ORIGINAL ARTICLE

A Novel Stability Indicating Reversed-Phase Liquid Chromatography System for Estimation of Fenofibrate in Bulk and Pharmaceutical Dosage Forms: Comparative Studies with Internal Standard Rosuvastatin

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Abstract

Introduction: Fenofibrate (FFB) is an anti-hyperlipidemic treatment that acts by lowering the lipid levels. A new constancy representing reversed-phase ultra-fast liquid chromatography system was planned for the evaluation of FFB within comparison to internal reference rosuvastatin (RS) calcium in pharmaceutical preparations. **Materials and Methods:** Mobile phase with a composition of 0.1% formic acid and acetonitrile with pace 0.8 mL/min has been utilized for analyze of FFB in existence of inner standard RS calcium. Forced degradation experiments were conducted by subjecting FFB to a range of stress environments, including acidic, oxidative, basic, and thermal circumstances, to assess the stability that indicates efficacy of the technique. **Results:** Analytical procedure demonstrated excellent linearity across the concentration interval of 0.5–50 µg/mL, described by the regression formula y = 0.1281x−00.0081 thru a correlation coefficient (R^2) of 0.9998. The method exhibited high sensitivity, with the limit of quantification determined as 0.4327 µg/mL and limits of detection calculated as 0.1427 µg/mL. **Conclusion:** Overall, the validated technique demonstrated as reliable and appropriate for monotonous quantitative examination of FFB in tablet dosage forms, fulfilling all acceptance criteria specified under International Council for Harmonisation validation guidelines.

Key words: Fenofibrate, forced degradation studies, International Council for Harmonisation guidelines, reversed-phase ultra-fast liquid chromatography, rosuvastatin calcium, validation

INTRODUCTION

Fenofibrate (FFB) (CAS: 49562-28-9) is an anti-hyperlipidemic drug[1,2] and it is chemically Isopropyl [4-(4-chlorophenyl)-2-phenoxy-2-methyl] propionate ($C_{20}H_{21}ClO_4$) with molecular weight 360.83 g/mole. It exhibits high solubility in dichloromethane, limited solubility in methanol, and is essentially insoluble in water. Its lipid-lowering effect is mediated through activation[3] of peroxisome proliferator-activated receptor alpha, which acts as a vital part within the rules of lipid metabolism. Rosuvastatin (RS) $(C_{22}H_{27}FN_3O_6S)_2$ is a lipid-lowering drug[4] with a molecular weight of 1001.1 g/mol, which was used as an internal standard (Figure 1).

FFB was determined by different liquid chromatographic techniques in pharmaceutical preparations and body fluids.

Salama *et al*.[5] have reported the development of two novel analytical approaches that are selective, correct, and exact quantification of FFB within the existence of its

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alkaline degradation product. These approaches include an algorithm-assisted bivariate calibration derivative spectrophotometric technique and a reversed-phase high-performance liquid chromatography (RP-HPLC) technique. Chromatographic parting has been attained using RESTEK Pinnacle II phenyl column through a mobile phase serene of methanol and 0.1% phosphoric acid within proportion of 60:40 (v/v; 2 mL/min). UV exposure was conducted on 302 nm for the internal standard (salicylic acid) and at 289 nm for FFB. Procedures demonstrated decent linearity within concentration ranges of 2–20 µg/mL to the spectrophotometric method and 1–25 µg/mL, HPLC method, such as reported by Salama *et al*.

Kumar *et al*.[6] reported the formulation of an extremely vulnerable HPLC analytical technique for quantifying FFB within human blood, utilizing nevirapine as the standard used internally. The method utilized an Intensil C18 column having a mobile phase of 20 mM ammonium acetate solution acetonitrile with a 60:40 (v/v; 1 mL/min; 295 nm). Retention times for FFB and nevirapine have been recorded as 6.6 ± 0.05 min and 5.2 ± 0.03 min, respectively. The approach demonstrated strong linearity within a concentration ranging from 0.3–20 µg/mL.

Zzaman *et al*.[7] described the progress of a HPLC technique for quantitative purposes of FFB in plasma utilizing diazepam as interior reference. Chromatographic parting has attained on a Lithosphere 60 RP-Select B column by mobile phase entailing of 40 mM potassium dihydrogen orthophosphate solution, adjusted to pH 6 using potassium hydroxide, and acetonitrile within proportion of 70:30 (v/v). Recognition has been approved out using ultraviolet (UV) spectroscopy at 287 nm. The technique displayed satisfactory linearity within a concentration array of 0.095–19.924 µg/mL. Under the optimized conditions, FFB exhibited a retention time between 5.5 and 6.5 min, while the internal standard, diazepam, eluted earlier between 4.5 and 5.5 min, as reported by Zzaman *et al*.

Abid *et al*.[8] reported the development of a RP-HPLC technique for quantitative examination of FFB within huge drug substance same within pharmaceutical dose forms. The chromatographic separation has approved out utilizing a Capcell PAK C18 column having a mobile phase combination of acetonitrile and 0.1% phosphoric acid (75:25 v/v; 2 mL/min; 286 nm). It demonstrated good linearity on a wide choice of 0.024–100 µg/mL.

Jain *et al*. stated expansion of the RP-HPLC method[9] for quantitative analysis of FFB within both bulk pharmaceutical substance and dose formulations. A mobile phase of acetonitrile and acetate solution (pH 5.0) in a 95:5 (v/v) proportion, with UV detection performed at 268 nm. A linear response was achieved within the dose range of 10–50 µg/mL.

This study presents a novel stability-detecting RP-HPLC technique for quantifying FFB within tablet forms, utilizing RS calcium as an internal reference. The established procedure was rigorously validated in compliance with International Council for Harmonisation (ICH) regulatory standards.

MATERIALS AND METHODS

Chromatographic assessment has been carried out utilizing a Shimadzu HPLC device fitted by Photo Diode Array (PDA) sensor and Zorbax C18 column (250 mm × 4.60 mm i.d., 5 µm PS). Mobile phase comprised 0.1 % formic acid and acetonitrile within a proportion of 22:78 (v/v; 0.8 mL/min; 278 nm) for quantification of FFB within existence of an internal standard. Before examination, the mobile phase has been thoroughly sonicated and filtered by a 0.45 µm membrane filtered to ensure clarity and consistency. FFB was kindly supplied by Knoll Healthcare Pvt. Ltd. as a gift sample. The drug is commercially available in tablet dosage form under various brand names, including Lipicard (USV Private Ltd), Finobrate (Knoll Healthcare Pvt. Ltd.), and Finate (Franco-Indian Pharmaceuticals Pvt. Ltd.), each containing a labeled strength of 160 mg.

Preparation of FFB and RS calcium drug solutions

Accurately weighed quantities of 25 mg each of FFB and RS calcium were separately moved into 2 individual 25 mL volumetric flasks, melted, and the volumes were adjusted with HPLC-grade methanol for obtaining standard stock buffer of 1K µg/mL. Working standard buffers of FFB are then set by serial thinning using a mobile phase containing RS calcium as the internal standard at a concentration of 20 µg/mL. Entirely prepared buffers are sonicated and passed through a membrane filters (0.45 µm) preceding to chromatographic pumping.

Method validation[10]

Linearity

FFB working solutions with RS calcium at a constant concentration of 20 µg/mL were made. The solutions ranged in concentration from 0.5 to 50 µg/mL. A 20 µL portion of each solution was introduced into the HPLC apparatus by injection. Chromatograms were analyzed to evaluate the proportion of FFB peak area to that of the internal standard. The average peak areas corresponding to RS calcium and FFB were captured. The next step was to create a calibration plot by comparing the concentrations of FFB on the x-axis with the average peak proportion of area on the y-axis.

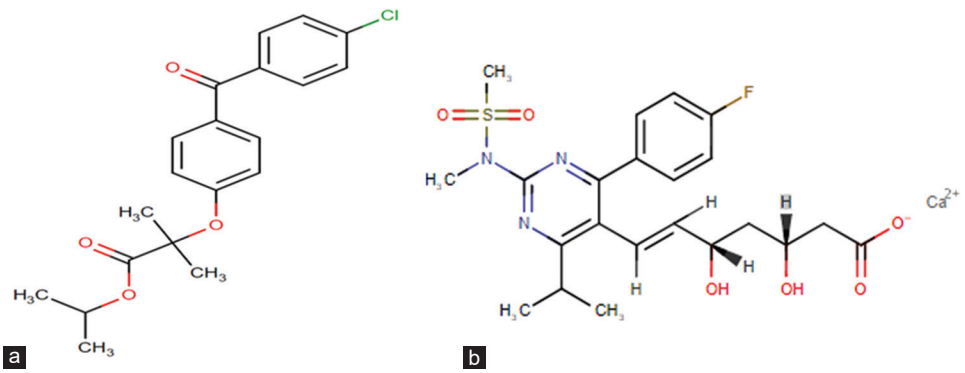

Figure 1: (a) Molecular configuration of fenofibrate, (b) Molecular configuration of rosuvastatin calcium

Precision, accuracy, and robustness

Intraday (same day) and Inter-day precision (3 serial days) was executed in triplicate at three levels and % relative standard deviation (RSD) was detected. Accuracy assessment was conducted with the usual addition technique (50, 100, and 150 %) and percentage recoveries were determined. Robustness of the method was evaluated by revealing drug solutions to slightly modified optimized chromatographic conditions, and the % RSD was calculated.

Forced degradation studies[11]

FFB was subjected to a range of stress circumstances, alkaline, including acidic, thermal environments and oxidative to evaluate its degradation behavior.

For alkaline stress test, the drug buffer has been treated with 1 mL of 0.1 N sodium hydroxide (NaOH) and heating at 80°C for approximately 30 min using an aquatic bath. After the stress period, the solution was allowed to cool, neutralized with 1 mL of 0.1 N hydrochloric acid (HCl), and subsequently diluted by the mobile phase. RS calcium at a concentration of 20 µg/mL was added as an internal standard immediately before injection, and a 20 µL aliquot was introduced into the HPLC device.

The acidic deterioration was conducted via subjecting the drug mixture to 1 mL of 0.1 N HCl and heating it at 80°C for approximately 30 min in a bath of water. The strained specimen was subsequently chilled and neutralize by utilizing 1 mL of 0.1 N NaOH. Volume has altered to achieve the desired concentration with mobile phase being used following the incorporation of RS calcium (20 µg/mL) as the internal standard, and 20µL of the resulting mixture was pumped to the HPLC apparatus.

Oxidative deprivation has initiated by subjecting the drug solution to 1 mL of 30% v/v hydrogen peroxide and heating it at 80°C for 30 min in a bath of water. After cooling, the mixture was diluted using the mobile phase, and RS calcium (20 µg/mL) was added before chromatographic analysis. A volume of 20 µL was utilized for HPLC assessment.

Thermal degradation experiments were conducted by heating the medication solution to 75°C for 1 h in a bath of water. Upon cooling, the solution became diluted by the mobile phase, and RS calcium was subsequently added at a concentration of 20 µg/mL as an internal standard. A 20 µL aliquot of resultant solvent had been introduced into the HPLC apparatus for analysis.

Assay of FFB tablets

20 pills of FFB, each purportedly containing 160 mg, were obtained from two distinct commercial brands at a local drugstore. The tablets weighed, pulverized, and 50 mg of FFB obtained utilizing acetonitrile. The extract was diluted to the specified volume. The resultant solution was subjected to sonication for 30 min and filtered using a 0.45 µm membrane filter. Before injection, internal standard, RS calcium, was included; a 20 µL aliquot of the prepared sample got introduced into HPLC. The peaks for FFB and the internal standard were identified at their respective retention periods using chromatograms produced. The mean peak size proportion was measured, and the percentage purity of FFB was ascertained utilizing a formula for linear regression.

RESULTS AND DISCUSSION

A novel stability indicated RP-HPLC technique has been established for quantitative determination of FFB using RS calcium as internal standard, and the technique has successfully authenticated. An extensive review of the available literature was conducted, andthe performance of the anticipated technique has been systematically equated with formerly conveyed analytical procedures [Table 1].

Several trials were made during the optimization process of FFB, and then a suitable method was established where both FFB and the internal standard, RS calcium, were processed with a resolution value >2.0. A suitable mobile phase with composition of acetonitrile and 0.1% Formic acid (78:22v/v) by flow pace 0.8 mL/min and UV detection at 278 nm was utilized to examine of FFB within the existence of an internal reference RS calcium using Zorbax C_{18} column. Sharp peak

Table 1: Literature search

Method	Mobile phase (v/v)	Detection wavelength (nanometer)	Linearity (µg/mL)	Reference
RP-HPLC (Human plasma) Internal standard: Salicylic acid)	Methanol: 0.1% Phosphoric acid (60:40)	289	1–25	Salama *et al.*[5]
RP-HPLC (Human plasma) Internal standard: Nevirapine)	20 mM Ammonium acetate solution: Acetonitrile (60:40)	295	0.3–20	Kumar *et al.*[6]
RP-HPLC (Human plasma) (Internal standard: Diazepam)	40 mM Potassium dihydrogen orthophosphate solution (6.0 pH): Acetonitrile (70:30)	287	0.095–19.924	Zzaman *et al.*[7]
RP-HPLC Stability indicating	Acetonitrile: 0.1% Phosphoric acid (75:25)	286	0.024–100	Abid *et al.*[8]
RP-HPLC Stability indicating	Acetonitrile: Acetate solvent (pH 5.0) (95: 5)	268	10–50	Jain *et al.*[9]
RP-HPLC (Internal standard: Rosuvastatin Calcium) Stability indicating	0.1% Formic acid: Acetonitrile (22:78)	278	0.5–50	Present method

RP-HPLC: Reversed-phase high-performance liquid chromatography

Table 2: Linearity

Concentration (µg/mL)		Mean peak area		Peak area proportion
FFB	RS	FFB	RS	(FFB/RS)
0.5	20	40101	634561	0.063195
1	20	80208	634592	0.126393
2	20	160307	634524	0.252641
5	20	408729	634589	0.644085
10	20	801445	634545	1.263023
20	20	1602979	634578	2.526055
40	20	3205974	634547	5.052382
50	20	4097616	634573	6.457281

*Mean of 3 replicates. FFB: Fenofibrate, RS: Rosuvastatin

Table 3: Intraday precision

Concentration (µg/mL)		*Mean peak area ratio			Statistical analysis *Mean±SD (% RSD)
FFB	RS	FFB	RS	(FFB/RS)	
10	20	801445	634545	1.263	1.2634±0.001153 (0.0913)
10	20	801432	634577	1.2647	
10	20	801398	634532	1.2625	
20	20	1602979	634578	2.5261	2.5253±0.000721 (0.0286)
20	20	1602917	634793	2.5251	
20	20	1602894	634885	2.5247	
40	20	3205974	634547	5.0524	5.0535±0.001277 (0.0253)
40	20	3205887	634214	5.0549	
40	20	3205893	634428	5.0532	

*Mean of 3 replicates. FFB: Fenofibrate, RS: Rosuvastatin, SD: Standard deviation, RSD: Relative standard deviation

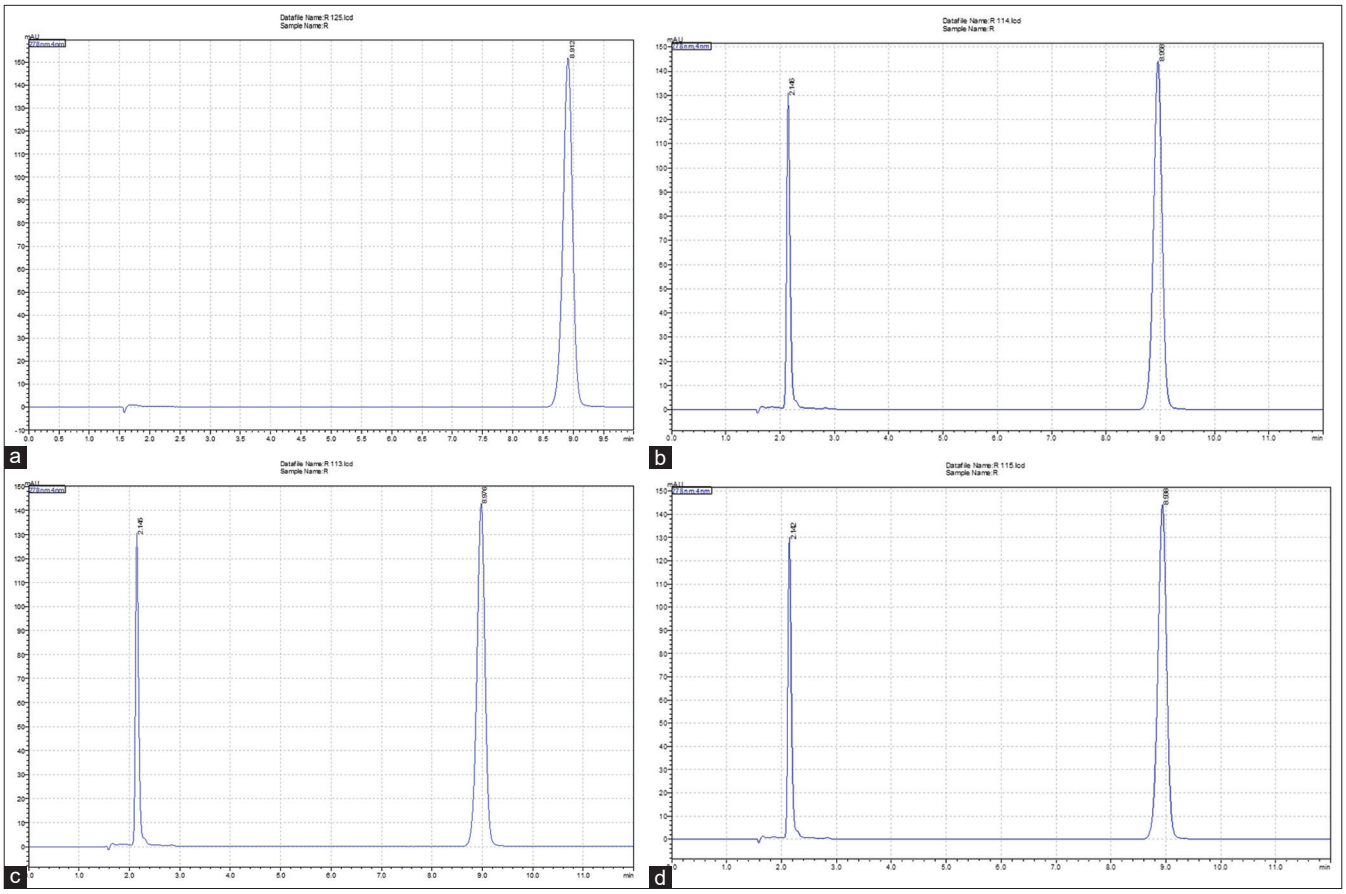

Figure 2: (a) Demonstrative chromatograms of fenofibrate (FFB) (API). (b) Demonstrative chromatograms of FFB (API) (20 µg/L) (Rt 8.958 min); Theoretical plates (14045) Tailing factor: 0.946. Rosuvastatin (RS) calcium (20 µg/L) (Rt 2.146 min); Theoretical plates (4074) Tailing factor: 1.313; Resolution: 31.190. (c) Representative chromatograms of FFB (20 µg/mL) tablets (Brand I) (Rt 8.976 min); Theoretical plates (13967) Tailing factor: 0.944. RS calcium (20 µg/L) (Rt 2.145 min); Theoretical plates (4066) Tailing factor: 1.314; Resolution: 31.166. (d) Representative chromatograms of FFB (20 µg/mL) tablets (Brand II) (Rt 8.938 min); Theoretical plates (14074) Tailing factor: 0.946. RS calcium (20 µg/L) (Rt 2.142 min); Theoretical plates (4222) Tailing factor: 1.322; Resolution: 31.377

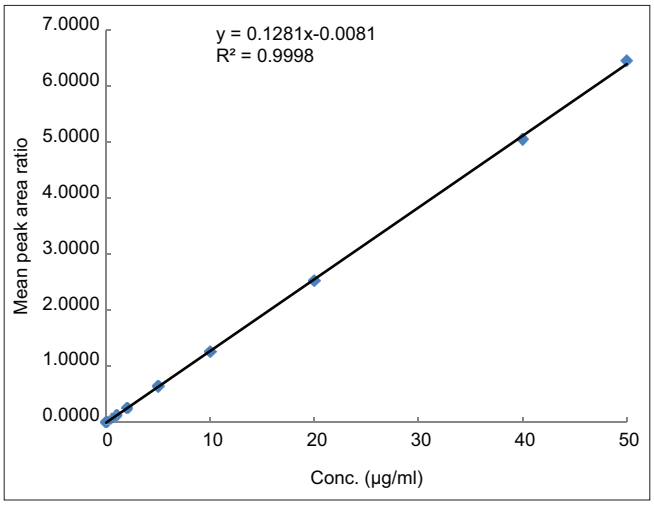

Figure 3: Calibration graph

for FFB has eluted at 8.956 ± 0.02 min and internal reference, RS calcium at 2.146 ± 0.003 min in a time of 10 min, and chromatograms obtained were shown in Figure 2.

Method validation

Linearity

FFB demonstrated compliance with Beer-Lambert's law, exhibiting a linear line in concentrations ranging of 0.5–50 µg/mL in the presence of the internal standard, RS calcium, as shown in Table 2. The calibration data produced a linear regression formula of y = 0.1281x−0.0081 with a correlation coefficient (R^2) equal to 0.9998, as illustrated in Figure 3. The sensitivity of the method was reflected via a limit of detection of 1.4012 µg/mL and a limit of quantification of 0.4247 µg/mL.

Robustness, accuracy, and precision

Intraday and inter-day accuracy of the proposed approach got assessed at three distinct concentration levels of FFB by evaluating specimens on the same day and over 3 straight days, respectively. The intraday precision exhibited % RSD values ranging from 0.0253 to 0.913 [Table 3], whilst inter-day precision displayed % RSD values among 0.6315 and

Table 4: Interday precision

Concentration (µg/mL)	*Mean peak area			Statistical analysis *Mean±SD (% RSD)
	FFB	RS	(FFB/RS)	
10	801445	634545	1.263	1.2607±0.0079 (0.6315)
10	801549	634582	1.2518	
10	801484	634591	1.2672	
20	1602979	634567	2.5261	2.5511±0.0265 (1.0394)
20	1603027	629082	2.5482	
20	1602983	621576	2.5789	
40	3205974	634545	5.0524	5.1029±0.0439 (0.8606)
40	3205911	624642	5.1324	
40	3205896	625687	5.1238	

*Mean of 3 replicates. FFB: Fenofibrate, RS: Rosuvastatin, SD: Standard deviation, RSD: Relative standard deviation

Table 5: Accuracy

Spiked conc. (µg/mL)	FFB formulation (µg/mL)	Conc. (µg/mL)	RS	*Mean Conc. (µg/mL)±SD (% RSD)	% Recovery
5 (50%)	10	15	20		99.27
	10	15	20	14.89±0.0313 (0.21)	
	10	15	20		
10 (100%)	10	20	20		99.55
	10	20	20	19.91±0.0777 (0.39)	
	10	20	20		
15 (150%)	10	25	20		99.88
	10	25	20	24.97±0.2023 (0.81)	
	10	25	20		

*Mean of 3 replicates, FFB: Fenofibrate, RS: Rosuvastatin, Conc.: Concentration, SD: Standard deviation, RSD: Relative standard deviation

Table 6: Robustness study

Parameter	Condition	*Mean peak area		*Mean peak area ratio (FFB/RS)±SD (% RSD)
		FFB	RS	
Flow rate=(±0.1 mL/min)	0.9	1602864	634619	2.5257±0.0276 (1.092)
	0.8			
	0.7			
Detection wavelength (±2 nm)	280	1603012	635427	2.5227±0.0046 (0.181)
	278			
	276			
Mobile phase composition 0.1% Formic acid: Acetonitrile (±2%, v/v)	24:76	1602957	634981	2.5244±0.0107 (0.423)
	22:78			
	20:80			

*Mean of 3 replicates, FFB: Fenofibrate, RS: Rosuvastatin, SD: Standard deviation, RSD: Relative standard deviation

1.0394 [Table 4], all remaining below 2.0, so affirming the method's precision.

Accuracy resulted in % RSD values under 2.0, namely, between 0.21 and 0.81 [Table 5]. The recovery rate ranged from 99.27% to 99.88%, demonstrating exceptional precision.

The resilience of the analytical method got evaluated by intentionally incorporating slight alterations in chromatographic parameters, such as detection wavelength (276 and 280 nm), acetonitrile concentration in mobile phase (±2%), and flow pace (±0.1 mL/min). Robustness testing conducted at FFB concentration of 20 µg/mL [Table 6], yielding % RSD values between 0.181

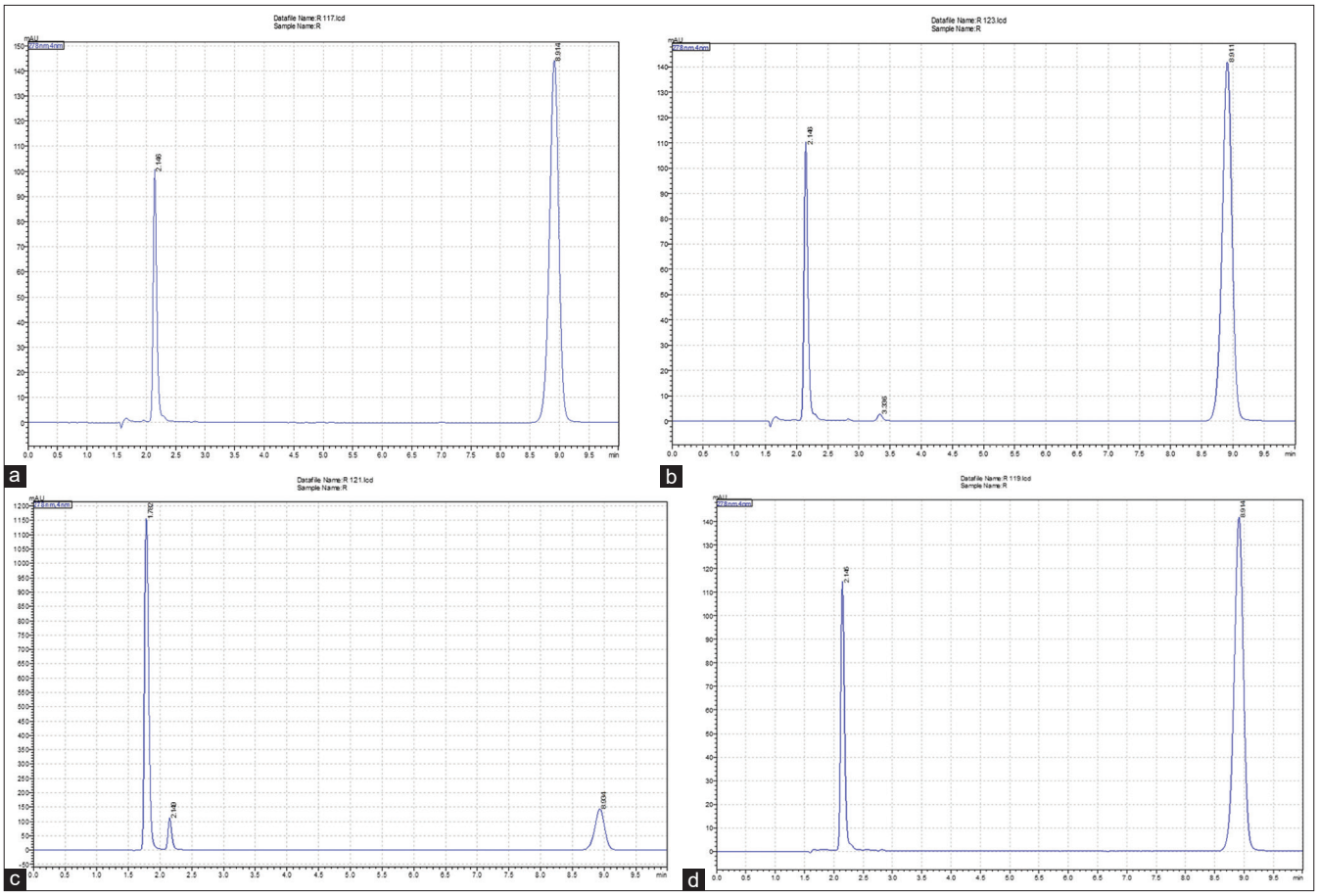

Figure 4: Flucytosine (10 μg/L) (Rt 3.0 ± 0.1 min) chromatogram thru stress degradation in occurrence of Linezolid (IS) (10 μg/mL). (a) Acidic deprivation (b) Alkaline deprivation (c) Oxidative deprivation (d) Thermal deprivation

Table 7: Forced degradation

Stress condition	Retention time (min)		% Recovery	%Drug degradation	Theoretical plates (>2000)		Tailing factor (<2.0)		Resolution (>2.0)
	FFB	RS			FFB	RS	FFB	RS	
Standard drug	8.958	2.146	100	------	14045	4074	0.946	1.313	31.190
Acidic degradation 0.1N HCl/80°C/30 min	8.914	2.146	99.49	0.51	14033	4127	0.943	1.314	31.147
Alkaline degradation 0.1N NaOH/80°C/30 min	8.911	2.146	97.80	2.20	14099	4202	0.941	1.308	23.794
Oxidative degradation 30%H_2O_2/80°C/30 min	8.934	2.149	98.79	1.21	14173	4771	0.942	1.268	2.786 31.955
Thermal degradation Water/80°C/30 min	8.914	2.145	98.19	1.81	13943	4066	0.947	1.305	31.017

FFB: Fenofibrate, RS: Rosuvastatin, HCl: Hydrochloric acid, NaOH: Sodium hydroxide, H_2O_2: Hydrogen peroxide

Table 8: Assay of fenofibrate tablets

Brand	Label claim (mg)	Observed amount (mg)	% Recovery*
I	160	159.91	99.94
II	160	159.62	99.76

*Mean of 3 replicates

and 1.092, all of which are within the acceptable threshold of <2.

Forced deprivation

FFB eluted at 8.958 ± 0.05 min, RS calcium at 2.146 ± 0.05 min. Throughout acidic degradation, FFB has eluted

at 8.914 min (internal standard, RS calcium at 2.146 ± 0.05 min) and in alkaline degradation, FFB was eluted at 8.911 min (internal standard, RS calcium at 2.146 ± 0.05 min), and one more degradant has eluted at 3.336 min. Throughout oxidation, as long by FFB peak (8.934 min) (internal standard, RS calcium at 2.149 ± 0.05 min) and one more degradant was eluted at 1.782 min, and in thermal degradation, FFB got eluted at 8.914 min (internal standard, RS calcium at 2.145 ± 0.05 min). FFB was completely resilient toward all the degradation conditions and degradants were well parted. Less than 2.5% degradation was observed in all the degradation studies and hence it's established that the technique is discerning and precise. System suitability variables have revealed that tailing factors have been <2.0 and the theoretical plates were more than 2000 with resolution >2.0 [Table 7]. Distinct chromatograms generated through forced deprivation experiments are presented within Figure 4, illustrating the separation behavior of FFB and its degradation products under each stress condition.

Assay of FFB tablets

The assay analysis was carried out using two different commercial brands of FFB tablets, each containing 160 mg of active pharmaceutical ingredient. The results showed that the FFB content ranged from 99.76% to 99.94%, as summarized in Table 8. No interference from formulation excipients was observed, as confirmed by the chromatograms presented in Figure 2c and d.

CONCLUSION

A new constancy representing reversed-phase ultra-fast liquid chromatography (RP-UFLC) system was planned for the evaluation of FFB within comparison to internal reference RS calcium in pharmaceutical preparations. Mobile phase with a composition of 0.1% formic acid and acetonitrile with pace 0.8 mL/min has been utilized for the analysis of FFB in existence of inner standard RS calcium. Forced degradation experiments were conducted by subjecting FFB to a range of stress environments, including acidic, oxidative, basic, and thermal circumstances, to assess the stability that indicates efficacy of the technique. Analytical procedure demonstrated excellent linearity across the concentration interval of 0.5–50 µg/mL, described by the regression formula $y = 0.1281x-00.0081$ thru a correlation coefficient (R^2) of 0.9998. The method exhibited high sensitivity, with the limit of quantification determined as 0.4327 µg/mL and limits of detection calculated as 0.1427 µg/mL. The developed RP-UFLC method was authenticated in accordance with ICH guidelines and was demonstrated to be straightforward, cost-effective, vigorous, making it suitable for routine quantitative assessment of tablet dosage forms of FFB.

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REFERENCES

1. Chapman MJ. Pharmacology of fenofibrate. Am J Med 1987;83:21-5.
2. Balfour JA, McTavish D, Heel RC. Fenofibrate. A review of its pharmacodynamic and pharmacokinetic properties and therapeutic use in dyslipidaemia. Drugs 1990;40:260-90.
3. Barbier O, Villeneuve L, Bocher V, Fontaine C, Torra IP, Duhem C, *et al*. The UDP-glucuronosyltransferase 1A9 enzyme is a peroxisome proliferator-activated receptor alpha and gamma target gene. J Biol Chem 2003;278:13975-83.
4. Jones SP, Gibson MF, Rimmer DM 3rd, Gibson TM, Sharp BR, Lefer DJ. Direct vascular and cardioprotective effects of Rosuvastatin, a new HMG-CoA reductase inhibitor. J Am Coll Cardiol 2002;40:1172-8.
5. Salama FM, Nassar MW, Sharaf El-Din MM, Attia KA, Kaddah MY. Determination of Fenofibrate and the degradation product using simultaneous UV-derivative spectrometric method and HPLC. Am J Anal Chem 2011;2:332-43.
6. Manish Kumar T, Srikanth G, Pamulaparthya V, Venkateshwar Rao J, Sambasiva Rao KR. Development and validation of HPLC-UV method for the estimation of Fenofibrate in human plasma. J Pharm Res 2011;4:3735-7.
7. Zaman MT, Khan SA, Arora A, Ahmad O. Method development and validation of Fenofibrate by HPLC using human plasma. Rev Electron Biomed/Electron J Biomed 2009;3:41-54.
8. Yousaf AM, Kim DW, Choi HG, Oh E. Validation of a highly sensitive RP-HPLC method for quantification of Fenofibrate in pure and pharmaceutical dosage forms. Curr Pharm Anal 2014;10:97-104.
9. Jain N, Jain R, Jain S, Jain DK. Stability-indicating RP-HPLC method for analysis of Fenofibrate in the bulk drug and in a pharmaceutical dosage form. J Pharm Res 2011;10:16-20.
10. ICH Validation of Analytical Procedures: Text and Methodology Q2 (R1), International Conference on Harmonization; 2005.
11. ICH Stability Testing of New Drug Substances and Products Q1A (R2), International Conference on Harmonization; 2003.

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