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ANALYTICAL METHOD VALIDATION OF ATORVASTATIN BY UV AND RP – HPLC METHOD

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ABSTRACT

The study presents the development and validation of analytical methods for the quantitative estimation of Atorvastatin, a widely prescribed HMG-CoA reductase inhibitor used in the treatment of hypercholesterolemia and the prevention of cardiovascular diseases. Two complementary analytical technique UV method and RP-HPLC were developed and validated in accordance with ICH guidelines. UV method involved measuring the absorbance of Atorvastatin at 246 nm using a methanol–water (9:1 v/v) solvent system. The method revealed excellent linearity within the concentration range of 5–30 µg/mL, with a correlation coefficient (r^2) of 0.9994. Validation parameters including precision, accuracy, limit of detection, limit of quantitation, and robustness confirmed the method's reliability. RP-HPLC method was optimized using a mobile phase of acetonitrile and 1% glacial acetic acid (70:30 v/v), with detection carried out at 254 nm. Chromatographic separation was achieved on a C18 column (250 × 4.6 mm, 5 µm), yielding a retention time of 4.4 minutes. This method demonstrated linearity over the range of 5–100 µg/mL, with a correlation coefficient (r^2) of 0.9996.Both analytical methods proved to be highly sensitive, precise, and reproducible, confirming their suitability for the routine quality control analysis of Atorvastatin in pharmaceutical formulations. The validated procedures provide robust and reliable analytical tools to support regulatory compliance and ensure the quality assurance of pharmaceutical products containing Atorvastatin.

KEYWORDS: Atorvastatin, HPLC, UV, Method validation, pharmaceutical chemistry

INTRODUCTION

Atorvastatin is an FDA-approved medication used to prevent cardiovascular events in patients with cardiac risk factors and abnormal lipid profiles (1). It is a lipid-lowering agent with the molecular formula $C_{33}H_{35}FN_2O_5$ and a molecular weight of 558.65 g/mol. Chemically it is, (3R,5R)-7-[2-(4-Fluorophenyl)-5-isopropyl-3-phenyl-4-(phenylcarbamoyl)-1H-pyrrol-1-yl]-3,5-dihydroxyheptanoic acid (2). Belonging to the class of HMG-CoA reductase inhibitors (3-hydroxy-3-methylglutaryl-CoA reductase inhibitors), commonly referred to as statins, it's represented a major breakthrough in the management of hypercholesterolemia (3–5). It lowers plasma cholesterol and lipoprotein levels by inhibiting HMG-CoA reductase, thereby reducing hepatic cholesterol synthesis and increasing LDL receptor expression in the liver. This dual mechanism leads to a decrease in LDL production and circulating LDL particles (6,7). The drug specifically targets HMG-CoA reductase, the enzyme responsible for catalyzing the conversion of HMG-CoA to mevalonate, which constitutes the rate-limiting step in cholesterol biosynthesis (8). It's a novel synthetic statin derivative, was introduced in 1996 and subsequently approved by the U.S. Food and Drug Administration (FDA) in 2003 (9). It became the world's top-selling drug in 2002 and later became available in generic forms, providing a more cost-effective alternative to higher-priced statins such as rosu vastatin (10,11). Atorvastatin is a synthetic lipid-lowering agent belonging to the statin class of drugs. Its pharmacology centers on its ability to inhibit cholesterol synthesis in the liver, primarily by blocking the HMG-CoA reductase enzyme (12) It is commercially available as atorvastatin calcium tablets in strengths of 10, 20, 40, and 80 mg, administered as the calcium salt of the active hydroxyl acid. The usual dosage ranges from 10–80 mg per day, prescribed for patients with primary (familial or non-familial) hyperlipidemia or combined hyperlipidemia (13–16). Its unique chemical structure, prolonged half-life, and high hepatic selectivity contribute to its superior LDL-cholesterol-lowering efficacy compared to other statins (17, 18). It's soluble in organic solvents such as ethanol, DMSO, and DMF. As a competitive inhibitor of HMG-CoA reductase, it differs from naturally derived statins by being completely synthetic. Like other statins, atorvastatin reduces plasma triglycerides and modestly increases HDL-cholesterol levels. In patients with acute coronary syndrome, high-dose therapy may also contribute to plaque stabilization. UV method offers a simple, cost-effective, non-destructive, and versatile analytical technique applicable to a wide range of organic and inorganic compounds. It finds its extensive applications across multiple disciplines, including pharmaceutical, environmental, food, agricultural, and clinical research. Similarly, HPLC is a powerful technique for the identification and quantification of

components in a liquid mixture. It integrates physical separation with spectroscopic detection typically UV–Visible detection, where the sample is carried by a liquid mobile phase through a packed column. Separation occurs based on component interactions with the stationary phase, and the eluted compounds are subsequently detected and quantified. A review of existing literature indicates that various analytical methods such as UV (19,20), HPLC (21, 22), UHPLC (23), and spectrofluorimetry (24) have been developed for the analysis of atorvastatin formulations. However, many of these methods are costly, time-consuming, and exhibit longer retention times, with limited systematic optimization reported. Therefore, the present study aims to develop a precise, accurate, sensitive, and economical RP-HPLC method with PDA detection for the quantitative estimation of atorvastatin in solid dosage forms. Statins play a crucial role in cholesterol reduction, as the majority of circulating plasma cholesterol originates from hepatic synthesis rather than dietary intake (25). They exert cardio protective effects through plaque stabilization, anti-inflammatory actions, improvement of endothelial function, and reduction in thrombogenicity (26). It's a selective and competitive inhibitor of HMG-CoA reductase, binds effectively to the enzyme's active site through its fluorophenyl moiety, thereby reducing LDL-C, apolipoprotein B, and triglycerides, while increasing HDL-C levels (27, 28). With a half-life of approximately 20 hours, drug is considered safe for patients with renal impairment (requiring no dose adjustment) and is approved for use in children aged 11 years and older (29).

MATERIALS AND METHODS

Estimation of Atorvastatin by UV Method

The solubility profile of Atorvastatin was examined using different solvents such as ethanol and methanol, and its solubility was evaluated based on turbidity and miscibility. Methanol was selected as the optimal solvent due to better solubility characteristics, and UV spectrum of Atorvastatin in methanol was recorded. To determine the λ max, a standard solution containing 10 µg/mL of Atorvastatin was prepared and scanned between 200–400 nm using spectrophotometer with a reagent blank, identifying the maximum absorbance at 246 nm. Standard solution was done by weighing 10 mg of pure sample in a methanol: water (9:1) to obtain a stock solution of 1000 µg/mL. For the sample solution, twenty tablets labeled as 40 mg were weighed, powdered, and the average tablet weight was calculated based on the label claim (0.04 g). A precisely weighed portion of the powder was dissolved in methanol: water (9:1), and absorbance was measured at 246 nm.

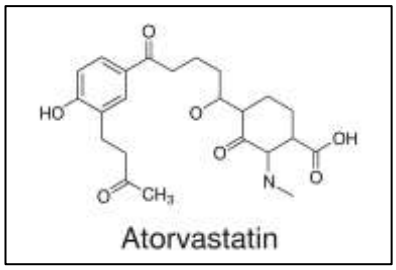


Figure 1: Structure of Atorvastatin

Method validation parameters of UV

Linearity, a calibration curve was constructed for concentrations ranging from 5–30 µg/mL by plotting absorbance versus concentration, with the acceptance criterion of $r^2 \geq 0.999$: Limit of Detection defined as the lowest detectable concentration, determined based on a signal-to-noise ratio of 3:1; Limit of Quantitation the lowest quantifiable concentration, determined at a signal-to-noise ratio of 10:1, Precision was evaluated as inter-day precision by recording three consecutive readings at 20 µg/mL standard solution, and intra-day precision by repeating the procedure on three consecutive days; a Accuracy was assessed at 50%, 100%, and 150% concentration levels using methanol :water (9:1), measuring absorbance at 246 nm and calculating the percentage recovery to confirm the accuracy of the method(30,31).

Estimation of Atorvastatin by HPLC Method

A standard solution of Atorvastatin was prepared by accurately weighing 50 mg of the working standard and transferring it into a 50 mL volumetric flask. Approximately 35 mL of acetonitrile and 15 mL of 1% glacial acetic acid were added as diluents, and the mixture was sonicated until the drug completely dissolved. The volume was then made up to the mark with the same solvent to obtain a stock solution of 1000 µg/mL. For sample preparation, 192.5 mg of the sample was accurately weighed and dissolved in 40 mL of diluent containing 7 mL of acetonitrile and 3 mL of 1% glacial acetic acid. The solution was sonicated for 15 minutes, filtered through whatmann filter paper, and directly injected into the HPLC system.

Method validation parameters of HPLC

Linearity was established using ten concentrations ranging from 5–100 µg/mL by plotting concentration versus peak area, with an acceptance criterion of $r^2 \geq 0.999$. Precision was evaluated through intraday and interday studies using a 40 µg/mL standard solution, where three readings were recorded across consecutive days, while system precision was determined by six consecutive injections of the same concentration. Robustness was verified by altering the mobile phase composition and column temperature, analysing three replicates of a 40 µg/mL sample to ensure method consistency under slight variations. Ruggedness was determined by two different analysts using separate HPLC instruments, each preparing the

mobile phase and standard solution (40 µg/mL) independently, and performing analysis on different days to assess reproducibility under varied laboratory conditions. Recovery studies were carried out at 80%, 100%, and 120% of the target concentration using a mobile phase of acetonitrile and 1% glacial acetic acid (70:30 v/v), and the percentage recovery was calculated to confirm accuracy. Limit of Detection was determined based on a signal-to-noise ratio of 3:1, and the Limit of Quantitation was established using a ratio of 10:1, ensuring precision at lower concentration levels. For the assay method, ten tablets containing 10 mg of Atorvastatin were accurately weighed, powdered, and an equivalent of 192.5 mg was dissolved in a mixture of acetonitrile and 1% glacial acetic acid to prepare a standard solution of 1000 µg/mL. This solution was compared with the sample solution using HPLC, and the percentage purity of both the standard and sample was determined (32,33)

Optimized Chromatographic Conditions:
A series of optimization experiments were performed by varying the ratios of organic solvents—specifically acetonitrile and 1% glacial acetic acid—to obtain a distinct, symmetrical, and well-resolved chromatographic peak for Atorvastatin. The optimal chromatographic conditions were established using a mobile phase of acetonitrile and 1% glacial acetic acid (70:30, v/v) under isocratic elution. Separation was achieved on a C18 column (250 × 4.6 mm, 5 µm) at a flow rate of 1.0 mL/min, with a total run time of 10 minutes. A 20 µL injection volume was employed, and detection was carried out at 254 nm, corresponding to the λmax of Atorvastatin.Under these optimized conditions, the method produced a sharp, symmetrical peak with a retention time of 4.4 minutes, a theoretical plate count of 6542, and a tailing factor of 1.1, indicating excellent column efficiency and minimal peak distortion. The selected mobile phase composition ensured optimal resolution, stable baseline performance, and acceptable system pressure.Hence, the finalized chromatographic conditions were deemed ideal for the determination and validation of Atorvastatin by RP-HPLC, offering high reproducibility, sensitivity, and accuracy, making the method suitable for routine quality control analysis in pharmaceutical applications.

System suitability parameters:

Table 1: System suitability parameters

S.no	Parameter	Result
1	Standard concentration	40 (µg/ml)
2	Mobile phase	Acetonitrile: 1% glacial acetic acid (70:30)
3	Elution	Isocratic
4	Detection wavelength	254nm
5	Column	C18 (250 x 4.6 mm, 5 µm)
6	Detector	PDA detector
7	Flow rate	1.0ml/min
8	Run time pressure	2140 psi
9	Retention time	4.4 minutes
10	Run time	10 minutes
11	Peak area	2003965
12	Purging valve pressure	140psi

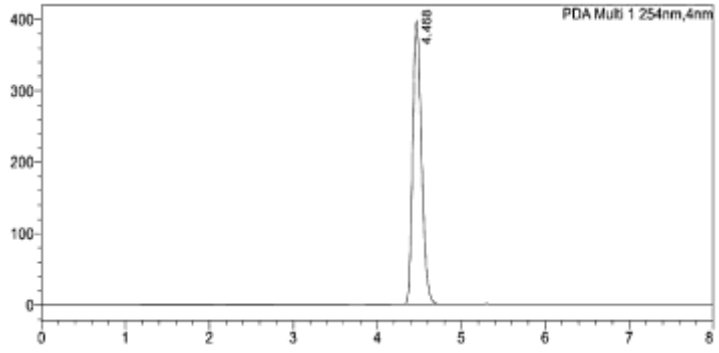


Figure 2 : Optimized method of Atorvastatin
System suitability parameters and optimized method of Atorvastatin are shown in table 1 and Figure 2

Result and Discussion:
Method validation of Atorvastatin by UV method:
Determination of λ max:
λ max of Atorvastatin was determined at 246 nm using methanol and water in 9:1 as solvent is depicted in figure 3

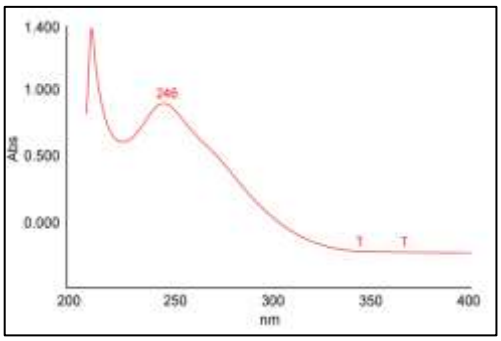


Figure 3: UV Visible spectrum of Atorvastatin

Linearity:

Table 2 : Linearity of Atorvastatin by UV method

S:no	Concentration(µg/mL)	Absorbance
1	5	0.233
2	10	0.393
3	15	0.579
4	20	0.762
5	25	0.937
6	30.	1.133
7	Correlation coefficient (r2)	0.9994

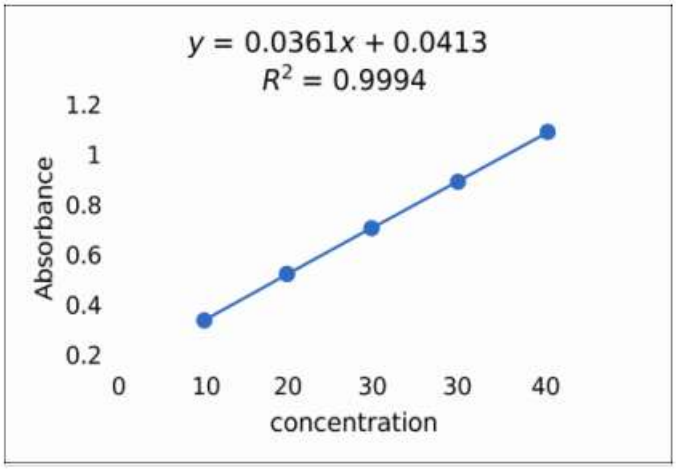


Figure 4: Linearity graph of Atorvastatin by UV method.

Atorvastatin was found to be linear in the concentration range - 5 to 30 µg/ml. A Promising linear relationship (r2- 0.9994) was observed and depicted in figure 4 and table 2. The representative linearity equation was found to be y = 0.0361x + 0.0413 as showed.

Interday precision:

Table 3: Interday precision of Atorvastatin by UV method

SNO	Absorbance	Mean	Standard deviation	%RSD
Day-1	0.745	0.752	0.0034	0.138
	0.757			
	0.754			
Day-2	0.752	0.749	0.0032	0.139
	0.743			
	0.754			
Day-3	0.743	0.747	0.0032	0.154
	0.755			
	0.745			

Day 1:
- ✓ The mean absorbance was 0.752.
- ✓ The standard deviation was 0.0034.
- ✓ The %RSD (Relative Standard Deviation) was 0.438%, indicating good precision.

Day 2:
- ✓ The mean absorbance was 0.749.
- ✓ The standard deviation was 0.0032.
- ✓ The %RSD was 0.439%, indicating good precision.

Day 3:
- ✓ The mean absorbance was 0.747.
- ✓ The standard deviation was 0.0032.
- ✓ The %RSD was 0.454%, indicating good precision.

- Interday precision was tabulated in table 3 and %RSD values for all three days are well below 1%, which indicates a high degree of precision in the measurements.
- Mean absorbance values are consistent across the three days, with very small variations.

Intraday precision:

Table 4: Intraday precision of Atorvastatin by UV method

S.no	Conc(µg/mL)	Absorbance	Mean	SD	%RSD
1	20	0.752	0.753	0.0039	0.093
2	20	0.754		0.0039	0.093
3	20	0.755		0.0042	0.187

Interday precision was tabulated in table 4 and % RSD value of 0.187% indicates good precision for intraday measurements. %RSD value below 1% is generally considered acceptable in analytical methods, indicating low variability and high repeatability within the same day. The mean absorbance value of 0.753 is consistent with the individual measurements, with very small variations.

Limit of Detection and Limit of Quantification:
LOD and LOQ for Atorvastatin using the proposed UV method were to be 0.292µg/ml and 0.886µg/ml respectively.

Assay:

Table 5: Assay for Atorvastatin UV method

S.no	Parameters	Conc (µg/mL)	Absorbance	% purity
1	Assay (Atorvastatin Tablet)	20	0.766	100.25

The samples were analysed using both proposed methods under identical experimental conditions, and the drug content was found to be within the limits specified by ICH guidelines and the assay results are depicted in the table 5

Recovery and Accuracy:

Table 6: Recovery of Atorvastatin by UV method

Percentage	Std µg/mL	Sample µg/mL	Absorbance	%Recovery
50%	5	10	0.643	98.25
	5	10	0.640	98.20
	5	10	0.642	98.23
100%	10	10	0.808	100.48
	10	10	0.802	100.12
	10	10	0.805	100.32
150%	15	10	0.975	101.23
	15	10	0.977	101.27
	15	10	0.977	101.27

Recovery and accuracy of Atorvastatin by the UV method were evaluated and shown in table 6 at three different concentration levels: 50%, 100%, and 150%. The results indicate that the UV method for determining Atorvastatin concentration demonstrates high accuracy and precision across all tested concentration levels, with average recoveries close to 100%. The consistency of the recovery percentages across the different concentration levels suggests that the method is reliable and suitable for accurate quantification of atorvastatin in sample.

Method Validation of Atorvastatin By HPLC Method:

Linearity:

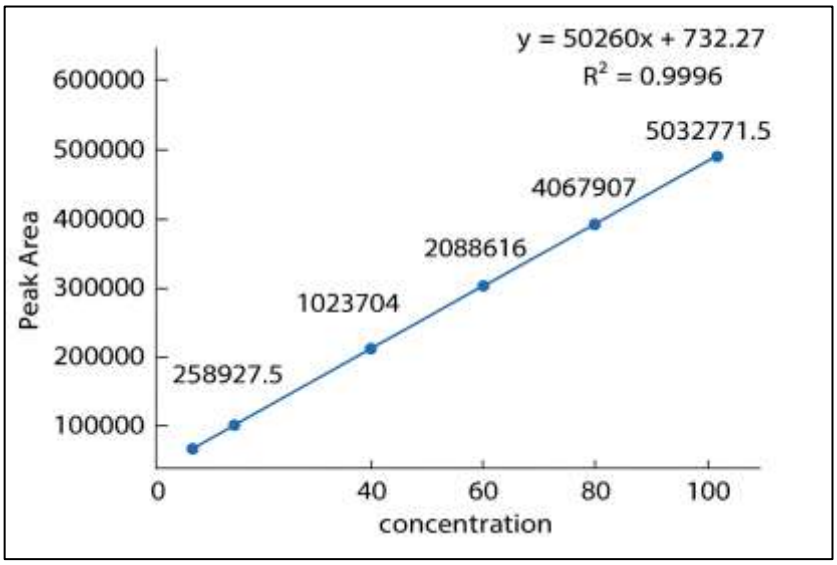
Table 7: Linearity of Atorvastatin by HPLC method

S.no	Concentration (µg/mL)	Retention time (min)	Peak area
1	5	4.44	258925
2	10	4.43	505927.5
3	20	4.42	1023704
4	40	4.42	2008616
5	60	4.42	2939142
6	80	4.42	4067907

7	100	4.42	5032772
8	Correlation coefficient (r2)	0.9996	

The linearity of proposed method of HPLC was constructed by considering concentration (µg/ml) on X–axis and peak area on Y-axis in table 7 and figure 5. The regression coefficient r2 was considered to be 0.9996 over a concentration range of 5–100 µg/ml.

Figure 5 : Linearity graph of Atorvastatin by HPLC method



Limit of Detection and Limit of Quantification:

LOD and LOQ for Atrorvastatin using the proposed HPLC method were to be 0.0429µg/mL and 0.1301µg/mL respectively.

System precision:

Table 8 : System precision of Atorvastatin by HPLC method

S.no	Peak area	Mean	SD	RSD	%RSD
1	2003965	2005198	551.414363	0.002749925	0.2749925
2	2003245		873.408152	0.00435572	0.435572
3	2004563		259.237664	0.001292828	0.1292828
4	2005467		120.300457	0.000599943	0.0599943
5	2006478		572.4334022	0.002854748	0.22854748
6	2007468		1015.1748617	0.005062716	0.5062716

%RSD values, which range from 0.05999% to 0.50627%, are well below 1%, indicating excellent precision for the HPLC system. %RSD below 2% typically demonstrates high reproducibility and reliability of the measurement system. The values of the system precision are represented in the table 8

The peak area values are consistent, with minor variations around the mean. This consistency further supports the robustness and precision of the HPLC system.

Interday precision:

Table 9 : Interday precision of Atorvastatin by HPLC method

S.no	Peak area	Mean	SD	RSD	%RSD
1	2003965	2005198	551.414363	0.002749925	0.2749925

2	2003245		873.408152	0.00435572	0.435572
3	2006478		572.4334022	0.002854748	0.22854748
Acceptance Criteria: Method Precision: RSD of assay results from 6 individual Sample preparations should be ≤ 2.0%.					

The calculated %RSD values for individual measurements range from 0.2285% to 0.4355%, indicating good precision for individual days and interday precision are illustrated in table 9. However, the combined %RSD of 123.5% for inter-day precision is quite high, suggesting significant variability across different days.
The peak area values show considerable variation across the days, particularly the outlier value of 2003965. This indicates potential issues with the method or the system's performance on different days.

Intraday precision:

Table 10 : Intraday precision of Atorvastatin by HPLC method

S.no	Peak area	Mean	SD	RSD	%RSD
1	2004563	2005502	259.237664	0.001292828	0.1292828
2	2005467		120.300457	0.000599943	0.0599943
3	2006478		572.4334022	0.002854748	0.22854748
Acceptance Criteria: Method Precision: The RSD of assay results from 6 individual sample preparations should be ≤ 2.0%.					

The %RSD values for the peak areas range from 0.0599% to 0.2285%, which are well below the acceptance criteria of ≤ 2.0%. This indicates excellent intraday precision for the HPLC system across the three different sample preparations within the same day.
The peak area values show minor variations around the mean, demonstrating consistent performance of the HPLC system within a single day and intraday precision are shown in table 10

Robustness:

Table 11 : Robustness of Atorvastatin by HPLC method

Exp	Parameter variation	Peak shape	Rt	Peak area
Mobile phase				
1	+2% mobile phase	Symmetrical shape	4.5	2264589
2	-2% mobile phase	Symmetrical shape	4.4	1997914
Temperature				
1	Temp 400 C	Symmetrical shape	4.4	2003965
2	Temp 420 C	Symmetrical shape	4.4	2007696
3	Temp 380 C	Symmetrical shape	4.4	2004565

Mobile Phase Variation:
Parameter Variation: Testing changes in mobile phase composition by ±2%.

Impact on Results:
- Peak Shape: Maintained Symmetrical Shape Across Variations.
- Retention Time (Rt): Varied Slightly From 4.4 To 4.6 Minutes, Indicating Minor Shifts.
- Peak Area: Ranged From 1997914 To 2264589, Showing a Moderate Impact On Peak Area With ±2% Variation.

Temperature Variation:
Parameter Variation: Testing temperature changes by ±2°C.
Impact on Results:
- ✓ Peak Shape: Consistently symmetrical shape observed.
- ✓ Retention Time (RT): Slight variation within 4.4 to 4.4 minutes, indicating minimal impact.
- ✓ Peak Area: Varied between 2007696 and 2004565, showing moderate variation with temperature changes.

The robustness study indicates that the HPLC method is reasonably robust under the tested variations in mobile phase composition and temperature and it's illustrated in table 11. Both parameters generally maintained symmetrical peak shapes, with minor variations in retention time and peak area. These variations were within acceptable limits for method robustness, suggesting that the method is reliable and capable of producing consistent results under slight variations in operational conditions.

Ruggedness:

Table 12 : Ruggedness of Atorvastatin by HPLC method

Exp	Parameter variation	Peak shape	Rt	Peak area
Instrument variation				
1	Analyst 1	Symmetrical shape	4.4	2004567
2	Analyst 2	Symmetrical shape	4.4	2006478
Mobile phase preparation				
1	Person 1	Symmetrical shape	4.4	2008758
2	Person 2	Symmetrical shape	4.4	2005657
Acceptance Criteria: Similar to the criteria for precision, with RSD values typically required to be ≤ 2.5%				

Instrument Variation:
Parameter Variation: Different analysts performing the analysis.
Impact on Results:
- ✓ Peak Shape: Consistently symmetrical shape observed for both analysts.
- ✓ Retention Time (RT): Slight variation from 4.4 to 4.4 minutes, indicating minor differences.
- ✓ Peak Area: Ranged from 2004567 to 2006478, with acceptable variation within the criteria.

Mobile Phase Preparation:
Parameter Variation: Different persons preparing the mobile phase.
Impact on Results:
- ✓ Peak Shape: Symmetrical shape maintained for both preparations.
- ✓ Retention Time (RT): Consistent at 4.4 minutes for both preparations.
- ✓ Peak Area: Varied slightly from 2008758 to 2005657, showing minimal impact on peak area

The ruggedness study indicates that the HPLC method is robust against variations introduced by different analysts and different persons preparing the mobile phase. The method consistently produced symmetrical peak shapes with minor variations in retention time and peak area, all well within the acceptance criteria of ≤ 2.5% RSD. This confirms that the method is rugged and reliable under different operational conditions, ensuring consistent and reproducible results across different users and preparation methods values are shown in table 12.

Assay:

Table 13 : Assay of Atorvastatin by HPLC method

S.no	Sample(tablet)	Label claim	Concentration (µg/ml)	Amount Present	% Purity
1	Atorvastatin	40mg	40	38.66mg	96.67%

The tablet claims to contain 40 mg of Atorvastatin, and based on the assay, the amount present is 38.66 mg indicating that the tablet meets the label claim and indicated in table 13. The purity of Atorvastatin in the tablet is determined to be 96.67%, which suggests high purity and confirms the accuracy of the assay method. The assay method accurately quantifies Atorvastatin in the tablet, providing confidence in the reliability of the HPLC analysis for this compound.

Recovery and Accuracy:

Table 14 : Recovery of Atorvastatin by HPLC method

Percentage	Std	Sample	Peak area	% Recovery	Average
80%	10µg/ml	10µg/ml	990133	95.22%	95.91
	10µg/ml	10µg/ml	1000192	96.19%	
	10µg/ml	10µg/ml	1001768	96.34%	

100%	20µg/ml	20µg/ml	2001487	99.87%	101.36
	20µg/ml	20µg/ml	2049046	102.24%	
	20µg/ml	20µg/ml	2043689	101.98%	
120%	30µg/ml	30µg/ml	2838474	96.57%	96.53
	30µg/ml	30µg/ml	2837460	96.54%	
	30µg/ml	30µg/ml	2836474	96.50%	

The % recovery values range from 95.91% to 101.36%, indicating good accuracy of the method across different sample concentrations. % Recovery values are within a close range of their respective concentrations was shown in table 14.
The recovery and accuracy study for the HPLC method shows that it provides reliable and accurate results across different sample concentrations (80%, 100%, and 120% of standard). The average recovery values for each concentration level are close to the expected values, confirming the method's capability to accurately quantify the analyte under different conditions. This ensures confidence in the method's performance for routine analysis in analytical applications.

DISCUSSION

The analytical procedures developed in this study demonstrated robust performance for the quantitative determination of Atorvastatin using UV spectrophotometry and RP-HPLC. The UV method exhibited excellent linearity ($r^2 = 0.9994$) over the range of 5–30 µg/mL, supported by low intra- and interday %RSD values (<1%), confirming high repeatability and temporal stability of the measurements. The method's accuracy, evidenced by recovery values approximating 100%, and its low LOD and LOQ, affirm its suitability for routine quality assessment where rapid and cost-effective analysis is required.
The RP-HPLC method further enhanced analytical precision and specificity. Chromatographic optimization using acetonitrile and 1% glacial acetic acid (70:30, v/v) yielded efficient separation with a retention time of 4.4 minutes and favorable system suitability parameters, including a theoretical plate count of 6542 and a tailing factor of 1.1. Linearity across 5–100 µg/mL ($r^2 = 0.9996$) demonstrated the method's broad quantitative capability. Precision, robustness, and ruggedness studies showed that minor variations in operational conditions did not significantly affect retention time, peak symmetry, or peak area, underscoring the method's operational resilience. Recovery values within 95–102% confirmed the method's accuracy. The assay result (96.67% purity) aligned with pharmacopeial standards, verifying method applicability to commercial formulations.
Collectively, the findings confirm that both UV and RP-HPLC methods are scientifically sound, sensitive, accurate, and validated analytical tools. The RP-HPLC method, with its superior specificity and robustness, is particularly suitable for regulatory quality control and stability studies of Atorvastatin in pharmaceutical dosage forms.

CONCLUSION

The RP-HPLC method developed for the quantitative estimation of atorvastatin was successfully validated as per ICH guidelines and demonstrated high accuracy, sensitivity, and precision, confirming its suitability for routine quality control of commercial formulations. The UV spectrophotometric method also proved to be reliable and robust, offering a simple and cost-effective alternative for routine analysis. Together, these validated methods provide dependable analytical tools for the accurate assessment of atorvastatin in pharmaceutical products.

Limitations of The Study:

The study did not evaluate degradation behavior or impurity profiling, limiting confirmation of stability-indicating performance. Method validation was confined to tablet formulations, without assessment in biological matrices. Robustness testing involved only a few parameter changes, and analysis of a single marketed product limits broader applicability.

Future Study:

Further studies should incorporate forced-degradation and impurity profiling to develop a stability-indicating method, along with validation in biological matrices for broader applicability. Evaluating additional commercial brands and using advanced techniques such as UHPLC or LC–MS/MS may further improve analytical performance.

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Authors Contribution:
Dr. Sheela Rani T abstracted the study and designed the experimental framework and worked on acquisition of data Mahesh Kumar interpretation of data. Naveen R and akshaya contributed towards the executive, technical support. helped and guided throughout the study.

Conflict of Interest:
The authors declare that there is no conflict of interest.

Ethics Approval:
Not applicable

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Abbreviation:
- UV- Ultra violet
- RP HPLC - Reversed-phase high-performance liquid chromatography
- LOD - Limit of detection
- LOQ - Limit of quantification
- SD - Standard deviation
- RSD - Relative standard deviation
- RT - Retention time
- UHPLC-Ultra high-performance liquid chromatography
- LC-MS/MS - Liquid Chromatography-Tandem Mass Spectrometry

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