ISSN: 0975-766X
Available Online through
www.ijptonline.com
Research Article

SPECTROPHOTOMETRIC METHODS FOR THE DETERMINATION OF FENOFIBRATE

P.H.Prathyusha*, B.Anupama, V.Jagathi, P.Sai Praveen
K.V.S.R.Siddhartha College of Pharmaceutical Sciences, Siddhartha Nagar,
Vijayawada – 520 010, A.P., India.
Email: vallurijagathi@g.mail.com

Received on 23-07-2010 ***Accepted on 08-08-2010***

ABSTRACT:

Two simple and sensitive spectrophotometric methods have been developed for the estimation of fenofibrate in pure and pharmaceutical dosage forms. Method A is based on oxidation followed by complex formation of the drug with potassium permanganate at 460nm. Method B is based on the interaction of the drug with 2,4-dinitrophenylhydrazine in the presence of an acid catalyst, followed by treatment with a methanolic solution of potassium hydroxide; an intensely colored chromogen was formed that was measured in dimethyl formamide as the diluting solvent at 520 nm. These methods have been statistically evaluated and found to be precise and accurate.

KEYWORDS: Spectrophotometric, Enofivrate, Dinitrophenylhydrazine, Dimethyl formamide.

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 tryglycerides 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 chloranilic acid, picric acid and potassium permanganate. The colored chromogens showed the absorption maximum at 520nm, 460nm respectively. Beers law is obeyed in the concentration ranges of 2.5-15µg/ml, and 5-30µg/ml respectively. The results of analysis for the three methods have been validated statistically and by recovery studies in table-2.

EXPERIMENTAL:

Preparation of reagents:

1. Potassium permanganate (0.05%w/v) : 25 mg in 50ml distilled water
2. 0.005M 2,4-Dinitro Phenyl Hydrazine Reagent: The reagent was freshly prepared by dissolving 0.1 g of 2,4-Dinitro Phenyl Hydrazine in a mixture of 10 ml of methanol and 0.5 ml of conc.HCl and diluting the resultant mixture to 100 ml with methanol
3. Standard drug solution for method B: A stock solution of 1 mg/ml was prepared in methanol. This solution is diluted to obtain the required concentration (100 µg/ml)
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 0.5-3.0 ml were transferred into a series of 10ml volumetric flasks. To this 1 ml of Potassium Permanganate solution was added and allowed to stand for 20 minutes. The total volume was made up to 10ml with water. The absorbance of the cherry red colored chromogen was measured at 460nm against reagent blank. The amount of drug present in the sample solution was computed from its calibration curve.

Method B:

Aliquots of working standard solution of fenofibrate 0.25-1.5 ml (100 µg/ml) were transferred into a series of 10 ml calibrated test tubes. To this 2 ml of 2,4-DNP reagent was added followed by 1 drop of conc.HCl. The mixture was placed on a boiling water bath for evaporation of the solvent to almost dryness. The residue was cooled to room temperature and 3 ml of 0.1786 M KOH solution was added. The contents of the tubes were mixed thoroughly and allowed to stand for 30 minutes with occasional shaking at room temperature. The contents of the tubes were transferred quantitatively to a 10 ml volumetric flask

and made upto the volume with Dimethyl formamide. The contents in the flask were mixed well and the pink colored chromogen was measured spectrophotometrically at 520 nm against a reagent blank.

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)	520	460
Beer's law limit (µg/ml)	2.5-15µg/ml	5-30µg/ml
Sandell's sensitivity (µg/cm^2/0.001 abs. unit)	0.0083	0.010
Molar absorptivity(litre.mole^{-1}.cm^{-1})	0.0000339	0.0000264
Regression equation(Y*)		
Slope(b)	0.0997	0.1236
Intercept(a)	0.3624	0.018
Correlation Coefficient(r)	0.9993	0.9995
%Relative standard deviation	0.88	0.906
% Range of error	0.00314	0.0017
0.05 Significance level	0.735	0.757
0.01 Significance level	1.088	1.120

*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 C	Method A	Method B	Method C
Tablet 1	200mg	149.2	149.6	149.3	99.46	99.73	99.53
Tablet 2	200mg	149.3	149.6	149.5	99.53	99.73	99.66
Tablet 3	200mg	148.9	149.2	148.8	99.26	99.46	99.20

***** 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.

REFERENCES:

1. The Merck Index,13th edition, pg no-1698, 9600
2. Kocsis P, Farkas S, Fodor L, Bielik N, Thán M, Kolok S, Gere A, Csejtei M, Tarnawa I (2005). *J Pharmacol Exp Ther* 315 (3): 1237–46.
3. Jung-Woo Bae, Young-Seo Park, Uy-Dong Sohn, Chang-Sun Myung, Byung-Kwon Ryu, Choon-Gon Jang, and Seok-Yong Lee, Arch Pharm Res Vol 29, No 4, 339-342, 2006.
4. Napaporn Youngvises, Boonsom Liawruangrath and Saisunee Liawruangrath, Journal of Chromatography.
5. Osama H Abdelmageed, Journal of AQAC International, March-April 2007.
6. G.Devala Rao, S.Vijaya Saradhi,Acta Cienca Indica, Vol XXXV C,No. 1,101(2009)

Corresponding Author*
P.H.Prathyusha*,
Email: *vallurijagathi@g.mail.com*