

Precise and accurate UV spectrophotometric estimation of atorvastatin in bulk and dosage form: A validation study

Deepika Kumari^{1*} and Shoaeb Mohammad Syed^{1,2*}

¹Shri Venkateshwara University, Gajraula Amroha, UP, India 244236

²Dayanand Education Society's Dayanand College of Pharmacy Latur, MS India 413531

Abstract

The present study aimed to develop and validate a simple, precise, and accurate UV spectrophotometric method for the estimation of atorvastatin in bulk and pharmaceutical dosage forms. The method exhibited excellent linearity over the concentration range of 20–120 µg/ml with a correlation coefficient (R^2) of 0.9996 and a regression equation of $y = 0.01x + 0.0048$. Precision was confirmed through intra-day and inter-day studies, showing low %RSD values of 0.2598 and 0.2987, respectively. Accuracy, evaluated *via* recovery studies at 80%, 100%, and 120% concentration levels, yielded a mean recovery of $99.65\% \pm 1.25$, demonstrating the method's reliability. The method also proved sensitive with a Limit of Detection (LOD) of 0.19872 µg/ml and a Limit of Quantification (LOQ) of 0.652387 µg/ml. Specificity studies confirmed no interference from formulation excipients. Additional parameters, including molar absorptivity (2289.23) and Sandell's sensitivity (0.125), further validated the method's robustness. The results affirm that this UV spectrophotometric method meets ICH validation criteria and is suitable for routine quality control of atorvastatin.

Introduction

The creation of straightforward and repeatable analytical techniques for medication estimation is a crucial component of quality assurance and control. A member of the statin medication class, atorvastatin is used to treat hypercholesterolaemia and associated conditions [1,2]. The parent component of atorvastatin is a white to off white powder that is insoluble in distilled water or very little soluble in it, soluble to readily soluble in methanol, and insoluble in aqueous solutions at pH 4. Chemically Atorvastatin is [R-(R',R'')]-2-(4-fluorophenyl)-β,δ-dihydroxy-5-(1-methylethyl)-3-phenyl-4-[(phenylamino)carbonyl]-1H-pyrrole-1-heptanoic acid (Figure 1). The 3-hydroxy methyl glutaryl coenzyme A (HMG-CoA) reductase enzyme, which is involved in converting HMG-CoA to mevalonate (a precursor of sterols, including cholesterol), is selectively and competitively inhibited by atorvastatin. Patients with hypercholesterolaemia, mixed dyslipidaemia, and homozygous familial hypercholesterolaemia are treated with atorvastatin, a selective, competitive HMG-CoA reductase inhibitor, which lowers cholesterol and triglycerides. HMG-CoA reductase inhibitors also lower blood levels of VLDLs (very low-density lipoproteins) by preventing their production and encouraging their breakdown, which is another way they lower cholesterol.

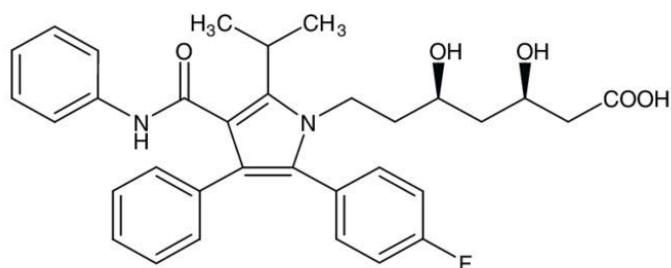


Figure 1. Atorvastatin chemical structure

In order to improve the uptake and degradation of LDL, atorvastatin additionally raises the hepatic LDL receptors on the cell surface and suppresses the liver's production of cholesterol. Additionally, the medication lowers both the quantity of LDL particles and their synthesis [3-6]. There is a need to develop and validate a UV spectroscopic method for atorvastatin to ensure a simple, cost-effective, and reliable analytical approach for its quantitative estimation in pharmaceutical formulations. UV spectroscopy offers a rapid and accessible alternative to more complex techniques like HPLC, making it suitable for routine quality control, especially in resource-limited settings. Method validation is essential to confirm that the developed procedure is accurate, precise, specific, and reproducible according to regulatory standards, thereby ensuring consistent drug quality, efficacy, and patient safety [7-10].

Molecular Formula: $C_{33}H_{35}FN_2O_5$

Molecular Weight: 558.6 g/mol.

Materials and methods

UV spectroscopic method:

A UV-Visible Spectrophotometer (UV-1700 SHIMADZU) with 10 mm matched quartz cells was used for Spectrophotometric method. All weighing were done on electronic balance (Model Shimadzu AUW-220D) [11].

***Correspondence to:** Shoaeb Mohammad Syed, Dayanand Education Society's Dayanand College of Pharmacy Latur, MS India 413531, E-mail: ybccpsh@gmail.com

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Reagents and chemicals:

Atorvastatin (pure drug) was received as a gift sample from Dr. Reddy's Laboratories, Hyderabad and ethanol was purchased from Research-Lab Fine Chem Industries, Mumbai.

Preparation of standard stock solution:

Standard stock solution of atorvastatin was prepared by accurately weighing 10 mg of the drug, and dissolved in 100 ml ethanol.

Determination of analytical wavelength:

0.1 ml of the stock solution mentioned above was pipetted into a 10-ml volumetric flask, and the volume was increased to 10 ml using ethanol. After that, the sample was scanned from 200 to 400 nm in a UV spectrophotometer [11].

Preparation of calibration curve:

A series of 10 ml volumetric flasks were filled with 2 to 12 ml portions of stock solutions, and the volume was adjusted with ethanol. Serial dilutions were made in the following ranges: 20, 40, 60, 80, 100, and 120 µg/ml. At λ_{max} 241 nm, the absorbance was measured [11].

UV method validation

Linearity and range:

A series of 10 ml volumetric flasks were filled with 2 to 12 ml portions of stock solutions, and the volume was adjusted with ethanol. Serial dilutions were made in the following ranges: 20, 40, 60, 80, 100, and 120 µg/ml. At λ_{max} 241 nm, the absorbance was measured [12].

Precision:

The accuracy of the approach was verified using recovery experiments. Following three rounds of each solution, the recovery percentage was calculated. The accuracy of the approach was demonstrated by studies of intra- and inter-day variance.

Limit of detection (LOD) and Limit of quantification (LOQ):

LOD and LOQ were calculated by the equations;

$$\text{LOD} = 3.3\sigma / S \text{ and } \text{LOQ} = 10\sigma / S$$

Where S is the slope of the calibration curve and σ is the residual standard deviation [12].

Recovery study:

Through recovery trials, the method's accuracy was examined. At 80, 100, and 120% of the atorvastatin standard concentration, the recovery was carried out. The recovery samples were made for each recovery level according to the previously described process. Following analysis of the solutions, the calibration curve was used to determine the percentage recoveries [12].

Results

Precision:

The method's accuracy was assessed for atorvastatin. The method's repeatability (intra-day precision) and reproducibility (inter-day precision) were assessed in the same lab. The results were, respectively, 0.2598 and 0.2987 (Table 01).

Table 1. Precision determinations

Precision	Intra-Day Precision*	Inter-Day Precision*
Result	0.2598	0.2987

Table 2. Recovery study

Formulation stock	Total conc	Drug Recovered	% Recovery	Mean % Recovery	SD	%RSD
32	72	72	100	99	0.0789	0.7896
32	72	72.1	99			
32	72	71.99	99			
40	80	80	100	99.99	0.00698	0.006982
40	80	79.99	99.928			
40	80	80	100			
48	88	87.9	99.9887	99.98	0.05489	0.05384
48	88	88	100			
48	88	88	100			
Mean				99.65	0.04541	0.043316

Table 3. Validation parameters

Parameter	Result
Linearity range	20-120 µg/ml
Regression eq.	$y=0.01x + 0.0048$
Correlation coefficient	0.9996
Slope (m)	0.01
Avg % RSD	0.364392
SD Average	0.000606
λ_{max}	241 nm
LOD	0.19872
LOQ	0.652387
Molar absorptivity	2289.23
Sandells sensitivity	0.125
Interday precision	0.2987
Intraday precision	0.2598

Accuracy (Recovery study):

Through recovery trials, the method's accuracy was examined. At three different atorvastatin standard concentrations—80, 100, and 120%—the recovery was carried out. For every level of recovery, three samples were created. Following analysis of the solutions, the calibration curve was used to determine the percentage recoveries. The approach has good repeatability, as evidenced by the atorvastatin recovery value of 99.65 ± 1.25 (Table 2).

Limit of detection (LOD) and limit of quantification (LOQ):

Limit of detection and limit of quantification was found to be 0.19872 & 0.652387 respectively

Specificity:

The method's specificity is its capacity to precisely quantify the analyte response when all possible sample constituents (excipients) are present. The outcomes were contrasted with an investigation of generic atorvastatin and tablet forms. The solid dosage form's excipients had no effect on the analyte. Validation parameters as provided in Table 3. A typical UV spectrum of atorvastatin is provided as per Figure 2 and calibration curve in Figure 3.

Discussion

The present study focused on developing and validating a UV spectrophotometric method for the estimation of atorvastatin, and the results demonstrate that the method is reliable, reproducible, and accurate for routine analysis. Precision studies, both intra-day and inter-day, revealed low %RSD values of 0.2598 and 0.2987 respectively,

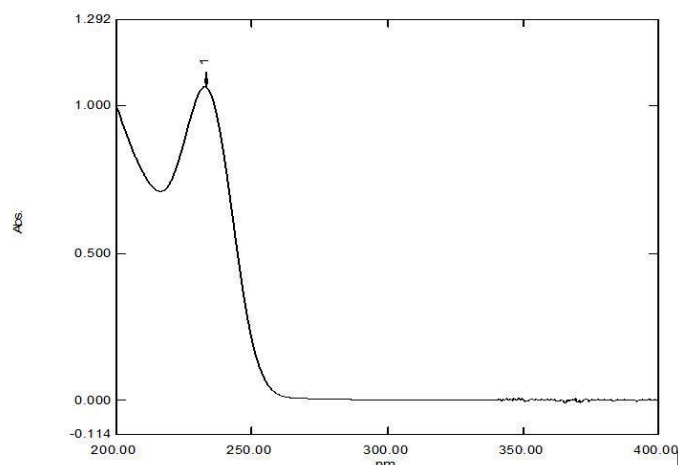


Figure 2. A typical UV Spectrum of Atorvastatin

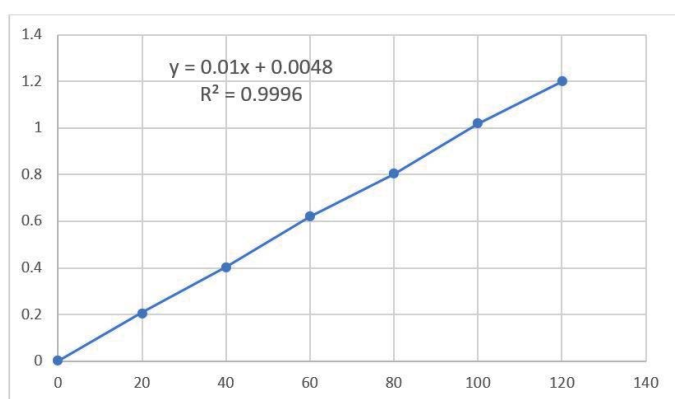


Figure 3. Calibration Curve of Atorvastatin

confirming that the method possesses excellent repeatability and reproducibility under similar laboratory conditions. Accuracy was evaluated using a standard recovery method at three different concentrations (80%, 100%, and 120%). The mean recovery rate was found to be $99.65\% \pm 1.25$, which falls well within the acceptable limits, indicating that the method is accurate and unaffected by matrix interferences or excipients. The standard deviation and %RSD values were minimal, supporting the reliability of the recovery data [13-15]. The method showed a strong linear relationship in the concentration range of 20–120 $\mu\text{g/ml}$, with a correlation coefficient (R^2) of 0.9996, signifying excellent linearity. The regression equation obtained ($y = 0.01x + 0.0048$) further supports the method's suitability for quantitative analysis [16].

The Limit of Detection (LOD) and Limit of Quantification (LOQ) were determined to be 0.19872 $\mu\text{g/ml}$ and 0.652387 $\mu\text{g/ml}$ respectively, suggesting that the method is sensitive enough to detect and quantify even trace levels of atorvastatin [16,17]. In terms of specificity, the method effectively differentiated atorvastatin in the presence of excipients, as there was no interference observed from the tablet formulation, confirming that the method is specific for atorvastatin alone. Additional validation parameters, such as the molar absorptivity (2289.23) and Sandell's sensitivity (0.125), further underscore the method's robustness and sensitivity [18]. Overall, the validated UV spectrophotometric method fulfills all the ICH validation criteria, proving to be simple, accurate, precise, specific, and sensitive. Hence, it is suitable for the routine analysis of atorvastatin in bulk and pharmaceutical dosage forms.

Conclusion

The UV spectrophotometric method developed for the estimation of atorvastatin has been successfully validated in accordance with ICH guidelines. The method demonstrated excellent linearity, precision, accuracy, specificity, and sensitivity, with minimal interference from excipients. The low values of LOD and LOQ indicate the method's capability to detect and quantify even small concentrations of atorvastatin. Given its simplicity, cost-effectiveness, and robustness, this method is well-suited for routine quality control and analysis of atorvastatin in both bulk and pharmaceutical dosage forms.

Conflicts of interest

The authors declare no conflicts of interest.

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Author's contribution

Concept and design: Shoaeb Mohammad Syed, methodology and original draft: Deepika Kumari, critical revision: Shoaeb Mohammad Syed and Deepika kumari

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