International Journal of Scientific Research and Engineering Development-– Volume 7 Issue 4, July-Aug 2024
Available at www.ijsred.com

RESEARCH ARTICLE OPEN ACCESS

Development and validation of UV- Spectrophotometric Method for The Determination of Atorvastatin

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ABSTRACT:

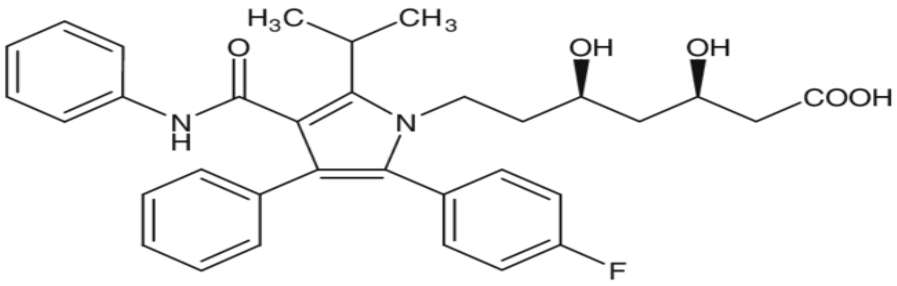
Atrovastatin is medication used to lower cholesterol and triglycerides (fats) levels to help prevent prevent heart disease, angina (chest pain), strokes, and heart attacks. Atorvastatin calcium belongs to a class of medications called HMG-CoA reductase inhibitors (statins). Atorvastatin calcium works by slowing the production of cholesterol in the body to decrease the amount of cholesterol that may build up on the walls of the arteries and block blood flow to the heart, brain, and other parts of the body. Atorvastatin is also used to lower the amount of fatty substances such as low-density lipoprotein (LDL) cholesterol ('bad cholesterol') and triglycerides in the blood and to increase the amount of high-density lipoprotein (HDL) cholesterol ('good cholesterol') in the blood. Atorvastatin may also be used to decrease the amount of cholesterol and other fatty substances in the blood in children and teenagers 10 to 17 years of age who have familial heterozygous hypercholesterolemia (an inherited condition in which cholesterol cannot be removed from the body normally).

KEY WORDS: Atrovastatin, UV-Visible Spectrophotometric, HPLC-UV, Spectro-fluriometry.

INFORMATION:

Atorvastatin is a member of the class of drugs known as statins, used for treatment of hypercholesterolemia and related diseases. Atorvastatin parent compound appears as white to off-white powder, soluble to freely soluble in methanol, slightly soluble in alcohol, insoluble or very slightly soluble in distilled water, and insoluble in aqueous solutions at pH 4. Hydrotropes are defined as compounds that could significantly improve the aqueous solubility of sparingly soluble solute under normal conditions. This phenomenon termed hydrotropy is considered as unique and unprecedented solubilization technique because of the easy recovery of dissolved solute and possible re-use of hydrotropic solutions. Atorvastatin calcium is an important member of statins group which is the first line treatment of hyper-lipidemia because of their effectiveness. Statins inhibit hydroxyl-methyl glutaryl Co-A reductase, a rate-controlling enzyme in cholesterol biosynthesis, reducing the cholesterol production which positively affects the rates of cardiovascular complications and general mortality in patients with coronary artery disease.Atorvastatin calcium hydrate chemically is [R-(R', R')]-2-(4-fluorophenyl)-beta, delta-dihydroxy-5-(1-methylethyl)-3-phenyl4[(phenyl amino) carbonyl]- lH-pyrrole-1- heptanoic acid, calcium salt (2:1) 1, 2 . Atorvastatin calcium is a white to off-white crystalline powder1 used for Antilipemic agents (synthetic cholesterol lowering agent), Anti-cholesteremic agents.

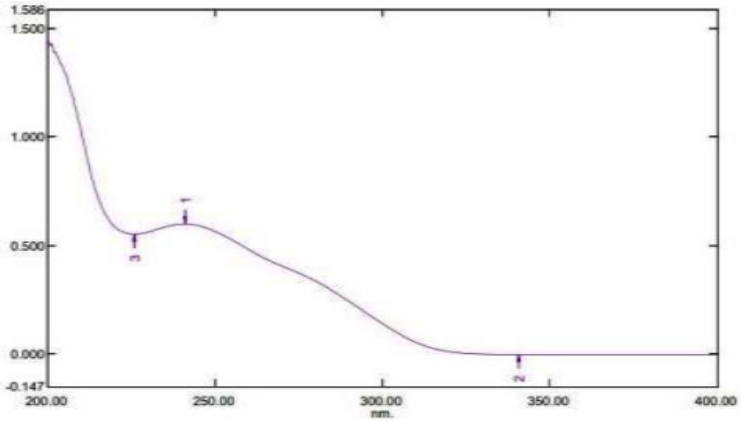
Atorvastatin, a selective, competitive HMG-CoA reductase inhibitor, is used to lower cholesterol and triglycerides in patients with hypercholesterolemia and mixed dyslipidemia and in the treatment of homozygous familial hypercholesterolemia.. As an additional cholesterol-lowering mechanism, HMG-CoA reductase inhibitors also decrease the blood concentrations of VLDLs (very low-density lipoproteins) by inhibiting their synthesis and promoting their catabolism. Atorvastatin calcium also inhibits the cholesterol synthesis in the liver and increases the hepatic LDL receptors on the cell surface to enhance the uptake and catabolism of LDL. The drug also reduces the LDL production and the number of LDL particles.



Structure of Atrovastatin

UV-VISIBLE SPECTROPHOTOMETRIC METHOD:

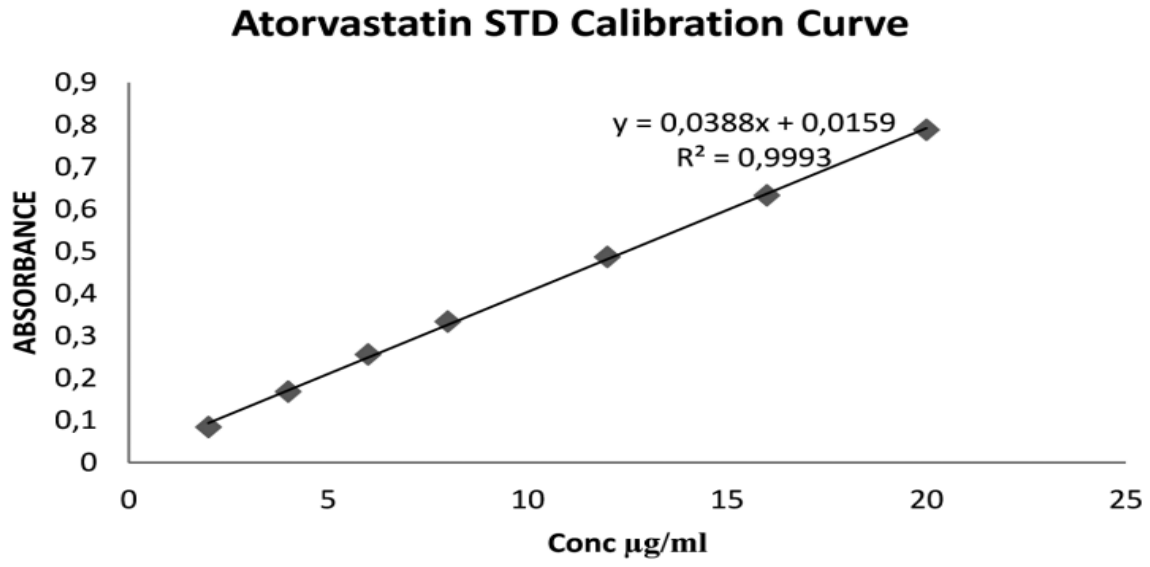
VISHAL et al,2023: was developed the method and validated the Atrovastatin calcium by UV-Visible spectroscopy. The objective of this research is to describe the optimization, validation, and application of spectrophotometric techniques for determination of Atorvastatin Calcium in their pharmaceutical formulation (tablets). In this paper simple, rapid, accurate and sensitive spectrophotometric methods have been developed and validated. This method is a direct spectrophotometric analytical method depends on dissolve of Atorvastatin calcium in diluted in water and methanol in ratio of (90:10). The maximum absorption wavelength for determination of ATR drug was found to be 241 nanometer (nm), for Beer's law was obeyed in the concentration range from 4 to 32 µg/ml for UV- Spectrophotometric analysis method[6]



UV-spectrum of atorvastatin calcium

SUBRAMANAYA RAJ et al, 2020: was estimated the atorvastatin calcium in pharmaceutical preparation by sing spectrophotometric method as Present study describes development and validation of UV-Spectrophotometric method for the estimation of Atorvastatin Calcium in pharmaceutical preparation. During development of analytical methods, methanol and hydrotropic solubilization reagent is employed to enhance aqueous solubility of poorly water soluble Atovastatin Calcium in dosage forms. In the proposed methods 2M Urea and 2M Thiourea solution is used as hydrotropic solubilizing agent. Absorption maxima was determined with 10µg/ml solution by scanning in the range 200-400nm. Standard stock solution prepared in methanol (max:247nm) and hydrotropic solubilization agent in water(max:240nm). The proposed methods obeys Beer's law in the range 5-40 µg/ml. The methods were validated in terms of Linearity, Precision and Accuracy. Results of analysis were validated statistically and by recovery studies. It was observed that there is no interference of impurities or excipients during the estimation of drug. This shows the adoptability of the methods for routine analysis of drugs in marketed formulations in quality control laboratories[7]

TILAL ELSAMAN et al, 2020: was developed and validated the atorvastatin calcium using sodium citrate as hydrotropic agent by using UV-Spectrophotometric method as Simple, rapid, precise, accurate and specific UV-spectrophotometric method has been developed for atorvastatin calcium determination in bulk and in tablets dosage form. The method was based on using sodium citrate 0.01M as hydrotropic agent. Measurements of the UV absorbance were performed at 241 nm, and the developed method was validated as per ICH guidelines. The method obeyed Beer's law (R2 = 0.999) in a concentration range of 2 – 20 µg/mL. The limits of detection (LOD) and quantification (LOQ) were 0.64 and 1.9 µg/mL, respectively. At all levels of precision, RSD% values were below 2%. Accuracy of the proposed method was ascertained by standard addition method and the percentage recovery (n = 3) was within 100 – 100.43%. The method was applied to analysis of three atorvastatin tablet brands each claimed to contain 20 mg atorvastatin, and the percentage drug content was found to be 101.42 ± 1.56%, 99.04 ± 0.33%, and 97.71 ± 0.98%[8]



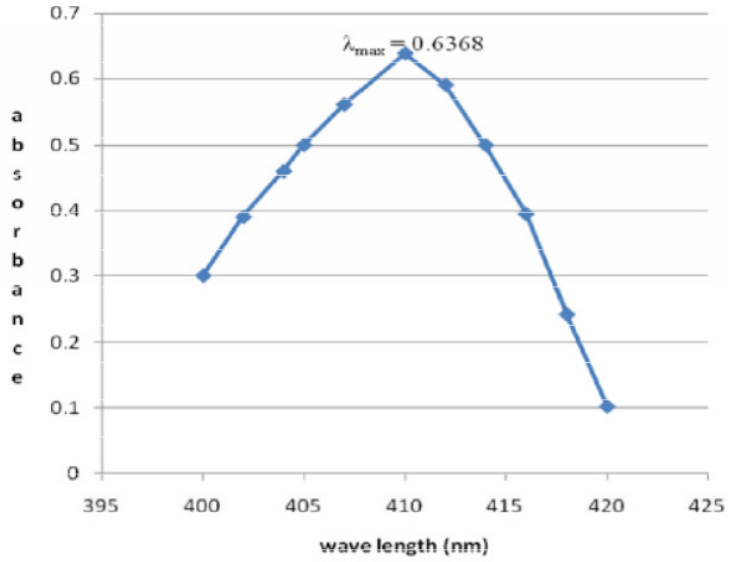
S. K. RATH et al,2013: developed and validated the new analytical method for the estimation of atorvastatin calcium hydrate residue by using spectrophotometer as it ia a new, simple and sensitive spectroscopic method has been developed for the estimation of Atorvastatin calcium hydrate

residue by using swabbing technique. In the proposed method the absorbance was measured 245.0nm corresponding to the absorbance maxima of Atorvastatin calcium in the ratio methanol and water as 90:10 as a solvent. Shimadzu-2450 UV-Visible spectrophotometer with UV Prove 2.31 software, capable of multi-component analysis, was used for quantization. Linearity range was observed in the concentration range of 1-10µg/ml for Atorvastatin. The % recovery of Atorvastatin was found out to be 100.2%. The method was validated statistically and recovery study was performed to confirm the accuracy of the method. The method was found to be rapid, simple, accurate and precise[5]

Y PADMAVATHI et al,2019: was developed and validated of first order derivative spectrophotometric method for simultaneous estimation of atorvastatin calcium and asprin in capsules as a simple UV spectrophotometric method using first order derivative technique was developed for the simultaneous estimation of atorvastatin calcium and aspirin in capsules. The atorvastatin calcium and aspirin stock solutions were prepared in (50: 50 v/v) methanol: water and scanned in UV- region for first order derivative spectrum. The zero crossing point for atorvastatin calcium and aspirin was 243 nm and 276 nm respectively. Linearity was established over the concentration range of 6-14 µg/ml and 20-100 µg/ml for atorvastatin calcium and aspirin with correlation coefficient (r2) value 0.998 and 0.999 respectively. The method was validated according to ICH guidelines for validation parameters like accuracy, precision, limit of detection and limit of quantification. They found to be within limits. The method was successfully applied for quantitative estimation of atorvastatin calcium and aspirin in capsules[9]

ALRASHEED A.W. et al, 2019: development and validation method for the determination of atorvastatin calcium tablets drugs by using UV-spectrophotometer in pharmaceutical formulation. The objective of this research is to describe the optimization, validation, and application of spectrophotometric techniques for determination of Atorvastatin Calcium in their pharmaceutical formulation (tablets). In this paper simple, rapid, accurat and sensitive spectrophotometric methods have been developed and validated. This method is a direct spectrophotometric analytical method depend on dissolve of atorvastatin calcium in diluted anhydrous methanol methanol. The maximum absorption wavelength for determination of ATV drug was found to be 291 nanometer (nm), for Beer's law was obeyed[4]

G MANASA et al, 2014: validated UV-Visible spectrophotometric method for the estimation of atorvastatin in pure and pharmaceutical dosage forms using methyl orange reagent as ,A simple UV-Visible spectrophotometric method has been developed for the determination of Atorvastatin in its pure form as well as pharmaceutical dosage form using Methyl Orange reagent. The method is based on the measurement of absorbance of Atorvastatin in methanol at 410 nm. The Beer's law is obeyed over the linear range 50-300µg /ml of Atorvastatin. All the variables were studied to optimize the reaction conditions. No interference was observed in the presence of common pharmaceutical excipients. The validity of the method was tested
by analyzing the drug in its pharmaceutical preparations. Good recoveries were also obtained. Assay for the tablet preparation was performed using UV-Visible spectrophotometric method and the results were found to be within acceptable limits[1]



Absorption spectrum

SPECTROFLURIOMETRY METHOD:

NISREEN AHMAD et al, 2023: was developed and validated a simple method for determination of atorvastatin calcium in pure and pharmaceutical formulations using spectrfluriometry as , A simple, accurate, precise, sensitive and selective spectrofluorimetric method was developed and validated for the determination of Atorvastatin calcium (ATV), an HMG-CoA reductase inhibitor, in its pure and tablet dosage form. The proposed method was based on direct measurement of the native fluorescence of ATV. Fluorescence analysis was accomplished by using an emission wavelength 385 nm after excitation at the wavelength of 270 nm in acetonitrile, without difficult preparation steps of the sample solution such as separation, extraction, pH adjustment or derivatization. All variables affecting the fluorescence intensity such as measurement time, temperature, and diluting solvent were investigated and optimized. Under the typical conditions, a validation study for linearity, range, accuracy, precision, selectivity and robustness of the proposed method was implemented according to ICH guidelines. The fluorescence intensity was linear over concentration range of (0.4–12) µg/ml (r = 0.9999), and the lower limits of detection and quantification were 0.079 and 0.24 µg/ml, respectively. Good accuracy and precision results were obtained through using the presented method with excellent mean recovery value 100.08 ± 0.32 which was in the acceptable range (98.0–102.0%), and RSD <2%, proving the precision of the developed method.

HPLC-UV METHOD:

KHALED MAGED et al,2023: developed and validated of an eco-friendly HPLC-UV method for determination of atorvastatin and vitamin d_3 in pure form and pharmaceutical formulation as Statin-associated muscle symptoms are considered as obvious adverse effects of prolonged statin therapy such as myopathy, myalgia, and rhabdomyolysis. These side effects are associated with vitamin D_3 deficiency and can be adjusted by amendment of serum vitamin D_3 level. Green chemistry aims to decrease the harmful effects of analytical procedures. Here we have developed a green and eco-friendly HPLC method for the determination of atorvastatin calcium and vitamin D_3. The two drugs were separated in less than 10 min on Symmetry column C_{18} (100 × 4.6 mm,

3.5 µm) using a mixture consisting of 0.1% ortho-phosphoric acid (OPA) (pH = 2.16) and ethanol as the mobile phase in gradient manner. We have used Green Analytical Procedure Index (GAPI) tools and the Analytical Grenness Metric Approach (AGREE) for assessment of the greenness of our proposed method. The method proved linearity over concentration ranges of (5–40) and (1–8) µg/ml with low limit of detection of 0.475 and 0.041 µg/ml for atorvastatin calcium and vitamin D_3 respectively. The method was successfully validated in accordance with ICH instructions and utilized for determination of the drugs of interest either in pure form or in their pharmaceuticals.

CONCLUSION:

In this review article, several analytical techniques, including High performance liquid chromatography-Ultraviolet method, Spectrofluriometry method, ultraviolet spectrophotometric methods have been discussed the development and validation of atorvastatin and estimation of atorvastatin.

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