WORLD JOURNAL OF PHARMACEUTICAL RESEARCH
Coden USA: WJPRAP Impact Factor 8.63
Volume 15, Issue 10, 1429-1439. Review Article ISSN 2277–7105

SYSTEMATIC REVIEW OF VALIDATED METHODS FOR THE CO-ANALYSIS OF AMLODIPINE AND ATORVASTATIN

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Article Received on 14 April 2026,
Article Revised on 04 May 2026,
Article Published on 16 May 2026,
https://doi.org/10.5281/zenodo.20265688

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How to cite this Article: Nidhi Dobariya[*1], Khushi Joshi[2], Dr. Ketan Shah[3], Dr. Ashok Akabari[4]. (2026). Systematic Review of Validated Methods For The Co-Analysis of Amlodipine And Atorvastatin. World Journal of Pharmaceutical Research, 15(10), 1429–1439.

ABSTRACT

Managing your cardiovascular health often involves a combination of medications that target different aspects of your heart's well-being. Amlodipine is a calcium channel blocker primarily used to treat high blood pressure and prevent chest pain, known as angina. By relaxing and widening your blood vessels, it allows blood to flow more easily, which significantly reduces the long-term risk of heart attacks and strokes. It is a convenient treatment, typically taken just once a day as a tablet or liquid, though it works best when taken at the same time every day to maintain a steady level in your system. Working alongside blood pressure management is the need to control cholesterol, which is where Atorvastatin comes in. As a member of the statin family, it works by blocking a specific enzyme in the liver that the body uses to produce cholesterol. By lowering the amount of cholesterol in your blood, it helps prevent the fatty buildup in your arteries that leads to heart disease. To ensure these medications are both safe and effective, researchers utilize advanced laboratory techniques like UV-Visible Spectrophotometry and High-Performance Liquid Chromatography (HPLC). These methods allow scientists to precisely measure the concentration and purity of the drugs, ensuring that every dose is consistent and reliable for the patient.

KEYWORDS: Amlodipine**,** Atorvastatin, UV-Vis Spectrophotometry, High-Performance Liquid Chromatography (HPLC).

1. INTRODUCTION

1.1 AMLODIPINE

Amlodipine besylate is a vital tool for anyone managing mild to moderate high blood pressure or chronic chest pain, known as stable angina. Chemically categorized as a dihydropyridine, its primary job is to act as a calcium channel blocker. Think of it as a "gatekeeper" that slows down the movement of calcium into the cells of your heart and blood vessel walls. Because calcium is what triggers muscles to contract, limiting its flow allows your blood vessels to relax and open up. This makes it much easier for the heart to pump blood, effectively lowering your blood pressure and reducing the overall strain on your cardiovascular system. Whether used on its own or as part of a combination therapy, amlodipine is highly effective at managing coronary artery issues and keeping chest pain at bay. One of its most reliable features is how steadily it works; after you take it, the medication is absorbed gradually, reaching its peak effectiveness in the bloodstream between 6 and 12 hours later. This slow and steady approach ensures that the heart doesn't have to work nearly as hard, providing consistent, long-term protection for your heart health.

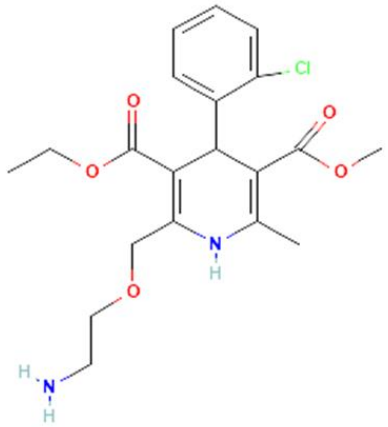

Fig. 1: Structure of Amlodipine besylate.

1.2 ATORVASTATIN

Atorvastatin calcium is a cornerstone of heart health, working as a "statin" to manage cholesterol and protect your cardiovascular system. It targets the liver to block a key enzyme responsible for producing cholesterol, which prompts your body to clear "bad" cholesterol (LDL) from the bloodstream more effectively. In many cases, it can reduce these harmful levels by 40% to 60%. Beyond just improving your lab results, Atorvastatin provides critical protection for your arteries. It helps stabilize plaque buildup, reducing the risk that it will rupture and trigger a heart attack or stroke. By lowering harmful fats like triglycerides while

boosting "good" cholesterol (HDL), the medication offers a comprehensive defense that strengthens your overall resistance to major cardiovascular events.

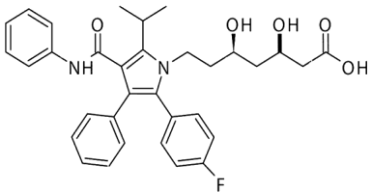

Fig. 2: Structure of Atorvastatin Calcium.

1.3 UV-VIS SPECTROSCOPY

UV-Vis spectroscopy is a cornerstone of pharmaceutical analysis, acting as a high-precision tool for identifying and quantifying substances. At its heart, the process involves measuring how much light a chemical solution absorbs across the ultraviolet (190–400 nm) and visible (400–800 nm) spectrums. This technique is indispensable throughout the drug manufacturing lifecycle, allowing researchers to monitor everything from raw materials to complex intermediates. The science behind this involves a delicate dance of energy: when molecules encounter light that matches their specific needs, electrons jump from stable or non-bonding orbitals to higher energy levels. These shifts—often coupled with subtle molecular vibrations and rotations—are what cause the light to be absorbed. This is particularly effective for compounds with conjugated double bonds, which naturally possess a strong "appetite" for UV or visible light. Interestingly, even if a compound doesn't naturally absorb UV light, scientists can often "tag" it with reagents to create colored complexes that are easily readable in the visible range. A helpful rule of thumb in this field is that as the complexity of a molecule's conjugated system grows, its absorption footprint shifts further into the visible spectrum, making the invisible world of chemistry perceptible and measurable.

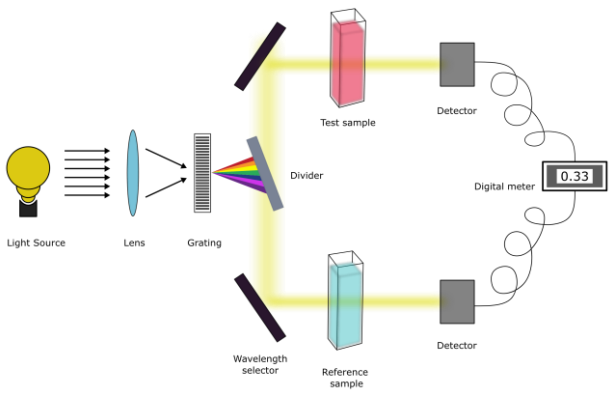

Fig. 3: Instrumentation of UV-Vis spectroscopy.

1.4 High-Performance Liquid Chromatography (HPLC)

Think of High-Performance Liquid Chromatography (HPLC) as the "gold standard" of the analytical world. It is a remarkably precise technique used to untangle complex mixtures, allowing scientists to identify exactly what is in a liquid sample and in what quantity. In the pharmaceutical industry, this is the go-to method for ensuring drug products are pure, safe, and consistent. The process generally operates in two distinct modes: Normal Phase, where the stationary part of the system is polar, and Reverse Phase, which is the more common approach using a non-polar setup. To get the sample moving through the system, scientists use a "mobile phase"—essentially a liquid carrier. While a mix of acetonitrile and water is the standard choice, experts often fine-tune this liquid by adding buffers, like orthophosphoric acid, to hit a specific pH that ensures the sample stays stable. The "heart" of the machine is the column, which acts as a molecular filter. Most labs rely on C18 columns (from brands like Cosmosil or Eclipse), though C8 columns are sometimes used for specific separation needs. Once the components are separated, they pass through a detector—usually a Photodiode Array (PDA) or a UV detector—which "sees" the chemicals as they emerge, translating a liquid mixture into a clear, readable graph of data.

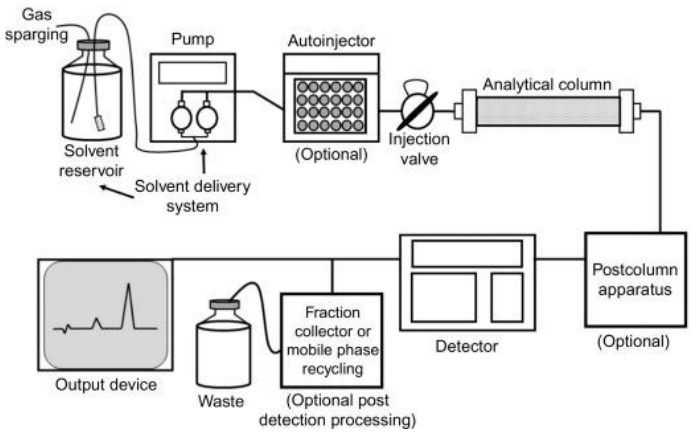

Fig. 4: Instrumentation of HPLC.

2. LITERATURE REVIEW

Sr. No.	Title name	Summary
1	Method development and validation of amlodipine besylate in API and pharmaceutical dosage form by UV spectroscopy	For the analytical profile of the substance, the maximum absorption wavelength was identified at 245 nm. The method demonstrated a clear linearity within the concentration range of 2-10 µg/ml, using distilled water as the primary solvent for the analysis.
2	Development And Validation of	Using dil.HCL as a solvent, the compound showed

	UV Spectrophotometric Method for The Estimation pf Amlodipine Besylate in Bulk and Dosage Form	a peak absorbance at 239 nm and demonstrated linearity within the concentration limits of 4 to 20 µg/ml
3	Method development, validation and stability study of Amlodipine in marketed formulation by UV spectrophotometric method	Spectrophotometric analysis in methanol revealed a λmax at 360 nm, with the Beer-Lambert law obeyed over a concentration range of 6-80 µg/ml
4	UV spectroscopic method for estimation of Amlodipine besylate in tablets	The UV-visible spectrum of the sample in Distilled Water displayed a characteristic absorption peak at 366 nm, maintaining a linear response across concentrations ranging from 5 to 25 µg/ml
5	Development and Validation of UV Spectrophotometric Method for Estimation of Amlodipine Besylate in Tablet Dosage Form	Spectrophotometric analysis in methanol revealed a λmax at 281 nm, with the Beer-Lambert law obeyed over a concentration range of 5-30 µg/ml.
6	Reversed phase HPLC method development and validation for the analysis of amlodipine besylate in tablets dosage form and human plasma.	The chromatographic analysis was conducted using a C-18 column 150 x 4.6mm) and a UV/Vis detector set at a λmax of 240 nm, where a mobile phase of acetonitrile: phosphate buffer (45:55 v/v) yielded a retention time of 2.25 minutes.
7	Stability Indicating Assay Method Development and Validation of Amlodipine Besylate in Bulk and Tablet Dosage form by UV Spectroscopy and RP-HPLC	The chromatographic analysis was conducted using a C-18 column 250 x 4.6mm) and a PDA detector set at a λmax of 238 nm, where a mobile phase of methanol: water (80:20 v/v) yielded a retention time of 3.253 minutes.
8	Analytical method development and validation of Amlodipine besylate in tablet dosage form	The chromatographic analysis was conducted using a C-18 column 250 x 3.9 mm) and an UV-Vis detector set at a λmax of 237 nm, where a mobile phase of acetonitrile: methanol: Buffer (15:35:50 v/v/v) yielded a retention time of 12.3 minutes
9	A high-performance liquid chromatographic (HPLC) method for the determination of amlodipine drug in dosage form using 1,2-naphthoquine-4-sulfonate	The chromatographic analysis was conducted using a C-18 column 250 x 3.9 mm) and an UV-Vis detector set at a λmax of 465 nm, where a mobile phase of potassium dihydrogen orthophosphate (0.05M) in water: acetonitrile (45:55%v/v) yielded a retention time of 3.132 minutes
10	UV and First Derivative Spectrophotometric Methods for the Estimation of Atorvastatin in Pharmaceutical Preparations	Spectrophotometric analysis in methanol revealed a λmax at 247 nm, with the Beer-Lambert law obeyed over a concentration range of 5-20 µg/ml
11	Development and validation of new analytical method for the estimation of atorvastatin calcium hydrate residue by using UV spectrophotometer	Spectrophotometric analysis in methanol revealed a λmax at 245 nm, with the Beer-Lambert law obeyed over a concentration range of 1-10 µg/ml

12	Determination of atorvastatin calcium in pure and its pharmaceutical formulations using iodine in acetonitrile by UV-visible spectrophotometric method	Spectrophotometric analysis in methanol revealed a λmax at 291 nm, with the Beer-Lambert law obeyed over a concentration range of 1-20 µg/ml
13	UV and First Derivative Spectrophotometric Methods for the Estimation of Atorvastatin in Pharmaceutical Preparations	Spectrophotometric analysis in methanol revealed a λmax at 320 nm, with the Beer-Lambert law obeyed over a concentration range of 5-20 µg/ml
14	A novel UV spectrophotometric method for simultaneous estimation of metoprolol tartrate and atorvastatin calcium based on absorbance correction principle	Spectrophotometric analysis in methanol revealed a λmax at 244.8 nm, with the Beer-Lambert law obeyed over a concentration range of 2-100 µg/ml
15	Validation of HPLC method for determination of Atorvastatin in tablets and for monitoring stability in solid phase	The chromatographic analysis was conducted using a C-18 column 250 x 4.6 mm) and an UV-Vis detector set at a λmax of 245 nm, where a mobile phase of water: acetonitrile(48:52v/v) yielded a retention time of 6.5 minutes
16	Stability-indicating RP-HPLC method for analysis of atorvastatin in bulk drug, marketed tablet and nanoemulsion formulation	The chromatographic analysis was conducted using a C-18 column 250 x 4.6 mm) and an UV-Vis detector set at a λmax of 237 nm, where a mobile phase of 0.05 M sodium phosphate buffer and methanol (3:7 v/v) yielded a retention time of 4.02 minutes
17	A Validated Reversed-Phase HPLC Method for the Determination of Atorvastatin Calcium in Tablets	The chromatographic analysis was conducted using a C-18 column 250 x 34.6 mm) and an UV-Vis detector set at a λmax of 246 nm, where a mobile phase of 0.1% acetic acid solution: acetonitrile (45:55, v/v) yielded a retention time of 6.312 minutes
18	Stability indicating RP-HPLC estimation of atorvastatin calcium and amlodipine besylate in pharmaceutical formulations	The chromatographic analysis was conducted using a C-18 column 250 x 4.6 mm) and an UV-Vis detector set at a λmax of 240 nm, where a mobile phase of : 0.02 M potassium dihydrogen phosphate: acetonitrile: methanol (30:10:60, v/v/v)yielded a retention time of 12.3 minutes
19	High performance liquid chromatographic-uv method for determination of atorvastatin calcium in pharmaceutical formulations	The chromatographic analysis was conducted using a C-18 column 250 x 4.6 mm) and an PDA detector set at a λmax of 246 nm, where a mobile phase of acetonitrile-dichloromethane-acetic acid (68.6: 30.6: 0.8 v/v/v) yielded a retention time of 2.68 minutes
20	Simultaneous Estimation of Amlodipine and Atorvastatin Using UV Spectroscopy Method	In this analytical study, the maximum absorption wavelengths were determined to be 365 nm for Amlodipine and 246 nm for Atorvastatin. Both substances exhibited a consistent linearity range of 2 to 10 µg/mL, with methanol utilized as the solvent for the procedure.

21	Simultaneous Estimation of Atorvastatin Calcium and Amlodipine Besylate from Tablets.	In this analytical study, the maximum absorption wavelengths were determined to be 360 nm for Amlodipine and 246 nm for Atorvastatin. Both substances exhibited a consistent linearity range of 5 to 30 µg/mL, with methanol utilized as the solvent for the procedure.
22	Simultaneous Estimation of Atorvastatin Calcium and Amlodipine besylate by UV Spectrophotometric method using hydrotropic solubilization	In this analytical study, the maximum absorption wavelengths were determined to be 243 nm for Amlodipine and 247 nm for Atorvastatin. Both substances exhibited a consistent linearity range of 10 to 60 µg/mL, with methanol utilized as the solvent for the procedure.
23	Simultaneous spectrophotometric determination of amlodipine besylate and atorvastatin calcium in amlodipine besylate and atorvastatin calcium in binary mixture	In this analytical study, the maximum absorption wavelengths were determined to be 238.2 nm for Amlodipine and 246.6 nm for Atorvastatin. Both substances exhibited a consistent linearity range of 5 to 30 µg/mL, with methanol utilized as the solvent for the procedure.
25	Sustainable and white HPLC method for simultaneous determination of amlodipine and atorvastatin in film-coated tablet	The chromatographic analysis was performed using a C18 column (250 × 4.0 mm, 5 µm) paired with a photo-diode array detector set at a wavelength of 254 nm. The system operated at a flow rate of 0.8 mL/min, utilizing a mobile phase composed of a 63:37% (v/v) mixture of ethanol and 0.02 M sodium dihydrogen phosphate monohydrate. Under these conditions, the substances were effectively separated, with Amlodipine showing a retention time of 5.6 minutes and Atorvastatin appearing at 9.4 minutes.
26	Stability Indicating RP-HPLC Method for Simultaneous Determination of Atorvastatin and Amlodipine from Their Combination Drug Products	The chromatographic analysis was performed using a C18 column (250 × 4.0 mm, 5 µm) paired with UV-Vis detector set at a wavelength of 254 nm. The system operated at a flow rate of 1 mL/min, utilizing a mobile phase acetonitrile and 50 mM potassium dihdrogen phosphate buffer (60 : 40, v/v). Under these conditions, the substances were effectively separated, with Amlodipine showing a retention time of 2.79 minutes and Atorvastatin appearing at 5.02 minutes.
27	HPLC Method Development and Validation for the Estimation of Amlodipine and Atorvastatin in Bulk and Formulation	The chromatographic analysis was performed using a C18 column (250 × 4.0 mm, 5 µm) paired with a UV-Vis detector set at a wavelength of 237 nm. The system operated at a flow rate of 1 mL/min, utilizing a mobile phase monopotassium phosphate: Acetonitrile 20:80 v/v. Under these conditions, the substances were effectively separated, with Amlodipine showing a retention time of 1.9 minutes and Atorvastatin appearing at 8.9 minutes.

28	A stability-indicating high performance liquid chromatographic (HPLC) assay for the simultaneous determination of atorvastatin and amlodipine in commercial tablets	The chromatographic analysis was performed using a C18 column (250 × 4.0 mm, 5 µm) paired with an UV-Vis detector set at a wavelength of 237 nm. The system operated at a flow rate of 1 mL/min, utilizing a mobile phase acetonitrile–0.025 M NaH2PO4 buffer (55:45, v/v) pH 4.5. Under these conditions, the substances were effectively separated, with Amlodipine showing a retention time of 4.3 minutes and Atorvastatin appearing at 9.5 minutes.
29	Analytical method development and validation of simultaneous determination of atorvastatin calcium and amlodipine besilate in tablet dosage form by RP-HPLC	The chromatographic analysis was performed using a C18 column (250 × 4.0 mm, 5 µm) paired with a photo-diode array detector set at a wavelength of 246 nm. The system operated at a flow rate of 1 mL/min, utilizing a mobile phase mixture of phosphate buffer acetonitrile and methanol (53:43:4, v/v) Under these conditions, the substances were effectively separated, with Amlodipine showing a retention time of 3.337 minutes and Atorvastatin appearing at 6.067 minutes.
30	Stability indicating RP-HPLC estimation of atorvastatin calcium and amlodipine besylate in pharmaceutical formulations	The chromatographic analysis was performed using a C18 column (250 × 4.0 mm, 5 µm) paired with an UV-Vis detector set at a wavelength of 240 nm. The system operated at a flow rate of 1 mL/min, utilizing a mobile phase 0.02 M potassium dihydrogen phosphate: acetonitrile: methanol (30:10:60 v/v/v). Under these conditions, the substances were effectively separated, with Amlodipine showing a retention time of 4.5 minutes and Atorvastatin appearing at 11.6 minutes.

3. CONCLUSION

This review serves as a strategic roadmap for researchers navigating the analytical landscape of Amlodipine and Atorvastatin. By synthesizing the diverse array of light-based measurement techniques and sophisticated chemical separation tools currently available, the guide transforms complex technical data into a practical framework. The primary goal is to streamline the development and validation of drug assessments, providing scientists with the clarity needed to refine their methodologies. Ultimately, this leads to more reliable, efficient, and robust testing protocols, ensuring these critical cardiovascular medications meet the highest standards of pharmaceutical quality and safety.

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