Available online at http://jddtonline.info

RESEARCH ARTICLE

QUANTITATIVE ESTIMATION OF FENOFIBRATE IN BULK DRUG AND TABLETS BY U.V VISIBLE SPECTROSCOPY

*Jat R.K[1], Sharma S[2], Chippa R.C[1], Singh Rambir[1], Alam Imran[1]

[1]Gyan Vihar School of Pharmacy, SGVU Jagatpura, Jaipur-302025

[2]Department of Pharmaceutical Science, Guru Jambheshwar University, Hisar, Hariyana-125001

*Corresponding Auththor's E-mail: rakeshjat75@yahoo.co.in

Received 24 March 2012; Revised 20 April 2012; Accepted 24 April 2012, Available online 15 May 2012

ABSTRACT

A sensitive and rapid extractive spectrophotometer method has been developed for the assay of Fenofibrate in bulk drug and tablets. Fenofibrate shows maximum absorbance at 296 nm. Beer's law was obeyed in the concentration range of in the range of 5-35µg/ml. Beers law was obeyed in this concentration range with correlation coefficient of 0.999. The concentrations of this drug were evaluated in laboratory mixture and marketed formulation. Accuracy was determined by recovery studies from tablet dosages forms and ranges from 99.33 -100.92 %. Precision of method was find out as repeatability, day to day and analyst to analyst variation and shows the values within acceptable limit (R.S.D ≤ 2 percentage).

Keywords Fenofibrate, linearity, Beer's Law, U.V Spectrophotometry

INTRODUCTION

Fenofibrate, chemically is 2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl propanoic acid 1-methyl ethyl ester [1, 2]. It is the lipid regulating drug (BP 2009). Fenofibrate increases lipolysis and elimination of triglyceride-rich particles from plasma by activating lipoprotein lipase and reducing production of apoprotein C-III (an inhibitor of lipoprotein lipase activity) [3]. It is official in BP [4]. Literature survey revealed that HPTLC [5] HPLC [6] and Stability Indicating UPLC [7] Method for simultaneous determination of Atorvastatin, Fenofibrate and their degradation products in tablets were reported. Also HPLC method has been reported for determination of Fenofibrate in human serum [8-10] and urine [11].The present study describes the development and validation of a simple, specific, accurate and precise UVspectrophotometric method for determination of Fenofibrate in pharmaceutical dosage forms.

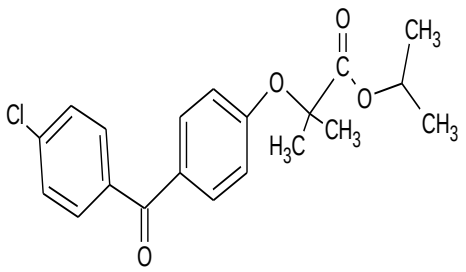

Figure 1: Chemical Structure of Fenofibrate

MARERIAL AND METHOD

Fenofibrate drug sample was supplied as gift sample by Sun Pharma Labs. Ltd., Jammu. Commercial tablets of Fenofibrate were procured from the market (FENOLIP-145 mg from Cipla Pharma., STANLIP-160 mg from Ranbaxy Ltd., LOTZL-200 mg from Grandix lab) All other chemicals used were of analytical grade.

Preliminary solubility studies of Fenofibrate[12-15]: solubilities of Fenofibrate were determined in 4 M sodium acetate and 1.25 M sodium citrate solution, distilled water sufficient excess amount of drug was added to screw-capped glass vials of 20 ml capacity, containing distilled water, and 4 M sodium acetate and 1.25 M sodium citrate solution. The vials were shaken mechanically for 12 hours at in orbital shaker (Khera Instrument Pvt. Ltd., India). The solutions were allowed to equilibrate for next 24 hours and then centrifuged for 5 min at 2000 rpm. The supernatant of each vial was filtered through Whatman filter paper # 41. Filtrates were diluted suitably and analyzed against corresponding solvent blanks. In this experiment mixed hydrotropy principle is applied in which to hydrotrops in different concentration were used for increasing the solubility of the drug for example 4 M sodium acetate and 1.25 M sodium citrate.

Analysis of Fenofibrate in tablets using 4 M sodium acetate and 1.25 M sodium citrate solution[13]: Twenty tablets of formulation-I (FENOLIP) were weighed and powdered. Powder equivalent to 145 mg Fenofibrate was transferred to a 50 ml volumetric flask containing 40 ml of 4 M sodium acetate and 1.25 M sodium citrate solution. The flask was shaken for about 5 min to solubilize the drug. Then volume was made up to the mark with distilled water. Solution was filtered through Whatman filter paper # 41. filtrate was divided in two parts, A and B. part A was kept at room temperature for 48 hours to check the effect on stability of drug in presence of sodium benzoate and also to note precipitation, if any, during this period. Part B filtrate was appropriately diluted with distilled water and absorbance was noted at 296 nm (λ_{max}) against solvent blank and the drug content was calculated (Table-1). After 48 hours, filtrate of part B was also appropriately diluted with distilled water and analyzed for drug content. There was no precipitation in the filtrate in 48 hours. Similar procedures were adopted in cases of formulation-II (STANLIP) and formulation-III (LOTZL).

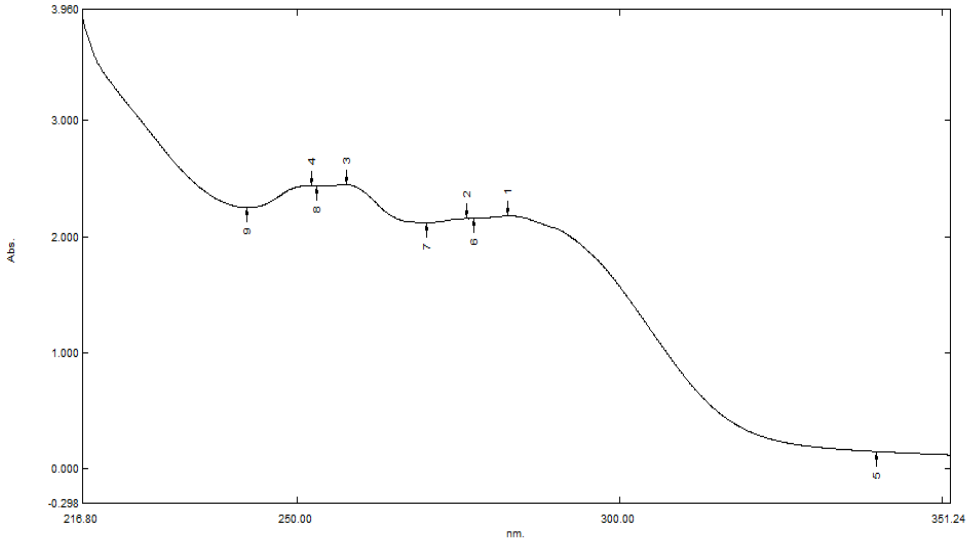

Figure 2 Scanning spectra of Fenofibrate

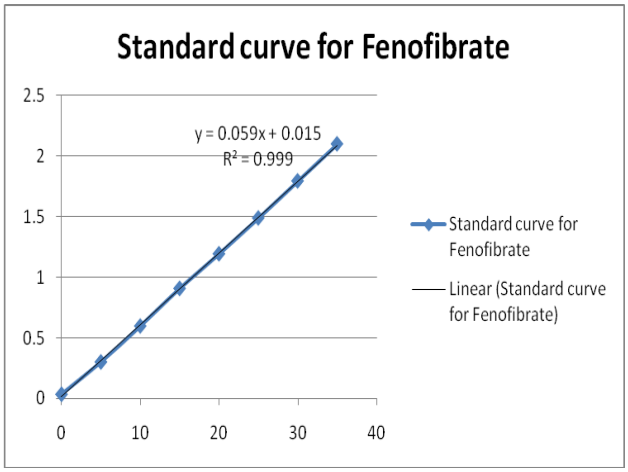

Figure 3 Standard Curve of Fenofibrate

Table 1: Results of analysis of commercial tablets of Fenofibrate

Tablet Formulation	Label claim (mg)	% Label claim Estimated* (Mean ± S.D.)	% Coeff. of variation	Standard error
I (FENOLIP)	145	100.073± 0.7481	0.7476	0.3054
II (STANLIP)	160	99.90 ± 0.1008	0.1009	0.0411
III (LOTGL)	200	100.596 ±0.6114	0.6078	0.2734

***Average of six determinations**

Recovery Studies[13-14]**:**

Recovery studies are performed by adding extra bulk drug nearly forty percent of formulations or more. For recovery studies, tablet powder of formulation I ((FENOLIP) equivalent to 145 mg drug was taken in a 25 ml volumetric flask. In this flask 70 mg of pure drug (corresponding spiked drug) was transferred and 20 ml of 4 M sodium acetate and 1.25 M sodium citrate solutions were added and the flask was shaken for about 10 min. Then volume was made upto the mark with distilled water and filtered through Whatman filter paper # 41. The solution was diluted appropriately with distilled water and analyzed for drug content. Similar procedures were adopted for formulation II (STANLIP) & formulation III (LOTZL). The results of analysis of recovery studies are presented in (Table 2)

Table 2: Recovery studies of commercial tablets of Fenofibrate

Tablet Formulation	Label claim (mg)	Drug added (mg)	% Label claim Estimated*(Mean ± S.D.)	% Coeff. of Variation	Standard error
I (FENOLIP)	145	70	99.33 ± 1.762	0.1.774	0.719
II (STANLIP)	160	80	100.61 ± 0.1.322	1.314	0.540
III (LOTGL)	200	100	100.92 ±1.702	1.686	0.695

***Average of six determinations**

 ISSN: 2250-1177 CODEN: JDDTAO

RESULT AND DISCUSSION

The mean percent label claims estimated by proposed method for tablet formulations I, II and III were 100.073, 99.90 and 100.596, respectively which are very close to 100, indicating the accuracy of the method. This also indicates that there was no interference of sodium acetate, sodium citrate and the commonly used additives present in the tablet formulation in the estimation by the proposed method. Validation of the proposed method is further confirmed by the low values of standard deviation, percent coefficient of variation and standard error (Table 1). The mean percent recovery values ranged from 99.33 to 100.92 and were very close to 100. Also the values of statistical parameters viz. standard deviation, percent coefficient of variation and standard error were significantly low (Table 2). Thus, the proposed method of analysis was very well validated.

Table 3: Stastiscal Data & Regression Equation for Fenofibrate

Sr. No.	Parameter	Value
1.	λ_{max} (nm)	296
2.	Beer's range (µg/ml)	5-35
3.	Molar absorbtivity (l/mol/cm)	4.327×10^4
4.	Correlation coefficient (r^2)	0.999
5.	Regression equation	Y=0.059X +0.015
6.	Intercept (a)	0.015
7.	Slope (b)	0.059
8.	Limit of detection (LOD µg/ml)	0.126
9.	Limit of quantification(LOQ µg/ml)	0.406
10.	Linearity	1 – 18

CONCLUSION

Thus, it may be concluded that the proposed method of analysis, using sodium acetate as the hydrotropic solubilizing agent is new, simple, cost-effective, environmentally friendly, safe, accurate and reproducible. Sodium acetate and the commonly used tablet excipients did not interfere in Spectrophotometric estimation at 296 nm. Decided advantage is that organic solvents are precluded but not at the expense of accuracy. The proposed method is worth adopting in pharmacopoeia. By proper choice of hydrotropic agents, the use of organic solvents in analysis may be discouraged to a large extent. The proposed method shall prove equally effective to analyze Fenofibrate in the corresponding drug sample and may prove to be of great importance in pharmaceutical analysis.

ACKNOWLEDGEMENT

Authors are grateful to Suresh Kalwania (Senior Chemist) and M/s. Sun Pharma Lab, Jammu for providing the gift samples of drugs.

REFERENCES

1. The Merck Index, 14th Edn., Merck Research Laboratories, Division of Merck & Co, Inc. Whitehouse Station NJ USA, 679.
2. Martindale, 'The Complete Drug Reference", 36th Edition. The Pharmaceutical Press, London, 2009, 1, 1286.
3. Chaudhari BG, Patelnm, Shah PB. Determination of Simvastatin, Pravastatin sodium and Rosuvastatin in Tablet Dosage Forms by HPTLC. Indian J. Pharm. Sci. 2007, 69(1), 130 - 132.
4. British Phrmacopoeia, Controller of Her Majesty's Stationary Office, Norwish, 2004, 1, 805.
5. Gupta KR, Wankhede SB, Wadodkar SG, Ind. J. Pharm. Sci. 2005, 67, 762-764.
6. Lacroix PM , Dawrsen BA, Sears RW, Black DB, Cyr TD, Ethier JE, Journal of Pharmaceutical and Biomedical Analysis.1998, 18, 383-402.
7. Kadav AA, Vora DN. Stability Indicating UPLC Method for Simultaneous Determination of Atorvastatin, Fenofibrate and their degradation products in tablets. J. Pharm. Biomed. Anal. 2006, 48(1), 120 - 126.
8. Lossner A, Banditt P, Troger U, Phamazie. 2001, 56, 50-100.
9. Zzaman MT, Khan SA, Arora A, Ahmad O. Method development and validation of Fenofibrate by HPLC using human plasma. Electron. J. Biomed. 2009, 3, 41-43.
10. Straka R J, Burkhardt RT, Fisher JE, Ther Drug Monit. 2007, 29, 197-202.
11. The United States Pharmacopeia USP 28/ NF 23, Asian Edition, the United States Pharmacopoeial Convention, Inc., Rockville, MD. 2005, 2749-2751.
12. Jat R.K., Chhipa R.C. and Sharma S., spectrophotometric quantification of Carviedilol inbulk drug and tablets,.Pharmacophore ,2010, 1(2), 90-95.
13. Jat R.K., Chhipa R.C. and Sharma S., spectrophotometric quantification of Etiricoxib inbulk drug and tablets using hydrotropic agents.Pharmacophore ,2010, 1(2), 96-102.
14. Martindale the comlete drug reference,published by high street lodon ,Edition 36,2009,1286-87
15. Europian Pharmacopoeia. Council of Europe, Strasburg Cedex. 2002, 4th Edition,
16. Jat R.K., Chhipa R.C. and Sharma S., quantitative estimation of clobazam inbulk drug and tablet.IJCPRR, 2011, 1(3), 18-24.
17. Jat R.K., Chhipa R.C. and Sharma S., Spectrophotometric Estimation of Fluvoxamine Maleate in Tablets Using Hydrotropic Agent, IJPQR,2011,2(4); 73-

