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Development and Validation of a Reverse Phase High Performance Liquid Chromatographic Method for Simultaneous Estimation of Atorvastatin and Fenofibrate in Tablet Dosage Form

B. Akhila, D. Taruni, Dr. J. Gopala Krishna, Dr B.V. Ramana
Department of Pharmaceutical Analysis, Dr. K V Subba Reddy Institute of Pharmacy, Kurnool, A.P., India
Corresponding author Email: akhila33friend@gmail.com

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Abstract

A simple, fast, accurate, precise, and reproducible reverse phase high performance liquid chromatographic (RP-HPLC) method was developed for the simultaneous estimation of Atorvastatin and Fenofibrate in tablet dosage form. Chromatographic separation was achieved using a Universil C18 column (150 × 4.6 mm, 5 µm) with a mobile phase consisting of mixed phosphate buffer (pH 3.0 adjusted with orthophosphoric acid) and acetonitrile in the ratio 55:45 (v/v). The flow rate was maintained at 1.0 mL/min and detection was carried out at 220 nm. The retention times were found to be 2.5 min for Atorvastatin and 4.9 min for Fenofibrate. The method was validated according to ICH Q2(R1) guidelines for specificity, linearity, accuracy, precision, and robustness. The correlation coefficients were 0.9998 and 0.9987 for Atorvastatin and Fenofibrate, respectively. Percentage recovery was found within 98–102%, and %RSD values were below 2%. The developed method was found to be suitable for routine quality control analysis of both drugs in combined pharmaceutical dosage forms.

Introduction

Analytical chemistry plays a fundamental role in pharmaceutical quality control by ensuring the identity, purity, and potency of drug substances and dosage forms. Method development and validation are critical components of drug development programs, as defined by ICH guidelines, which describe validation as the process of demonstrating that an analytical method is suitable for its intended purpose (ICH Q2(R1)). Atorvastatin is a competitive inhibitor of HMG-CoA reductase and is widely used in the management of hypercholesterolemia. Fenofibrate is a fibric acid derivative used as an antihyperlipidemic agent, primarily reducing triglyceride levels. The combination therapy is frequently prescribed to manage mixed dyslipidemia. Jain et al. (2008) developed an RP-HPLC method for simultaneous

estimation of Atorvastatin and Fenofibrate using methanol–acetate buffer. Vinjam Swathi et al. (2008) reported a method using methanol and water adjusted with orthophosphoric acid. Shivani et al. developed a C18 column-based RP-HPLC method validated as per ICH guidelines. Although several methods have been reported, there remains a need for a simple, rapid, and robust RP-HPLC method suitable for routine quality control. Therefore, the present study aimed to develop and validate a new RP-HPLC method for simultaneous estimation of Atorvastatin and Fenofibrate in tablet dosage forms.

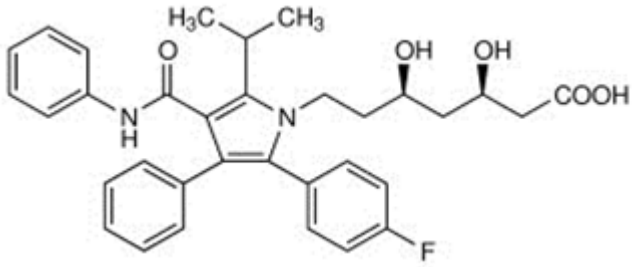

Fig.No:1 Structure of Atorvastatin

Chemical Name: Calcium (βR,δR)-2-(p-fluorophenyl)-β,δ-dihydroxy-5- isopropyl-3 phenyl-4-(phenylcarbamoyl)pyrrole-1-heptanoicacid (1:2) trihydrate

Molecular Formula: $[C_{33}H_{35}FN_2O_5]2Ca\ .3H_2O$

Generic Name : Atorvastatin

Molecular Weight : 1209.4 g/mol

Category : Cardiovascular Agents

Appearance: White to off white amorphous powder.

Solubility:

Freely soluble in methanol and soluble in dimethylsulphoxide (DMSO) and dimethyl formamide (DMF); insoluble in aqueous solution with pH less than 4.0. It is very slightly soluble in distilledwater, Phosphate buffer (7.4) and acetonitrile; slightly soluble in ethanol.20.4 ug/mL (pH 2.1), 1.23 mg/mL (pH 6.0)

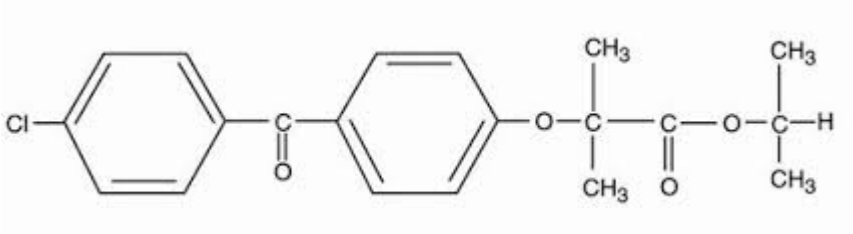

Fig.No:2 Structure of Fenofibarate

Brand name : Fenoglide

Chemical formula : $C_{20}H_{21}ClO_4$

Molecular weight : 360.831 g/mol

PKa : 5.7

Solubility : water, HCL

Melting point : 216-218º C.

Category : Anti Hyperlipiemic agent

Materials and Methods

Materials

Working standards of Atorvastatin and Fenofibrate were obtained from MSN Pvt Ltd and Aurobindo Pharma Ltd, respectively. HPLC grade acetonitrile, methanol, potassium dihydrogen phosphate, dipotassium hydrogen phosphate, orthophosphoric acid, and Milli-Q water were used

Instrumentation

- HPLC System: Waters 1200 series / Shimadzu LC-2010 CHT
- Column: C18 (150 × 4.6 mm, 5 µm)
- UV-Visible Spectrophotometer: Shimadzu UV-1800
- pH meter: Thermo Orion

Method Development

Selection of Wavelength

Overlay spectra of both drugs showed an isosbestic point at 220 nm, which was selected as the detection wavelength

Mobile Phase Optimization

After several trials, optimal separation was achieved using:

- Mixed phosphate buffer (pH 3.0)
- Acetonitrile (55:45 v/v)
- Flow rate: 1.0 mL/min
- Injection volume: 20 µL
- Run time: 7 min

Method Validation

Validation was performed according to ICH Q2(R1):

Specificity

No interference from blank at analyte retention times

Linearity

- Atorvastatin: 2–12 µg/mL (r^2 = 0.9998)
- Fenofibrate: 32–192 µg/mL (r^2 = 0.9987)

Accuracy

Recovery range: 98–102%

Precision

%RSD < 2% for system and method precision

RESULTS & DISCUSSION

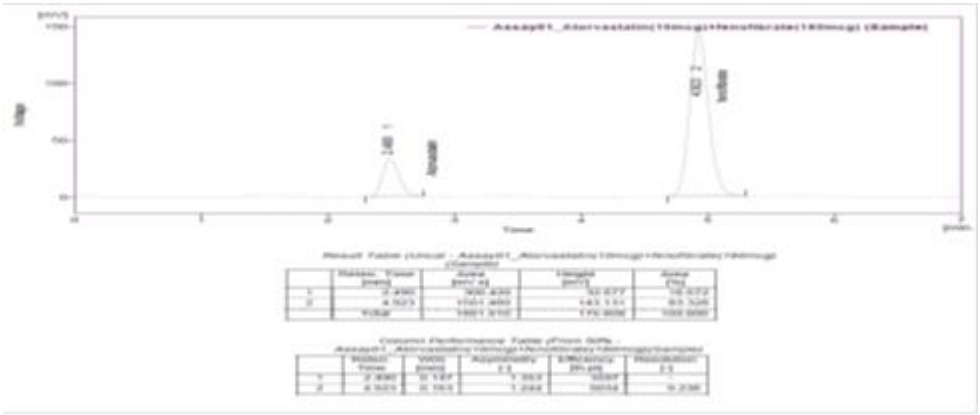

Fig.No:3 Chromatogram for sample solution

Linearity

Table. No:1 Linearity of Atrovastatin

S. No	Concentration (µg/ml)	Peak Area
1	2	75.801
2	4	136.908
3	6	195.876
4	8	256.068
5	10	317.625
6	12	373.232

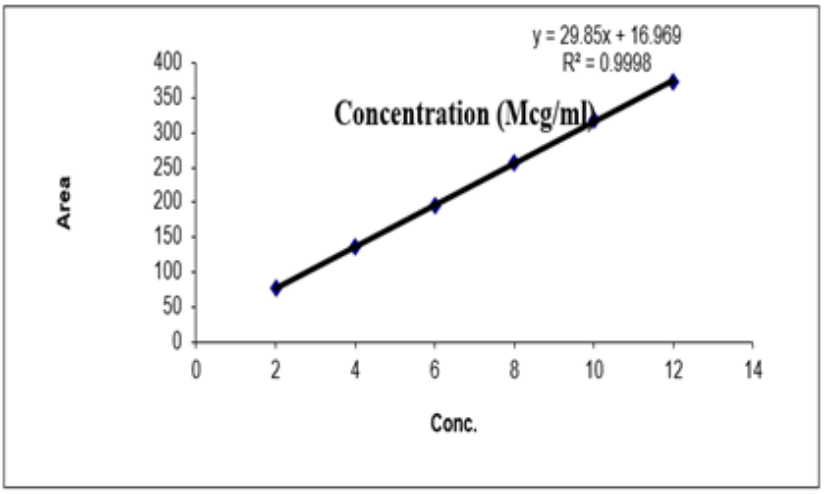

Fig.No:4 Linearity plot of Atrovastatin

Table. No:3 Linearity of Fenofibrate

S.No.	Concentration (µg/ml)	Peak Area
1	32	326.013
2	64	594.218
3	96	889.563
4	128	1155.966
5	160	1450.482
6	192	1669.688

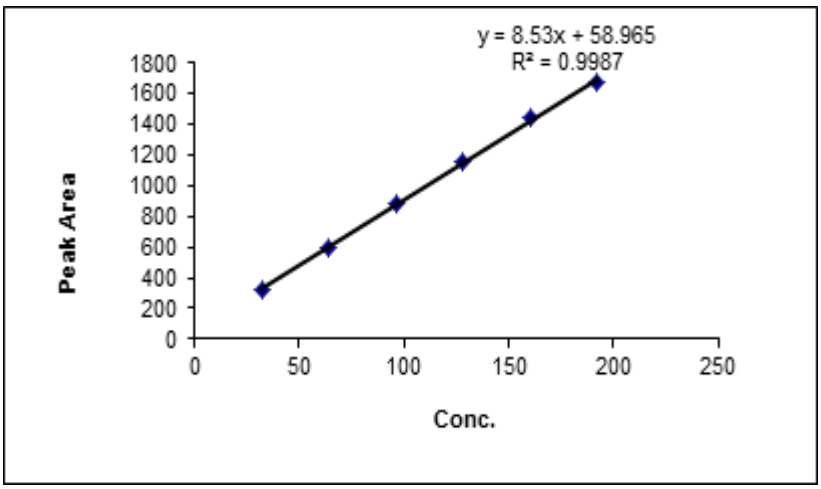

Fig.No:5 Linearity plot of Fenofibrate

Accuracy

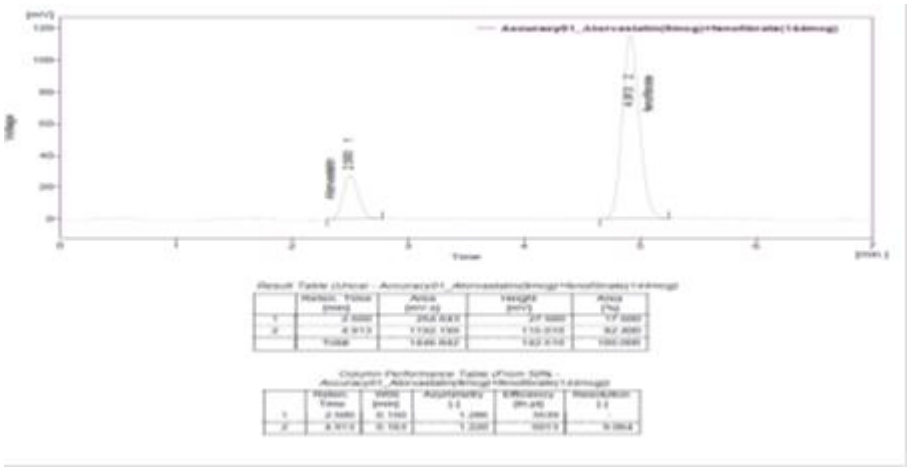

Fig. No. 6 Chromatogram for Accuracy at 80%Injection-1

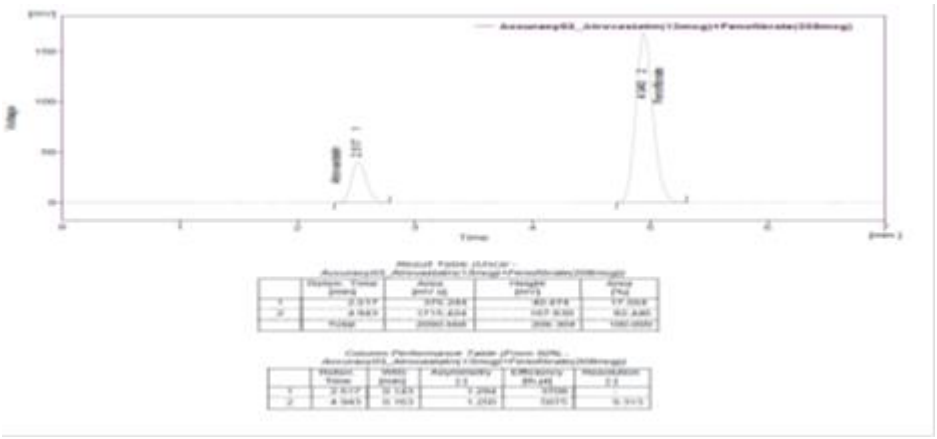

Fig.No.7 Chromatogram for Accuracy at 120%Injection-3

Table. No: 4 Results for Accuracy of Atrovastatin and Fenofibrate

Inj sample	Conc(µg)	Area 1	Area 2	Area 3	Std Area
Atrovastatin	9	254.643	245.608	251.824	252.279
	11	311.537	310.808	307.234	307.234
	13	382.027	375.244	376.027	386.463
Fenofibrate	144	1192.199	1186.567	1209.507	1209.507
	176	1490.723	1498.874	1476.986	1476.986

	208	1695.581	1715.424	1695.581	1678.203

Precision

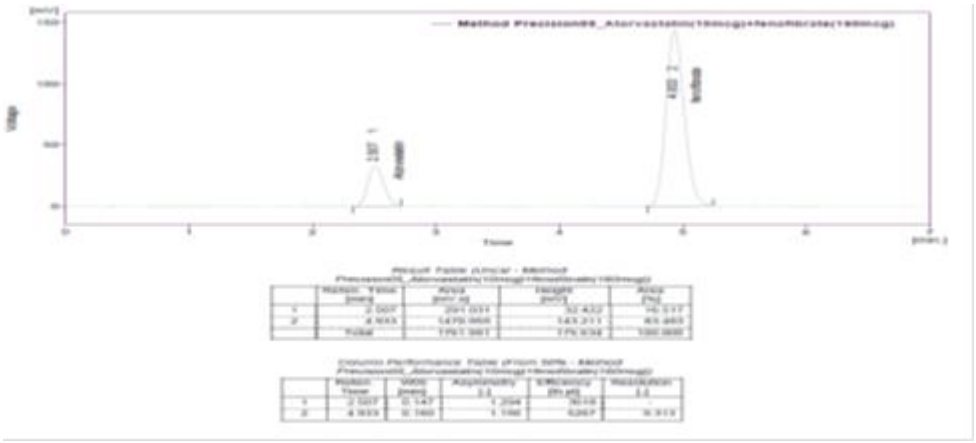

Fig.No:6 Chromatogram for Method Precision Injection-5

Table. No: 5 Method Precision for Atrovastatin

S.No.	Retention time (min)	Peak Area
1	2.513	293.605
2	2.507	292.448
3	2.507	291.031
4	2.51	294.819
5	2.507	291.031
AVG	**2.5088**	**292.5868**
STDEV	**0.00268**	**1.64922**
%RSD	**0.1070**	**0.5637**

Robustness

Table. No. 6 Results for robustness for Fenofibrate

S. No.	Parameter	Condition	System suitability results	
			USP tailing	USP Plate Count
1	Flow rate by ± 0.1ml/min	0.9 ml	1.195	5267
		1.0 ml	1.190	5263
		1.1 ml	1.201	5243
2	Wavelength of analysis ± 5nm	218 nm	1.102	5244
		220 nm	1.120	5201
		222 nm	1.183	5236

DISCUSSION

The developed RP-HPLC method provided effective separation with retention times of 2.5 min and 4.9 min for Atorvastatin and Fenofibrate, respectively. The use of phosphate buffer at pH 3 enhanced peak symmetry and minimized tailing. System suitability parameters such as theoretical plates, resolution, and tailing factor were within acceptable limits. Linearity studies showed excellent correlation coefficients, confirming proportionality between concentration and peak area. Accuracy studies demonstrated high recovery, indicating absence of interference from excipients. Precision studies showed low %RSD values, confirming reproducibility. Compared to previously reported methods, the developed method offers shorter run time, improved resolution, and economical mobile phase composition.

CONCLUSION

A simple, rapid, accurate, and precise RP-HPLC method was successfully developed and validated for the simultaneous estimation of Atorvastatin and Fenofibrate in tablet dosage form. The optimized chromatographic conditions provided good resolution within 7 minutes. Validation results complied with ICH Q2(R1) guidelines, demonstrating excellent specificity, linearity, accuracy, and precision. The method is suitable for routine quality control analysis and can be applied for pharmaceutical formulation assessment.

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