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Estimation of Fenofibric Acid in Pharmaceutical Oral Solid Dosage Form by UV-Spectrophotometry

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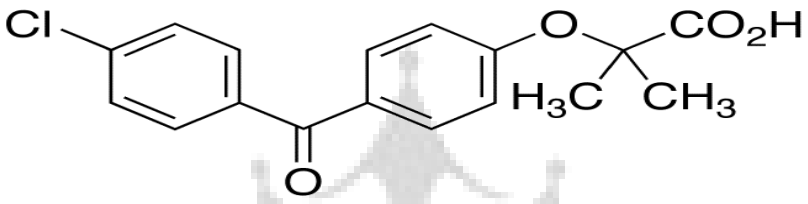
ABSTRACT

Four new, simple, sensitive and reproducible spectrophotometric methods have been developed for the estimation of fenofibric acid in tablet dosage form. Method A involves the determination of fenofibric acid by standard absorbance method at 299 nm. Method B and Method C involve the determination of fenofibric acid by first derivative spectrophotometry and second derivative spectrophotometry respectively. The normal spectrum was derivatized to first and second order derivative spectrum. The Beer's concentration was found to be 5-30 µg/mL; Method D involves the determination of fenofibric acid by area under curve.

INTRODUCTION

Fenofibric acid is 2-[4-(4-Chlorobenzoyl)phenoxy]-2-methylpropanoic acid. Fenofibric acid is an active ingredient in the cholesterol medication used for the management of high LDL and cholesterol; it helps to reduce triglycerides and increase the quantity of HDL cholesterol in blood. It is also used in combination with HMG-Co A reductase inhibitors [1-10].The estimation of fenofibric acid in biological fluids have been reported and review of literature indicated that no validated simple UV spectrophotometric methods have been reported for pharmaceutical formulation till date.



Fenofibric acid

MATERIALS & METHODS

Material and Reagents

Sodium hydroxide was purchased from Merck. Distilled water was used throughout the experiment. Fenofibric acid was obtained as a gift sample from well reputed pharmaceutical company. Fenofibric acid 35 mg was purchased from Indian market. The determinations were carried out at room temperature. All absorption spectra were measured by using Shimadzu UV-1650PC (UV-Visible) spectrophotometer with a scanning speed of 200 nm/min and band width of 2.0 nm, equipped with matched quartz cells.

Experimental/ methodology

Preparation of standard stock solution

A standard stock solution of the analyte was prepared by dissolving an adequate quantity of standard 0.1M Sodium hydroxide in a 100 mL standard flask and made up to the volume with 0.1M Sodium hydroxide to produce 1 mg/mL. The stock solution was further suitably diluted with distilled water to give a varied concentration ranging from 5-30 µg/mL.

Preparation of sample stock solution

Twenty tablets were accurately weighed and powdered. Powder equivalent to 100 mg of fenofibric acid was weighed and transferred to 100 mL volumetric flask. The powder was then shaken with 0.1M Sodium hydroxide and then made up to volume with 0.1M Sodium hydroxide to produce 1 mg/mL. The solution was then filtered through a Whatmann filter paper. The first few mL of the filtrate was discarded. The remaining filtrate was diluted with distilled water to get the required concentration.

Assay procedure

Method A – Standard absorbance method

Aliquots of standard solution of fenofibric acid were suitably diluted to give varying concentrations ranging from 5-30 µg/mL and the solutions were scanned in the range of 200 -400 nm using distilled water as blank. Graph was plotted by taking concentrations on X-axis and absorbance's on Y-axis. It was found that fenofibric acid exhibited an intense maximum absorbance at about 299 nm and obeyed Beer's law in the range of 5-30 µg/mL. The absorbance obtained for the sample was then interpolated on the calibration graph (Fig.1) and the concentration of fenofibric acid in the sample was then determined. The overlain fundamental spectra are shown in (Fig.2).

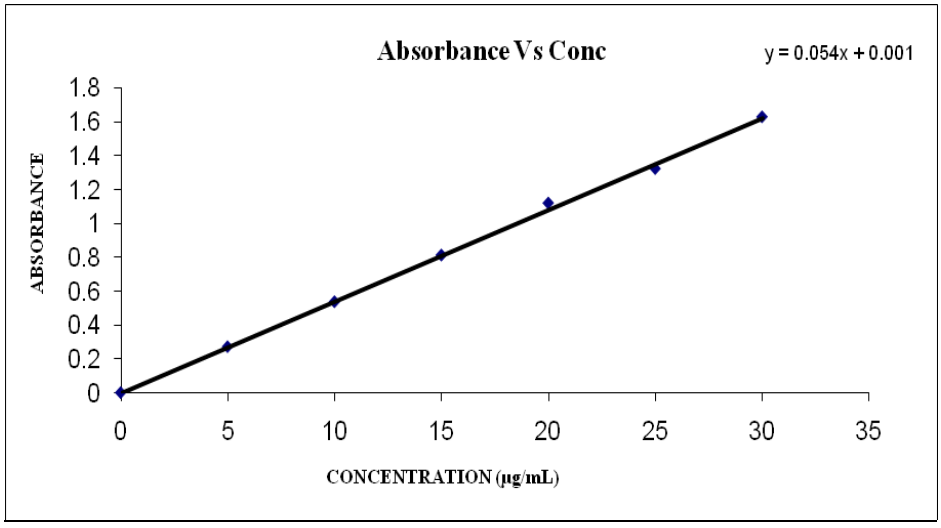


Figure 1: Calibration curve of fenofibric acid (Standard absorbance method)

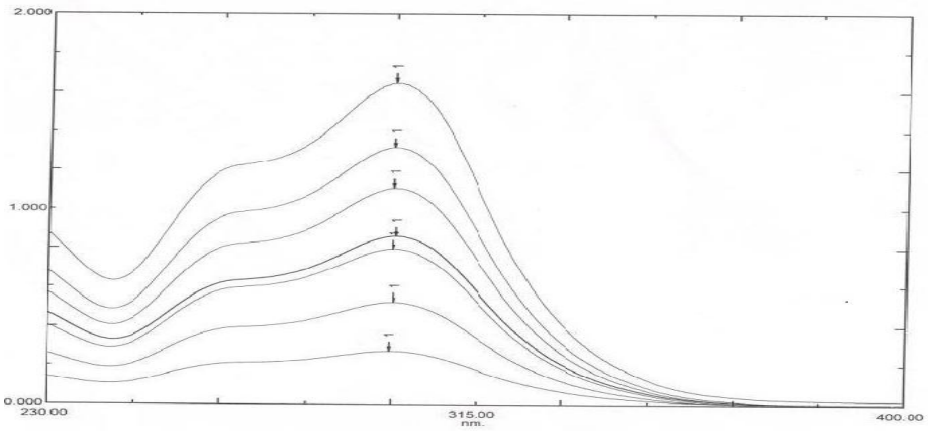


Figure 2: Over lain spectrum of fenofibric acid (Standard absorbance method)

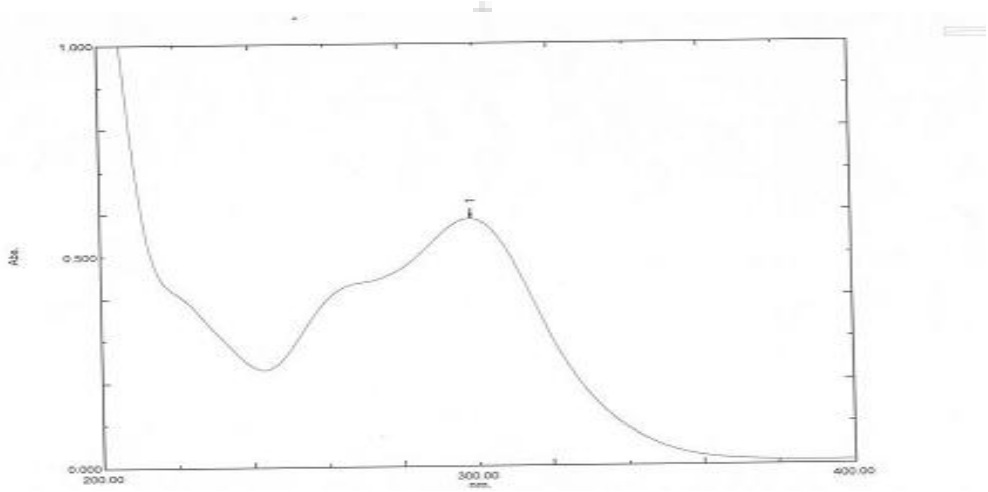


Figure 3: Fenofibric acid standard

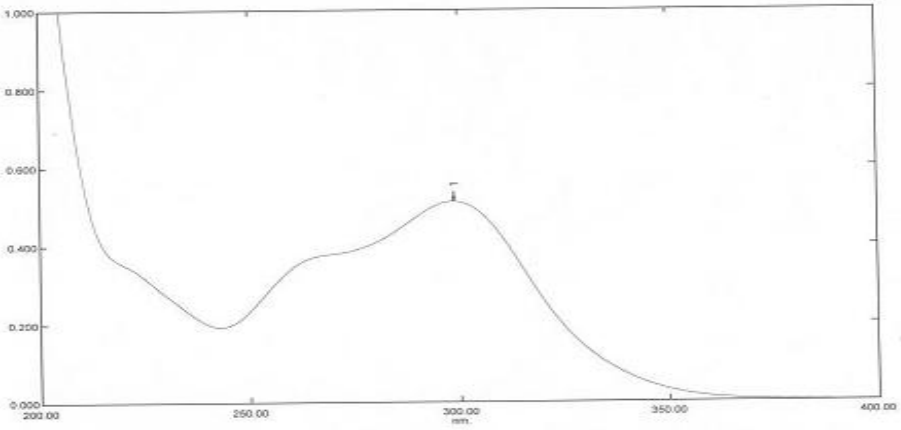


Figure 4: Fenofibric acid sample

Method B – First derivative spectroscopy

The standard stock solution of fenofibric acid was suitably diluted to give varying concentrations ranging from 5-30 µg/mL. The solutions were scanned in the range of 200- 400 nm and the primary absorption spectrum was recorded. The primary spectrum was then derivatized to the first order using derivative mode. The amplitude of the negative peak maximum at the zero crossing of the first order curve was measured in mm at 299 nm. A calibration graph was obtained by plotting concentration versus amplitude. The sample solution was suitably diluted to get the required concentration and the absorbance was recorded. The amplitude obtained for the sample was then interpolated on the calibration graph and the concentration of fenofibric acid in the sample was then determined (Fig.5). The linearity graph and the overlain spectra for this method are shown in (Fig 6).

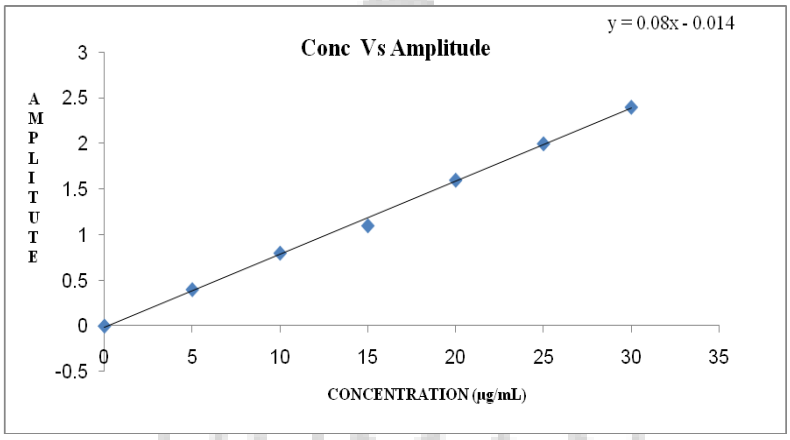


Figure 5: Calibration graph of fenofibric acid (First derivative spectroscopy)

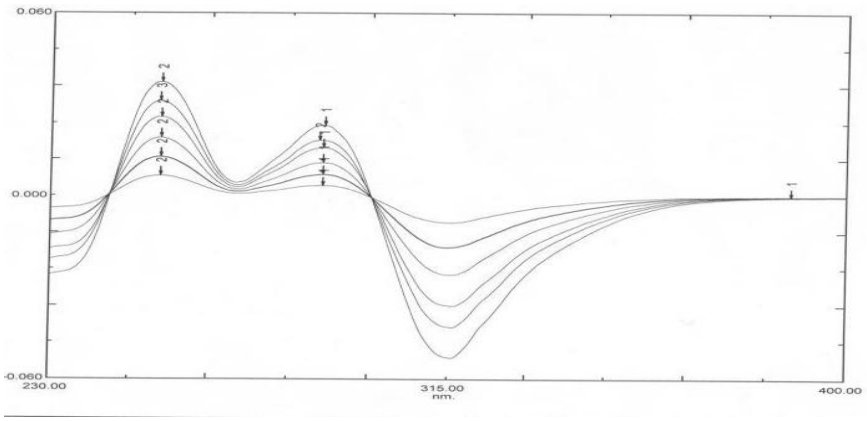


Figure 6: Over lain spectrum of fenofibric acid (*First derivative spectroscopy)*

Method C – Second derivative spectroscopy

The primary spectrum obtained for the above was then derivatized to the second order. The amplitude of the negative peak maximum was measured in mm at 299 nm. The respective linearity graph and the overlain spectra are shown in Fig 7&8.

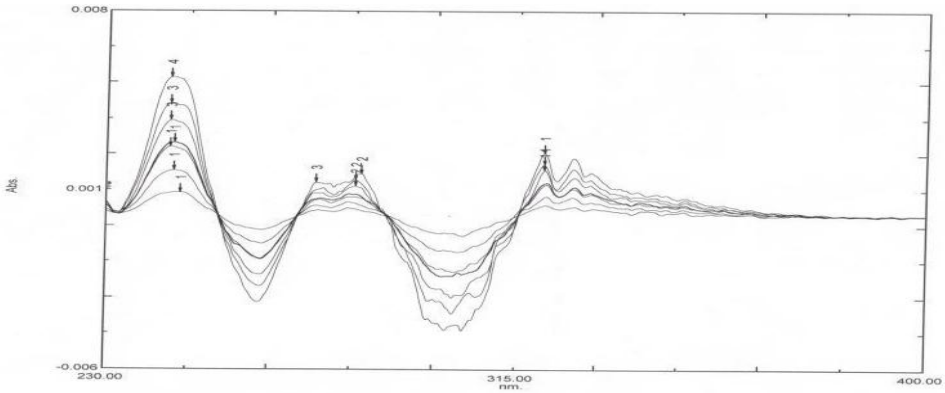


Figure 7: Over lain spectrum of fenofibric acid (Second derivative spectroscopy)

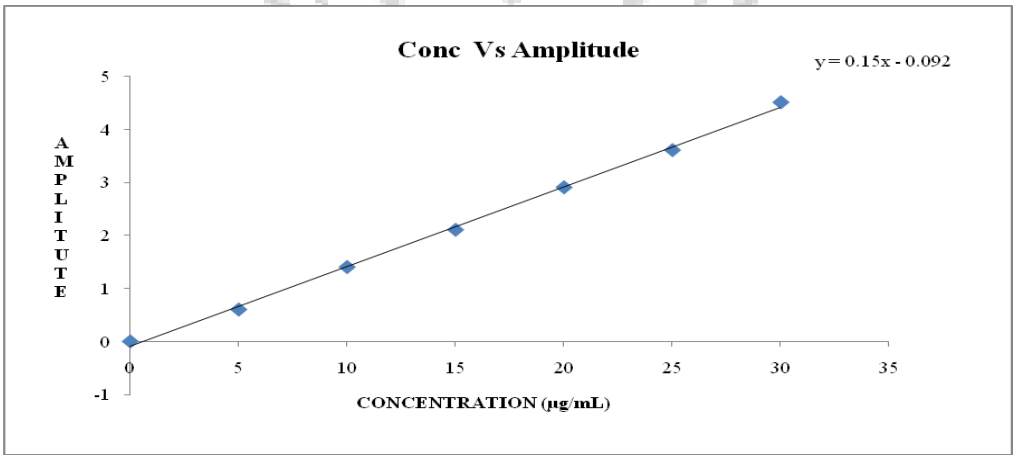


Figure 8: Calibration curve of fenofibric acid (Second derivative spectroscopy)

Method D – Area under curve

The standard stock solution of fenofibric acid was suitably diluted to give varying concentrations ranging from 5-30 µg/mL. The solutions were scanned in the range of 200-400 nm. The area under the curve between 275-316 nm was measured by using the inbuilt software. The inbuilt software calculates the area bound by the curve and the horizontal axis. The horizontal axis is

selected by entering the wavelength range over which the area has to be calculated .The wavelength range is selected on the basis of repeated observations so as to get the linearity between area under curve and concentration. The AUC spectrum is shown in Fig .9&10.

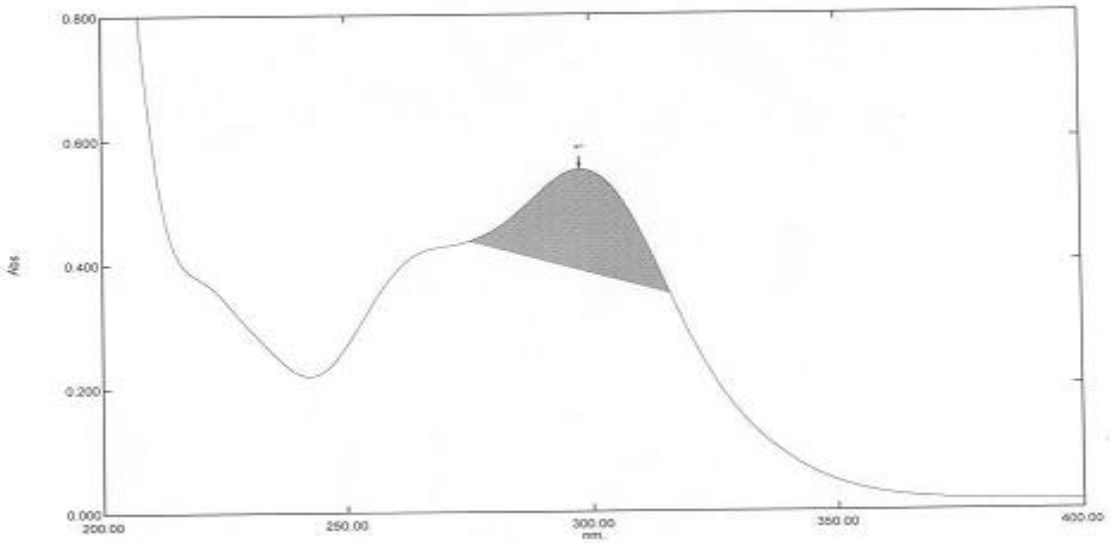


Figure 9: Fenofibric acid sample (Area under curve)

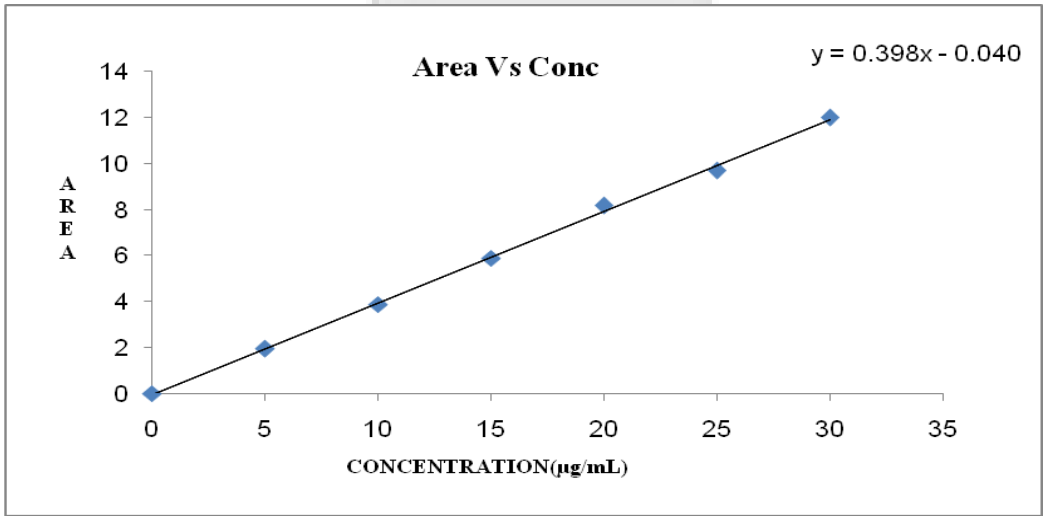


Figure 10: Calibration graph of fenofibric acid (Area under curve)

Table 1. Result of analysis of tablet formulation:

Method	Drug	Label Claim (mg)	% Label Claim*, Mean ± S.D	% R.S.D**.
Method A	Fenofibric acid	35.04	100.07 ± 0.350761	1.00113
Method B		35.13	100.36 ± 0.235443	0.67027
Method C		35.20	100.57 ± 0.301993	0.85794
Method D		35.34	100.98 ± 0.230289	0.65158

****** Each value is the mean of 3 determinations.

Recovery studies

To study the accuracy and reproducibility of the proposed methods, recovery experiments were carried out by adding a known amount of drug to preanalysed sample and the percentage recovery is calculated. The results indicate that there is no interference of other ingredients present in the formulation.

Table 2. Recovery result of fenofibric acid:

Sr. No.	Method	Label claim	Amount Drug added (%)	Amount Drug Recovered (%)	% Recovered
1.	UV Spectrophotometry	35 mg	20 40 100	19.93 40.25 99.68	99.65 100.62 99.68
2.	First Derivative Spectrophotometry		20 40 100	20.20 40.34 100.12	101.00 100.85 100.12
3.	Second Derivative Spectrophotometry		20 40 100	19.84 40.16 99.85	99.20 100.40 99.85
4.	Area Under Curve		20 40 100	20.02 40.43 100.39	100.10 101.07 100.39

RESULTS AND DISCUSSION

Quantitation of fenofibric acid was done by using UV spectrophotometry. Fenofibric acid exhibits an absorption maximum at 299 nm. The Beer's concentrations for all the four methods were found to be lie between 5-30 µg/mL. The correlation coefficient for all the four proposed methods was found to be 0.9991 which shows good linearity between concentration and absorbance. The percentage recovery for all the four methods obtained was 99.20% to 101.07% indicating the accuracy of the method. The results of the analysis of formulation show that the proposed methods are in good agreement with the labeled amount of the drug. The regression characteristics like slope, intercept, and correlation co-efficient (r), obtained from different concentrations were calculated and the results are summarized. All the four proposal methods are simply precise accurate and reproducible and could be used for routine analysis.

Table 3. Optical Characteristics for Fenofibric Acid:

Parameters	UV spectrophotometry	First derivative	Second derivative	Area under curve
λ_{max} (nm)	299	299	299	275-316
Beer's law limits (µg/mL)	5-30	5-30	5-30	5-30
Molar absorptivity (L mol^{-1} cm^{-1})	17255.35	-	-	-
Sandell's sensitivity (µg cm^{-2} /0.001absunit)	0.018478	-	-	-
Slope (m)	0.054000	0.080000	0.150000	0.398621
Intercept (c)	0.001857	-0.014286	-0.092857	-0.04075
Regression equation (*Y)	0.054X +0.001	0.080X - 0.014	0.150X - 0.092	0.398X - 0.040
Correlation coefficient (r)	0.999094	0.999045	0.999139	0.999431
Standard deviation	0.350761	0.235443	0.301993	0.23029
Relative standard deviation (%) **	1.001126	0.670268	0.857936	0.651579
Standard error	0.021518	0.135937	0.174361	0.132961

***** (Y=mx+c) ****** Each value is the mean of 3 determinations.

CONCLUSION

The percentage recovery of all the four methods lies between 99-102 %. The correlation coefficient for all the four methods is 0.9991 and the recovery studies indicate that there is no interference of other ingredients present in the formulation. Thus these four methods are simple, precise, accurate, less time consuming and useful for the routine analysis.

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