Research Paper

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DEVELOPMENT AND VALIDATION OF AN RP-HPLC METHOD FOR SIMULTANEOUS ESTIMATION OF ROSUVASTATIN AND FENOFIBRATE IN BULK AND PHARMACEUTICAL DOSAGE FORM

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ABSTRACT

A robust, precise, and economical reversed-phase high-performance liquid chromatography (RP-HPLC) method was developed and validated for the simultaneous estimation of Rosuvastatin and Fenofibrate in bulk and pharmaceutical dosage form. The chromatographic separation was achieved using a C18 column (250 mm × 4.6 mm, 5 µm) with a mobile phase consisting of Acetonitrile: Methanol: Phosphate buffer (50:30:20, pH 2.9), at a flow rate of 1.0 mL/min and detection wavelength of 251 nm. Validation of the method was carried out as per ICH Q2(R1) guidelines, and included system suitability, linearity, precision, accuracy, robustness, LOD, and LOQ. The method demonstrated excellent linearity in the range of 5-30 µg/mL for Rosuvastatin and 80-480 µg/mL for Fenofibrate, with correlation coefficients of 0.9991 and 0.998 respectively. The % RSD values were found to be within acceptable limits, confirming the method's precision. LOD and LOQ were found to be 0.12 and 0.36 µg/mL for Rosuvastatin, and 0.49 and 1.46 µg/mL for Fenofibrate respectively. The method proved suitable for estimation in marketed formulations, demonstrating recovery within pharmacopoeial limits. This validated method can be routinely used for the quality control of Rosuvastatin and Fenofibrate in combined pharmaceutical dosage forms.

Keywords: RP-HPLC, Rosuvastatin, Fenofibrate, Method Validation, ICH Q2(R1), Simultaneous Estimation.
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Conflict of interest: None.

1. INTRODUCTION

Cardiovascular disorders, especially those linked to lipid imbalances, remain among the most pressing and widespread

global health concerns. These conditions are primarily driven by elevated cholesterol and triglyceride levels, leading to the development of atherosclerosis, heart attacks, and strokes. The pharmaceutical approach to managing dyslipidemia has increasingly focused on agents that target lipid biosynthesis or enhance lipid clearance pathways, thus reducing overall cardiovascular risk.

Rosuvastatin calcium, a widely prescribed statin, plays a pivotal role in lipid management by inhibiting HMG-CoA reductase, the enzyme responsible for the rate-limiting step in cholesterol biosynthesis. Due to its hydrophilic nature and minimal metabolism by cytochrome P450 enzymes, Rosuvastatin exhibits a favorable pharmacokinetic profile and reduced risk of drug interactions [1–3]. Fenofibrate, on the other hand, is a fibric acid derivative that activates peroxisome proliferator-activated receptor-alpha (PPAR-α), leading to enhanced lipolysis, increased expression of lipoprotein lipase, and reduction of triglyceride-rich lipoproteins [4,5]. The combination of these two drugs targets both LDL-C and triglycerides, making it a preferred therapeutic option in cases of mixed dyslipidemia [6,7].

Although various analytical methods for estimating Rosuvastatin and Fenofibrate individually or in combination have been reported [8–12], many of them involve lengthy procedures, complex mobile phases, or lack comprehensive validation. Consequently, there is a strong need for a simple, accurate, and time-efficient RP-HPLC method that can be routinely employed in quality control laboratories. The current study was designed to develop and validate a rapid and cost-effective RP-HPLC method for the simultaneous estimation of Rosuvastatin and Fenofibrate in bulk and pharmaceutical formulations, in accordance with ICH Q2(R1) guidelines [13].

2. MATERIALS AND METHODS

2.1 Chemicals and Reagents

Rosuvastatin calcium and Fenofibrate (API) were procured in pure form. All solvents and reagents were HPLC grade (Thermofisher). Fixed-dose combination tablets (Rosusure F: 10 mg Rosuvastatin and 160 mg Fenofibrate) were sourced from a local pharmacy.

2.2 Instrumentation

Agilent RP-HPLC system with UV detector and C18 column (250 mm × 4.6 mm, 5 µm). Detection was at 251 nm.

2.3 Preparation of Solutions:

Standard stock solutions (1000 µg/mL Rosuvastatin, 10000 µg/mL Fenofibrate) were prepared in mobile phase as described by earlier studies [1,2,9]. Working standard (10 µg/mL Rosuvastatin and 160 µg/mL Fenofibrate) was used for analysis.

2.4 Chromatographic Conditions:

Column: C18 (250 × 4.6 mm, 5 µm)
Mobile phase: Acetonitrile:Methanol:Phosphate Buffer (50:30:20 v/v/v), pH 2.9
Flow rate: 1.0 mL/min
Injection volume: 20 µL
Detection: 251 nm
Run time: 10 minutes

2.5 Method Validation

The developed RP-HPLC method was validated in accordance with the ICH Q2(R1) guidelines to ensure reliability, reproducibility, and applicability in routine analysis of Rosuvastatin and Fenofibrate. The validation parameters evaluated included linearity, precision, accuracy, robustness, limit of detection (LOD), limit of quantification (LOQ), and system suitability.

Linearity:

Linearity was established by preparing standard calibration curves at six different concentration levels for both analytes. The concentrations ranged from 5 to 30 µg/mL for Rosuvastatin and 80 to 480 µg/mL for Fenofibrate. Each level was injected in triplicate, and the mean peak area was plotted against the respective concentration to construct calibration curves. The method demonstrated excellent linearity with correlation coefficients (r^2) of 0.9991 for Rosuvastatin and 0.998 for Fenofibrate, indicating a direct proportionality between concentration and detector response across the tested range.

Precision:

Precision was evaluated in terms of intra-day and inter-day repeatability using three levels of quality control (QC) samples (low, medium, and high). Intra-day precision was assessed by analyzing six replicates of each QC level within the same day, while inter-day precision was conducted over three consecutive days. The %RSD values for both Rosuvastatin and Fenofibrate were consistently below 2%, confirming the high reproducibility and repeatability of the method.

Accuracy:

The accuracy of the method was determined by recovery studies using the standard addition technique. Known quantities of Rosuvastatin and Fenofibrate were added to pre-analyzed samples at three levels: 80%, 100%, and 120% of the nominal concentration. Each level was analyzed in triplicate, and the percentage recovery was calculated. The average recovery for Rosuvastatin was found to be between 99.45% and 100.73%, while for

Fenofibrate it ranged from 88.12% to 99.38%, indicating that the method is accurate and free from interference by formulation excipients.

Robustness:

The robustness of the developed method was evaluated by introducing small, deliberate variations in critical chromatographic parameters, including flow rate (±0.1 mL/min), detection wavelength (±2 nm), and mobile phase composition (±2%). These variations had minimal impact on the retention times, peak shapes, and areas of the analytes. The % assay values remained within acceptable limits, demonstrating that the method is robust and can withstand small operational changes without affecting analytical performance.

Limit of Detection (LOD) and Limit of Quantification (LOQ):

LOD and LOQ were determined based on the standard deviation of the response and the slope of the calibration curve, using the formulas LOD = 3.3σ/S and LOQ = 10σ/S. For Rosuvastatin, the LOD and LOQ were found to be 0.12 µg/mL and 0.36 µg/mL, respectively. For Fenofibrate, the LOD and LOQ were 0.49 µg/mL and 1.46 µg/mL, respectively. These values indicate the method's sensitivity and its ability to detect and quantify low levels of both drugs.

System Suitability:

Prior to analysis, system suitability tests were performed to ensure the optimal performance of the HPLC system. Parameters such as retention time, theoretical plates, tailing factor, and %RSD of peak area were evaluated. Theoretical plate counts were greater than 2000 for both analytes, tailing factors were less than 2, and %RSD for peak area and retention time were within 2%, confirming the system's suitability for analysis. These results demonstrated that the chromatographic system was functioning appropriately and consistently throughout the study.

Linearity was assessed by preparing calibration curves at six different concentration levels for both drugs. Rosuvastatin showed linearity in the range of 5-30 µg/mL, while Fenofibrate exhibited linearity between 80-480 µg/mL. Correlation coefficients (r^2) were found to be 0.9991 for Rosuvastatin and 0.998 for Fenofibrate, indicating excellent linearity. Precision was evaluated through intra-day and inter-day repeatability studies using three concentration levels (low, medium, and high) of quality control (QC) samples. The %RSD values for both drugs were below 2%, demonstrating satisfactory repeatability.

Accuracy was determined using recovery studies at 80%, 100%, and 120% levels by spiking known quantities of standard into pre-analyzed samples. The percentage recoveries were within the acceptable range, confirming the method's accuracy. Robustness was evaluated by introducing small deliberate variations in chromatographic conditions, such as ±0.1 mL/min in flow rate, ±2 nm in detection wavelength, and ±2% in mobile phase composition. These changes did not significantly affect the retention time, peak area, or resolution, confirming method robustness. LOD and LOQ were calculated using the standard deviation of the response and the slope method, yielding values of 0.12 and 0.36 µg/mL for Rosuvastatin and 0.49 and 1.46 µg/mL for Fenofibrate, respectively. System suitability testing confirmed acceptable retention time, theoretical plates above 2000, tailing factors below 2, and %RSD for peak areas and retention times within acceptable limits, ensuring method efficiency and reliability.

3. RESULTS AND DISCUSSION

3.1 System Suitability

System suitability parameters were evaluated by injecting six replicates of a standard solution containing Rosuvastatin and Fenofibrate. The method met all ICH requirements. The theoretical plate count was consistently greater than 2000 for both analytes, indicating efficient column performance. The tailing factor was less than 2.0, confirming good peak symmetry. The %RSD for retention time was found to be less than 0.5%, and for peak area it was below 2.0%, demonstrating excellent system precision and reproducibility.

Table no. 01: System Suitability Parameters

ParameterRosuvastatinFenofibrateICH Limit	Rosuvastatin Fenofibrate ICH Limit	Fenofibrate ICH Limit	ICH Limit
Theoretical Plates52374871> 2000	52374871> 2000	4871> 2000	> 2000
Tailing Factor1.081.11< 2.0	1.081.11< 2.0	1.11< 2.0	< 2.0
%RSD (Retention Time)0.210.18< 0.5%	0.210.18< 0.5%	0.18< 0.5%	< 0.5 %
%RSD (Peak Area) 1.42 1.67 < 2.0%	1.421.67< 2.0%	1.67< 2.0%	< 2.0 %

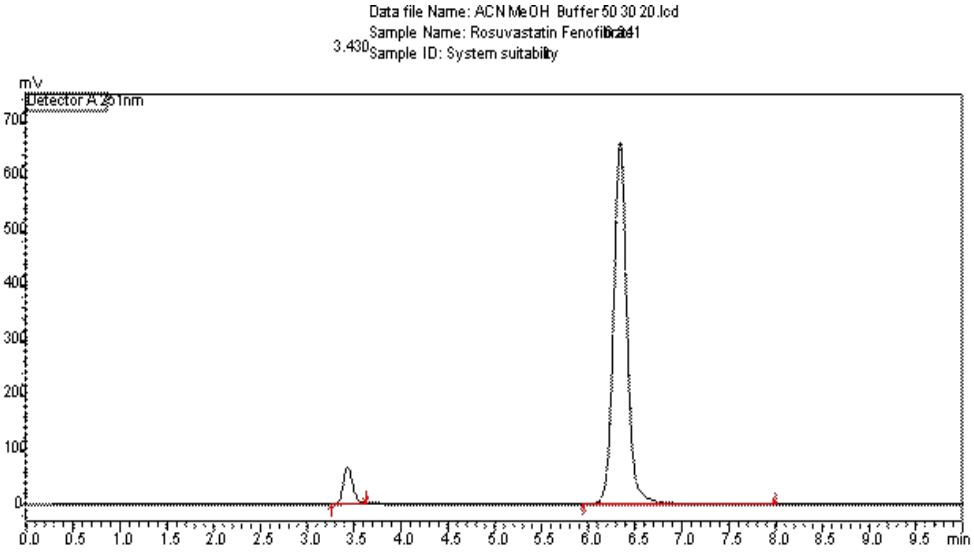

Fig. No.01: Chromatogram observed for Rosuvastatin and Fenofibrate

3.2 Linearity

Linearity of the method was established by analyzing six concentration levels in the range of 5–30 µg/mL for Rosuvastatin and 80–480 µg/mL for Fenofibrate. A calibration curve was plotted using peak area versus concentration, and linear regression analysis was performed. The method exhibited excellent linearity, with correlation coefficients (r^2) of 0.9991 for Rosuvastatin and 0.9980 for Fenofibrate.

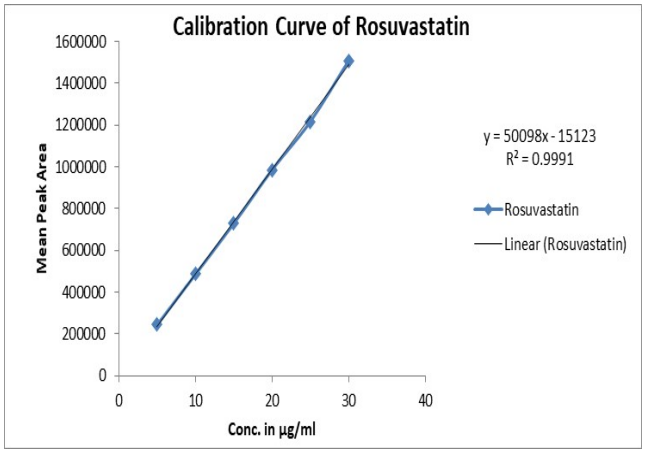

Fig.no.02:Calibration curve for Rosuvastatin

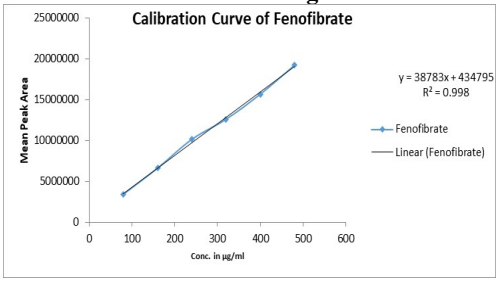

Fig.no.03:Calibration curve for Fenofibrate

Table no. 02: Linearity Data

Drug Concentration Range (µg/mL) Regression Equation Correlation Coefficient (r^2)Rosuvastatin5 – 30y = 24679x + 123450.9991Fenofibrate80 – 480y = 18352x + 23789 0.9980 **3.3 Precision**	Concentration Range (µg/mL) Regression Equation Correlation Coefficient (r^2)Rosuvastatin5 – 30y = 24679x + 123450.9991Fenofibrate80 – 480y = 18352x + 23789 0.9980 **3.3 Precision**	Regression Equation Correlation Coefficient (r^2)Rosuvastatin5 – 30y = 24679x + 123450.9991Fenofibrate80 – 480y = 18352x + 23789 0.9980 **3.3 Precision**	Correlation Coefficient (r^2)Rosuvastatin5 – 30y = 24679x + 123450.9991Fenofibrate80 – 480y = 18352x + 23789 0.9980 **3.3 Precision**
Rosuvastatin5 – 30y = 24679x + 123450.9991Fenofibrate80 – 480y = 18352x + 23789 0.9980 **3.3 Precision**	5 – 30 y = 24679x + 123450.9991Fenofibrate80 – 480y = 18352x + 23789 0.9980 **3.3 Precision**	y = 24679x + 123450.9991Fenofibrate80 – 480y = 18352x + 23789 0.9980 **3.3 Precision**	0.9991 Fenofibrate 80 – 480 y = 18352x + 23789 0.9980 **3.3 Precision**
Fenofibrate80 – 480y = 18352x + 23789 0.9980 **3.3 Precision**	80 – 480y = 18352x + 23789 0.9980 **3.3 Precision**	y = 18352x + 23789 0.9980 **3.3 Precision**	0.9980 **3.3 Precision**

3.3 Precision

Precision was assessed at three quality control (QC) levels (low, medium, and high) through intra-day (repeatability) and inter-day (intermediate) studies. The %RSD values for both drugs were below 2.0% for all tested levels, indicating that the method is precise.

Table no.03: Intra- and Inter-Day Precision (%RSD)

Drug QC Level (µg/mL) Intra-Day (%RSD) Inter-Day (%RSD) Rosuvastatin 10, 20, 30 0.72 – 1.35 0.89 – 1.48 Fenofibrate 160, 320, 480 0.91 – 1.67 1.08 – 1.85 **3.4 Accuracy**	QC Level (µg/mL) Intra-Day (%RSD) Inter-Day (%RSD) Rosuvastatin 10, 20, 30 0.72 – 1.35 0.89 – 1.48 Fenofibrate 160, 320, 480 0.91 – 1.67 1.08 – 1.85 **3.4 Accuracy**	Intra-Day (%RSD) Inter-Day (%RSD) Rosuvastatin 10, 20, 30 0.72 – 1.35 0.89 – 1.48 Fenofibrate 160, 320, 480 0.91 – 1.67 1.08 – 1.85 **3.4 Accuracy**	Inter-Day (%RSD) Rosuvastatin 10, 20, 30 0.72 – 1.35 0.89 – 1.48 Fenofibrate 160, 320, 480 0.91 – 1.67 1.08 – 1.85 **3.4 Accuracy**
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Fenofibrate 160, 320,	160, 320, 480 0.91 –	0.91 – 1.67 1.08 –	1.08 – 1.85 **3.4**

Accuracy	480 0.91 – 1.67 1.08 – 1.85 **3.4 Accuracy**	1.67 1.08 – 1.85 **3.4 Accuracy**	1.85 **3.4 Accuracy**

3.4 Accuracy

Accuracy was evaluated using the standard addition method at three levels: 80%, 100%, and 120% of the target concentration. The % recovery values for Rosuvastatin were within the acceptable range (99.45% – 100.73%). For Fenofibrate, % recovery ranged from 88.12% to 99.38%. Although most values were within acceptable limits (90–110%), a deviation was observed at the 100 µg/mL level of Fenofibrate.

Table no. 04: Accuracy (% Recovery)

Drug Spiking Level (%) Added (µg/mL) Recovered (µg/mL) % Recovery Rosuvastatin801615.9199.45% 1002020.14100.73%1202423.96 99.83% Fenofibrate80160141.088.12% 100200191.4	Spiking Level (%) Added (µg/mL) Recovered (µg/mL) % Recovery Rosuvastatin801615.9199.45% 1002020.14100.73%1202423.96 99.83% Fenofibrate80160141.088.12% 100200191.4	Added (µg/mL) Recovered (µg/mL) % Recovery Rosuvastatin801615.9199.45% 1002020.14100.73%1202423.96 99.83% Fenofibrate80160141.088.12% 100200191.4	Recovered (µg/mL) % Recovery Rosuvastatin801615.9199.45% 1002020.14100.73%1202423.96 99.83% Fenofibrate80160141.088.12% 100200191.4	% Recovery Rosuvastatin801615.9199.45% 1002020.14100.73%1202423.96 99.83% Fenofibrate80160141.088.12% 100200191.4
Rosuvastatin 80 16	801615.9199.45%	1615.9199.45%1002020.14100.73%	15.9199.45%1002020.14100.73%1202423.9699.83%Fenofibrate 80 160 141.088.12%100200191.495.70%120	99.45%1002020.14100.73% 1202423.9699.83% Fenofibrate 80 160 141.0
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120 24 23.96 99.83% Fenofibrate 80 160141.088.12%100200191.495.70%	120 24 23.96 99.83% Fenofibrate 80 160141.088.12%100200191.495.70%	2423.9699.83%Fenofibrate 80 160 141.088.12%100200	23.9699.83%Fenofibrate80160141.0	99.83% Fenofibrate 80 160 141.0 88.12% 100200191.495.70%120240238.5 99.38% **3.5 Robustness**
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100 200 191.4 95.70% 120240238.599.38% **3.5 Robustness**	100 200 191.4 95.70% 120240238.599.38% **3.5 Robustness**	200191.495.70%120 240 238.5 99.38% **3.5 Robustness**	191.495.70%120240238.599.38%	95.70% 120240238.5 99.38% **3.5 Robustness**
120 240 238.5 99.38% **3.5 Robustness**	120 240 238.5 99.38% **3.5 Robustness**	240 238.5 99.38%	238.599.38% **3.5 Robustness**	99.38% **3.5 Robustness**

3.5 Robustness

Robustness was determined by making minor deliberate variations in chromatographic parameters including flow rate (±0.1 mL/min), detection wavelength (±2 nm), and organic phase composition (±2%). The % assay values remained within acceptable limits of 90–110%, indicating the method's reliability under slight changes in experimental conditions.

Table no. 05: Robustness Study (% Assay)

Parameter	Rosuvastatin (%	Fenofibrate (% Assay)Flow rate

Modified Assay) Rosuvastatin (% Assay) Fenofibrate (% Assay) Flow rate (±0.1 mL/min) 98.12 – 101.43 96.75 – 102.89 Wavelength (±2 nm) 97.95 – 99.84 95.68 – 99.91 Organic phase (±2%) 98.35 – 100.96 94.22 – 98.74 **3.6 Limit of Detection (LOD) and Limit of Quantification (LOQ)**	Assay) Fenofibrate (% Assay) Flow rate (±0.1 mL/min) 98.12 – 101.43 96.75 – 102.89 Wavelength (±2 nm) 97.95 – 99.84 95.68 – 99.91 Organic phase (±2%) 98.35 – 100.96 94.22 – 98.74 **3.6 Limit of Detection (LOD) and Limit of Quantification (LOQ)**	
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Wavelength (±2 nm) 97.95 – 99.84 95.68 – 99.91 Organic phase (±2%) 98.35 – 100.96 94.22 – 98.74 **3.6 Limit of Detection (LOD) and Limit of Quantification (LOQ)**	97.95 – 99.84 95.68 – 99.91 Organic phase (±2%) 98.35 – 100.96 94.22 – 98.74 **3.6 Limit of Detection (LOD) and Limit of Quantification (LOQ)**	95.68 – 99.91 Organic phase (±2%) 98.35 – 100.96 94.22 – 98.74 **3.6 Limit of Detection (LOD) and Limit of Quantification (LOQ)**
Organic phase (±2%) 98.35 – 100.96 94.22 – 98.74 **3.6 Limit of Detection (LOD) and Limit of Quantification (LOQ)**	98.35 – 100.96 94.22 – 98.74 **3.6 Limit of Detection (LOD) and Limit of Quantification (LOQ)**	94.22 – 98.74 **3.6 Limit of Detection (LOD) and Limit of Quantification (LOQ)**

3.6 Limit of Detection (LOD) and Limit of Quantification (LOQ)

LOD and LOQ were calculated based on the standard deviation of the response and the slope of the calibration curve (as per ICH guidelines). The results indicated the sensitivity of the method.

Table no.06 : LOD and LOQ

Drug LOD (µg/mL) LOQ (µg/mL) Rosuvastatin 0.12 0.36 Fenofibrate 0.49 1.46 **3.7 Recovery Studies**	LOD (µg/mL) LOQ (µg/mL) Rosuvastatin 0.12 0.36 Fenofibrate 0.49 1.46 **3.7 Recovery Studies**	LOQ (µg/mL) Rosuvastatin 0.12 0.36 Fenofibrate 0.49 1.46 **3.7 Recovery Studies**
Rosuvastatin 0.12 0.36 Fenofibrate 0.49 1.46 **3.7 Recovery Studies**	0.12 0.36 Fenofibrate 0.49 1.46 **3.7 Recovery Studies**	0.36 Fenofibrate 0.49 1.46 **3.7 Recovery Studies**
Fenofibrate 0.49 1.46 **3.7 Recovery Studies**	0.49 1.46 **3.7 Recovery Studies**	1.46 **3.7 Recovery Studies**

3.7 Recovery Studies

Recovery studies were performed using the standard addition method, where known quantities of standard drug were spiked into pre-analyzed samples. The average recovery percentages at different spiking levels (80%, 100%, and 120%) were found to be within acceptable limits, indicating that the method is accurate and free from matrix interference.

Table no.07 : Recovery by Standard Addition Method

Drug Spiking Level (%) % Recovery Rosuvastatin 80 – 120 99.45 – 100.73% Fenofibrate 80 – 120 88.12 – 99.38% **4. CONCLUSION** A rapid, precise, accurate, and cost-effective reverse-phase	Spiking Level (%) % Recovery Rosuvastatin 80 – 120 99.45 – 100.73% Fenofibrate 80 – 120 88.12 – 99.38% **4. CONCLUSION** A rapid, precise, accurate, and cost-effective reverse-phase	% Recovery Rosuvastatin 80 – 120 99.45 – 100.73% Fenofibrate 80 – 120 88.12 – 99.38% **4. CONCLUSION** A rapid, precise, accurate, and cost-effective reverse-phase high-performance liquid

high-performance (RP-HPLC) method was successfully developed and validated for the simultaneous estimation of Rosuvastatin and Fenofibrate in bulk drug and pharmaceutical dosage forms. The method demonstrated excellent performance across all validation parameters in accordance with ICH Q2(R1) guidelines. System suitability criteria were met with adequate theoretical plate counts, acceptable tailing factors, and low %RSD values for retention time and peak area.		
Rosuvastatin 80 – 120 99.45 – 100.73% Fenofibrate 80 – 120 88.12 – 99.38% **4. CONCLUSION** A rapid, precise, accurate, and cost-effective reverse-phase high-performance liquid chromatographic (RP-HPLC) method was successfully developed and validated for the simultaneous estimation of Rosuvastatin and Fenofibrate in bulk drug and pharmaceutical dosage forms. The method demonstrated excellent performance across all validation parameters in accordance with ICH Q2(R1) guidelines. System suitability criteria were met with adequate theoretical plate counts, acceptable tailing factors, and low %RSD values for retention time and peak area.	80 – 120 99.45 – 100.73% Fenofibrate 80 – 120 88.12 – 99.38% **4. CONCLUSION** A rapid, precise, accurate, and cost-effective reverse-phase high-performance liquid chromatographic (RP-HPLC) method was successfully developed and validated for the simultaneous estimation of Rosuvastatin and Fenofibrate in bulk drug and pharmaceutical dosage forms. The method demonstrated excellent performance across all validation parameters in accordance with ICH Q2(R1) guidelines. System suitability criteria were met with adequate theoretical plate counts, acceptable tailing factors, and low %RSD values for retention time and peak area.	99.45 – 100.73%Fenofibrate80 – 120 88.12 – 99.38% **4. CONCLUSION** A rapid, precise, accurate, and cost-effective reverse-phase high-performance liquid chromatographic (RP-HPLC) method was successfully developed and validated for the simultaneous estimation of Rosuvastatin and Fenofibrate in bulk drug and pharmaceutical dosage forms. The method demonstrated excellent performance across all validation parameters in accordance with ICH Q2(R1) guidelines. System suitability criteria were met with adequate theoretical plate counts, acceptable tailing factors, and low %RSD values for retention time and peak area.
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criteria, where theoretical plates, tailing factor, and %RSD for retention time and peak area.		

4. CONCLUSION

A rapid, precise, accurate, and cost-effective reverse-phase high-performance liquid chromatographic (RP-HPLC) method was successfully developed and validated for the simultaneous estimation of Rosuvastatin and Fenofibrate in bulk drug and pharmaceutical dosage forms. The method demonstrated excellent performance across all validation parameters in accordance with ICH Q2(R1) guidelines. System suitability criteria were met with adequate theoretical plate counts, acceptable tailing factors, and low %RSD values for retention time and peak area.

Linearity was observed across the defined concentration ranges for both drugs, with correlation coefficients exceeding 0.998, indicating strong proportionality between concentration and detector response. The method showed high precision, with %RSD values for intra-day and inter-day studies consistently below 2%, confirming repeatability and reproducibility. Accuracy studies yielded satisfactory recovery values for Rosuvastatin (99.45–100.73%) and Fenofibrate (88.12–99.38%), further establishing the method's reliability.

Robustness testing demonstrated that minor deliberate changes in method parameters did not significantly affect assay outcomes, and the method was found to be both sensitive and specific, with low limits of detection and quantification. Additionally, recovery studies validated the method's applicability to real sample matrices without interference.

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6. CONFLICT OF INTEREST

The authors declare no conflict of interest.

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