EXTRACTIVE SPECTROPHOTOMETRIC METHODS FOR THE DETERMINATION OF FENOFIBRATE

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ABSTRACT: Two simple and sensitive spectrophotometric methods have been developed for the estimation of fenofibrate in pure and pharmaceutical dosage forms. Method A and B are based on ion association complex formation of the drug with Methylene Blue and Saffranine respectively. Beers law is obeyed in the concentration range of 5-15 µg/ml (Method A) and 10-30µg/ml (Method B) with good correlation coefficients. These methods have been statistically evaluated and found to be precise and accurate.

Key words : Fenofibrate, spectrophotometric methods , Methylene Blue, Saffranine

INTRODUCTION:

Fenofibrate which is chemically propan-2-yl 2-{4-[(4-chlorophenyl) carbonyl] phenoxy}-2-methyl propanoate. It is mainly used to reduce cholesterol levels in patients at risk of cardiovascular disease. Like other fibrates, it reduces both low-density lipoprotein (LDL) and very low density lipoprotein (VLDL) levels, as well as increasing high-density lipoprotein (HDL) levels and reducing triglycerides level. It also appears to have a beneficial effect on the insulin resistance featured by the metabolic syndrome The developed methods involve the formation of colored complexes with Methylene blue (MTB) and Saffranine (SFN). The colored chromogens showed the absorption maximum at 630 nm & 520 nm respectively. Beers law is obeyed in the concentration ranges of 5-15µg/ml, and 10-30µg/ml respectively. The results of analysis for the two methods have been validated statistically and by recovery studies in table-2.

INSTRUMENTATION:

A Systronics Double beam UV visible spectrophotometer 2201 with 1 cm matched quartz cells was used for all spectral and absorbance measurements. A systronics digital p^H meter was used for all p^H measurements.

EXPERIMENTAL:

Preparation of reagents:

1. Methylene blue : 0.5 g of MTB dye was dissolved in 100 ml of distilled water
2. Saffranine : 0.5 g of SFN was dissolved in 100 ml of distilled water
3. Acid phthalate buffer pH 2.4 [I.P]
4. Standard drug solution: About 100mg of fenofibrate was accurately weighed and dissolved in 100 ml of water to obtain a stock solution of 1 mg/ml. This solution was further diluted with distilled water to get working standard solution of 100 µg/ml

ASSAY PROCEDURES:

Method A:

Aliquots of working standard solution of fenofibrate ranging from 0.5-1.5 ml were transferred into a series of 125 ml separating funnels. To these 1 ml of buffer solution (pH 2.4) and 1 ml of MTB dye were added. The total volume of aqueous phase was adjusted to 10 ml with distilled water and 10 ml of chloroform was added. The contents were shaken for 2 minutes. The two phases were allowed to separate and the absorbance of the Blue colored chromogen was measured at 630 nm against reagent blank and the amount of Fenofibrate present in the sample solution was computed from its calibration curve.

Method B:

Aliquots of working standard solution of fenofibrate ranging from 1-3 ml were transferred into a series of 125 ml separating funnels. To these 1 ml of buffer solution (pH 2.4) and 1 ml of Saffranine dye were added. The total volume of aqueous phase was adjusted to 10 ml with distilled water and 10 ml of chloroform was added. The contents were shaken for 2 minutes. The two phases were allowed to separate and the absorbance of the Pink colored chromogen was measured at 520 nm against reagent blank and the amount of Fenofibrate present in the sample solution was computed from its calibration curve.

RESULTS AND DISCUSSION:

The optical characteristics such as Beer's law limits, Sandell's sensitivity, Molar Extinction coefficient, percent relative standard deviation, percent range of error (0.05 and 0.01 confidence limits) were calculated for all the methods and results are summarized in Table 1. The values obtained for the determination of fenofibrate in Pharmaceutical formulations (Tablets) by the proposed methods are presented in Table 2. Studies reveal that the common excipients and other additives usually present in the Tablets did not interfere in the proposed methods.

Table-1: Optical characteristics and statistical data of the regression equation for the reaction of the proposed method.

PARAMETERS	Method A	Method B
λ_{max} (nm)	630 nm	520 nm
Beer's law limit (µg/ml)	5-15µg/ml	10-30µg/ml
Sandell's sensitivity (µg/cm^2/0.001 abs. unit)	0.0089	0.013
Molar absorptivity(litre.mole^{-1}.cm^{-1})	0.0000336	0.0000265
Regression equation(Y*)		
Slope(b)	0.0995	0.1239
Intercept(a)	0.3623	0.0186
Correlation Coefficient(r)	0.9996	0.9999
%Relative standard deviation	0.86	0.903
% Range of error		
0.05 Significance level	0.733	0.795
0.01 Significance level	1.089	1.125

*Y = a + bx, where 'Y' is the absorbance and x is the concentration of fenofibrate µg/mL

**For six replicates

Table-2: Estimation of fenofibrate in Pharmaceutical Formulations

Formulations (Tablets)	Labelled amount(mg)	Amount found* by proposed method		% recovery** by proposed method	
		Method A	Method B	Method A	Method B
Tablet 1	200mg	189.5	189.6	99.16	99.35
Tablet 2	200mg	188.3	188.9	99.23	99.46
Tablet 3	200mg	189.6	189.5	98.85	99.33

* Average of six determinations : **Recovery of amount added to the pharmaceutical formulation (Average of three determinations)

CONCLUSION:

The proposed methods are simple, selective, and reproducible and can be used in the routine analysis of fenofibrate in bulk drug and formulations with reasonable accuracy and precision.

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