International Journal of Advances in Pharmaceutical Analysis
IJAPA Vol. 5 Issue 1 (2015) 14-16

IR Quantification of fenofibric acid in bulk and oral dosage form

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Abstract

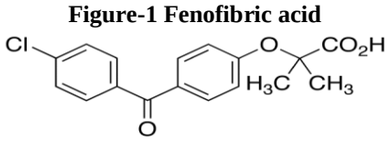
Simple and sensitive infrared spectrophotometric method has been developed for the estimation of Fenofibric acid in tablet dosage form. Beer's concentration range was found to lie between 5 to 15 mg. The correlation coefficient for the method was found to be 0.9946 and the developed method was analyzed for specificity, linearity of response, precision and accuracy; thus the proposed method could be adopted for routine analysis of bulk drug and its formulation.

Keywords: Infrared spectroscopy(IR), Potassium thiocynate(KSCN), Potassium bromide disc(KBr), Fenofibric acid.

1. Introduction

Fenofibric acid is an antilipidemic agent of the class of fibric acid derivatives widely used in antilipidemic pharmaceutical formulations, alone or in combination with other drugs. It reduces cholesterol levels in patients at risk of cardiovascular disease and also reduces both LDL, VLDL and triglycerides levels, as well as increases HDL levels. Fenofibric acid, the active metabolite of fenofibrate, increases apolipoprotein A-1 mediated high-density lipoprotein biogenesis by enhancing transcription of ATP-binding cassette transporter A1 gene in a liver X receptor–dependent manner. Fenofibric acid has been successfully used as single drug or in association with other drugs in the treatment of hyperlipidemia. Its molecular weight is 318.75. The chemical structure of Fenofibric acid is given in Figure 1.[1]

Figure-1 Fenofibric acid



Fenofibric acid is an antilipidemic drug whose chemical name is2-[4-(p-Chlorobenzoyl)phenoxy]-2-methylpropionic acid.

On the basx of literature survey FOR RP-HPLC methods estimation of fenofibrate and fenofibric acid in biological fluids[2][3]; The present work developed of IR spectrophotometric method for the determination of fenofibric acid in pure and pharmaceutical formulations which has not been reported till date. The proposed method is novel, simple and easy to perform.

2. Materials and Method

All chemicals used were of highest purity of IR grade. Potassium bromide, Potassium thiocyanate (Internal standard), Fenofibric acid(Bulk material) was obtained as a gift sample from Ordain Health Care Global Pvt Ltd, Fenofibric acid tablet (Dosage form) was purchased from local market.

2.1 Instrumentation:

All spectral measurements were made on ABB-IR instrument (Model no .MB 3000) with KBr press (model no.M15).

2.2 Method

2.2.1 Calibration of the standard

Potassium thiocyanate was used as an internal standard which was preground, dried, and then reground with dry KBr to make a concentration of about 0.2% by weight of potassium thiocyanate. The final mixture was stored over phosphorus pentoxide. Five different concentration of standard and KBr-KSCN were prepared by mixing known weights of the standard substance with a known weight of the KBr-KSCN mixture and then grinded by using agate mortar & pestle under IR lamp. A standard calibration curve was constructed using peak area and concentration as presented in Figure 2. The values obtained by proposed methods are presented in Table 1. The discs were prepared using KBr press and the infrared spectrum was recorded in absorbance mode; the calibration curve was obtained by plotting the area of the IR absorption at 2067.54 cm^{-1} (prominent band) against the concentration of the substance.[4][11]

2.2.2 Assay

Weighed 10 tablets of fenofibric acid, average weight was determined and ground to fine powder, weighed an aliquot quantity powder and the powder transferred to 100ml volumetric flask and added 50 ml acetone. The above mixture was shaken for 30 minutes and filtered the solution through Whatmann filter paper (15.0 cm). The filtrate was collected and poured into petridish and evaporated; the residue contains the extracted fenofibric acid. Aliquot quantity of the fenofibric acid residue is weighed and mixed with the KBr/KCNS mixture and then homogenized by using agate mortar & pestle. The final mixture was transferred to KBr press to form a disc and the infrared spectrum was recorded in absorbance mode. The sample absorbance was interpolated on the respective linearity chart of the fenofibric acid and the concentration was determined. The amount of drug present in each tablet was calculated and the assay results are presented in the **Table.2.**

2.2.3 Recovery studies

The recovery studies were carried out on spiked samples by adding predetermined amount of standard drug to the respective sample. The recovery study was performed at two levels (25% & 50%) to confirm the precision and accuracy of the above said method. The percentage recovery was calculated and the recovery results are presented in **Table.3.**

Table 1: Concentration of KBr /KSCN mixture and standard

KBR/KCN (in mg)	100	95	92.5	90	87.5	85
Standard (in mg)	0.0	5	7.5	10	12.5	15

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3. Results and Discussion

Fenofibric acid was found to obey Beer's law in the concentration range 5 to 15 mg. Fenofibric acid showed good linearity as indicated by correlation coefficient value 0.9946. 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 determined by recovery study. The recovery studies were carried out on spiked samples at two levels 25% & 50%.

The percent recovery was found to be 99% as represented in **Table 3.** The optical characteristics such as Beer's law limits and the regression characteristics like slope (m), intercept (c), correlation co-efficient (r) were calculated and the results were summarized in the Table-4.

Figure 2: Calibration curve for Fenofibric acid

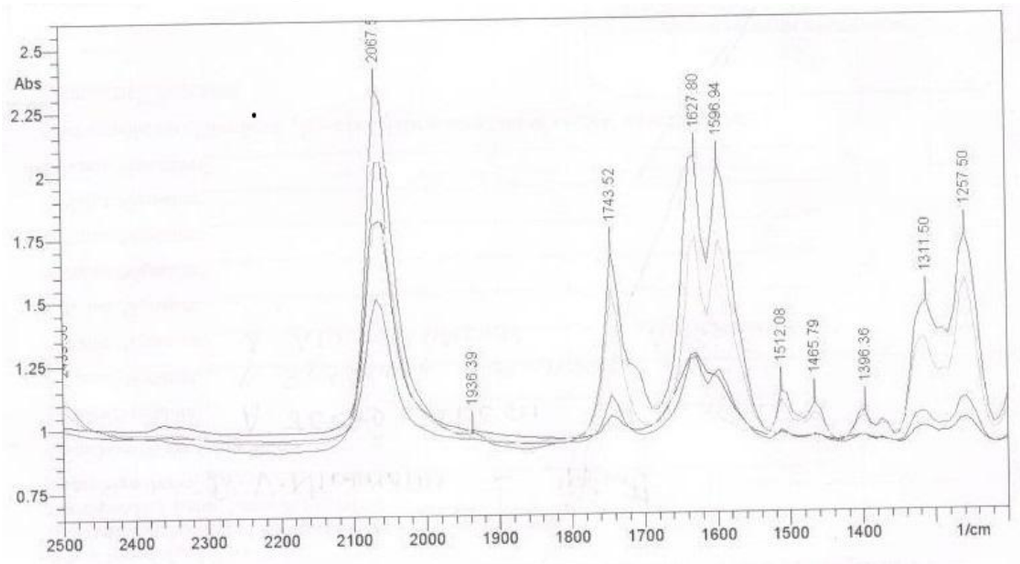

Figure 3: Calibration graph of Fenofibric acid standard

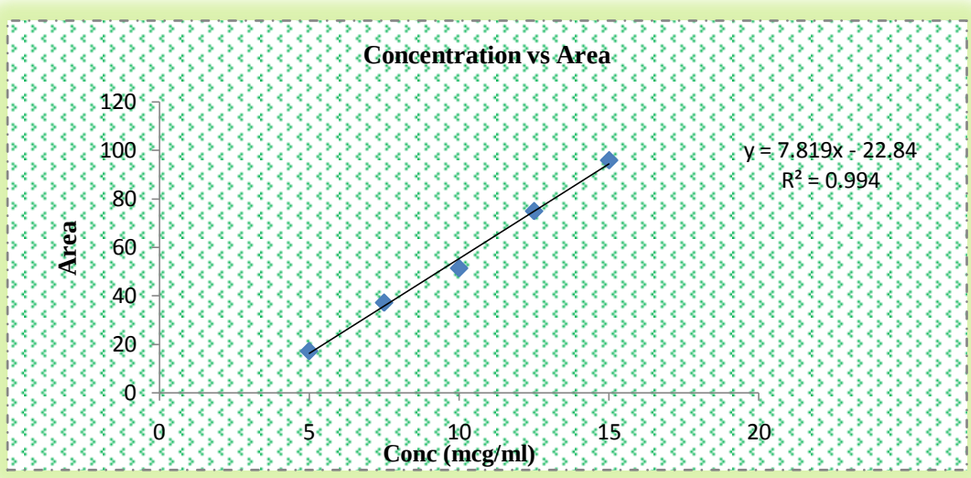

Table 2: Estimation of Fenofibric acid in tablet

Fenofibric acid	
Label claim (mg)	**35**
Amount present in tablet(mg)	**34.85**
Amount found (%)±SD*	**99.57±0.577**
%RSD	**0.0579**

* Each value is the mean of five readings.

Table 3: Recovery study for Fenofibric acid

Method	Label claim	Amount of drug added (mg)*	Amount of drug recovered (mg)*	% Recovery	Standard deviation
KBr disc method using internal standard	**35mg**	**2.5**	**2.48**	**99.2 %**	**0.57**
		5	**4.95**	**99.0 %**	**0.65**

***Each value is the mean of three readings**

Table 4: Optical parameters for the proposed method:

S.No.	Parameters	Values (IR Method)
1	Beer's law	5 – 15 mg
2	Regression equation (y = mx+ c)	y = 7.8196x - 22.842
3	Slope (m)	7.8196
4	Intercept ©	-22.842
5	Correlation coefficient	0.9946

4. Conclusion

The percentage recovery of the method was found to be 99% and the correlation coefficient was 0.9946. The recovery studies indicate that there is no interference of other ingredients present in the formulation. Thus the method is simple, precise, accurate, less time consuming and could be used for routine analysis.

Acknowledgement

The authors are thankful to the Department of Pharmaceutical Chemistry, College of Pharmacy, Madras Medical College for rendering full support to carry out the study.

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