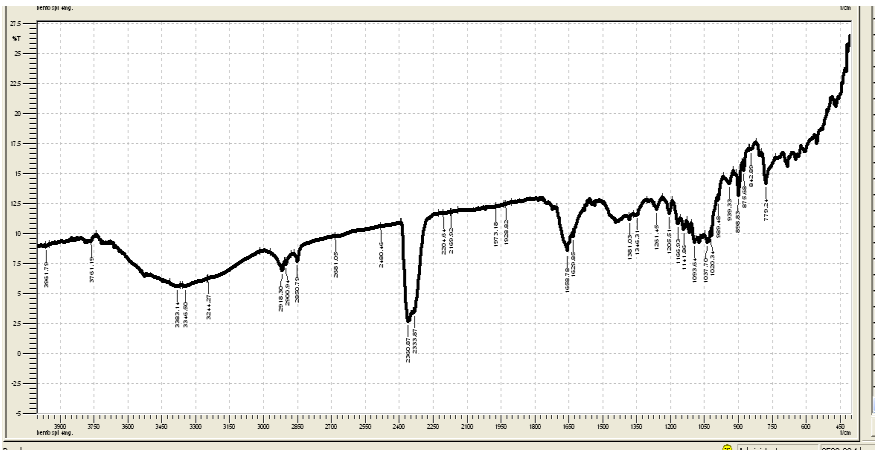
*****Each value is a mean of 3 readings.

**IR SPECTRUM**

**Benfotiamine standard**



**Benfotiamine sample**



**Calibration graph**

A graph was constructed by plotting the area against concentration and is shown below. It was observed that benfotiamine obeyed linearity in the concentration range of 2-10 mg.

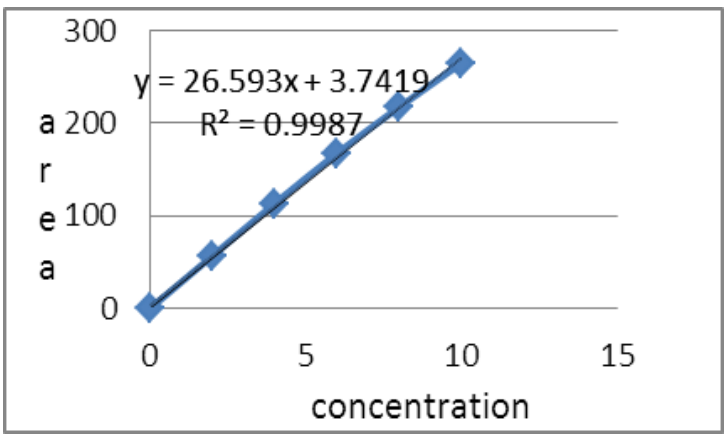


**Table 4: Optical characteristics by infrared spectrophotometry method**

| S.no. | Parameters | Infrared spectrophotometric method |
|---|---|---|
| 1 | Linearity range (mg) | 2-10 |
| 2 | Regression equation(y=mx+c) | 26.59x+3.741 |
| 3 | Slope(m) | 26.59 |
| 4 | Intercept(c) | 3.74 |
| 5 | Correlation coefficient | 0.9993 |

The optical parameters for the method are tabulated above. Recovery study confirms that the method is accurate and reproducible.

## CONCLUSION

The proposed method for benfotiamine by IR spectrophotometry is simple, less time consuming, more accurate and it could be used for future analytical procedures.

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