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ANALYTICAL METHOD DEVELOPMENT AND VALIDATION FOR (S)-(-)-AMLODIPINE-O, O-DI-P-TOLUOYL-D-TARTRATE BY HIGH-PERFORMANCE LIQUID CHROMATOGRAPHY

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ABSTRACT: A novel, robust, and sensitive high-performance liquid chromatography (HPLC) method was successfully developed and validated for the quantitative determination of (S)-(-)-amlodipine-o, o-di-p-toluoyl-D-tartrate, a crucial chiral intermediate in pharmaceutical synthesis. The analysis was carried out on a reversed-phase C18 column using a mobile phase comprising acetonitrile and phosphate buffer (pH 3.0) in a 60:40 (v/v) ratio, delivered at a flow rate of 1.0 mL/min. Detection was performed at 237 nm using a UV detector. Method validation followed ICH Q2(R1) guidelines and confirmed the approach's linearity, accuracy, precision, specificity, robustness, and sensitivity. The method exhibited excellent linearity within the concentration range of 0.5–100 µg/mL, with a correlation coefficient (R^2) of 0.9998. The limit of detection (LOD) and limit of quantification (LOQ) were found to be 0.15 µg/mL and 0.45 µg/mL, respectively. Precision results showed a relative standard deviation (RSD) of less than 1.5%, and recovery values ranged between 98.5% and 101.2%, indicating high accuracy. This validated HPLC method is well-suited for routine quality control and stability testing of (S)-(-)-amlodipine-o, o-di-p-toluoyl-D-tartrate in Pharmaceutical environments.

INTRODUCTION: (S)-(-)-amlodipine-o, o-di-p-toluoyl-D-tartrate is a critical chiral intermediate in the synthesis of amlodipine, a dihydropyridine calcium channel blocker widely used for the management of hypertension and angina pectoris [1, 2]. The enantiomeric purity and chemical stability of this intermediate are paramount to ensuring the safety, efficacy, and quality of the final pharmaceutical product [3, 4].

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Given the stringent regulatory requirements for chiral drug intermediates, the development of robust, sensitive, and validated analytical methods is essential for quality control and process optimization in pharmaceutical manufacturing [5, 6]. High-performance liquid chromatography (HPLC) is a cornerstone analytical technique for the quantification of chiral compounds due to its high sensitivity, selectivity, and reproducibility [7, 8].

HPLC methods are particularly advantageous for resolving enantiomers and detecting impurities in complex matrices, making them indispensable in pharmaceutical analysis [9, 10]. Despite the widespread use of amlodipine, there is a paucity of literature on validated HPLC methods specifically tailored for the determination of (S)-(-)-

amlodipine-o, o-di-p-toluoyl-D-tartrate [11]. Existing analytical methods for amlodipine intermediates often lack comprehensive validation or are not optimized for routine quality control, highlighting the need for a dedicated method for this chiral intermediate [12, 13].

Method development for chiral intermediates involves optimizing chromatographic conditions to achieve adequate resolution, peak symmetry, and minimal run time while ensuring compatibility with regulatory guidelines, such as those outlined by the International Council for Harmonisation (ICH) Q2(R1) [14, 15]. Validation of such methods encompasses parameters like linearity, precision, accuracy, specificity, limit of detection (LOD), limit of quantification (LOQ), and robustness to ensure reliability in routine applications [16, 17]. Recent advancements in HPLC, including the use of reversed-phase columns and UV detection, have facilitated the development of efficient methods for chiral intermediates, yet challenges remain in achieving high sensitivity and enantiomeric resolution for compounds like (S)-(-)-amlodipine-o, o-di-p-toluoyl-D-tartrate [18, 19]. This study aims to address these gaps by developing and validating a novel HPLC method for the quantitative determination of (S)-(-)-amlodipine-o, o-di-p-toluoyl-D-tartrate. The method is designed to be simple, rapid, and robust, suitable for routine quality control and stability studies in pharmaceutical settings [20]. By adhering to ICH Q2(R1) guidelines, the proposed method seeks to provide a reliable tool for ensuring the quality of this critical chiral intermediate, contributing to the broader field of pharmaceutical analysis.

EXPERIMENTAL:

Chemicals and Reagents: HPLC-grade acetonitrile and methanol were purchased from Merck. Potassium dihydrogen phosphate (KH_2PO_4), orthophosphoric acid (H_3PO_4), and triethylamine were procured from Fisher Scientific. Ultrapure water (resistivity ≥ 18.2 MΩ·cm) was generated using a Milli-Q purification system. All other chemicals were of analytical grade unless otherwise specified.

Instrumentation: Chromatographic analysis was performed using an Agilent 1260 Infinity II HPLC system (Agilent Technologies, Santa Clara, CA, USA) equipped with a quaternary pump (G7111B), autosampler (G7129A), thermostatted column compartment (G7116B), and variable wavelength UV-Vis detector (G7114A). Data acquisition and processing were conducted using OpenLab CDS 2.5 software (Agilent Technologies). A Zorbax Eclipse Plus C18 column (250 mm × 4.6 mm, 5 µm particle size, Agilent Technologies) was used for separation. A pH meter was employed for buffer pH adjustments.

Chromatographic Conditions: The mobile phase consisted of acetonitrile and 20 mM potassium dihydrogen phosphate buffer (pH adjusted to 3.0 ± 0.1 with orthophosphoric acid) in a 60:40 (v/v) ratio. The mobile phase was filtered through a 0.45 µm nylon membrane filter and degassed by sonication for 15 min before use. The flow rate was set at 1.0 mL/min, and the column temperature was maintained at 25 ± 1°C. The injection volume was 10 µL, and detection was performed at 237 nm, based on the UV absorption maximum of (S)-(-)-amlodipine-o, o-di-p-toluoyl-D-tartrate [21]. The total run time was 8 min.

Preparation of Standard and Sample Solutions: A stock solution of (S)-(-)-amlodipine-o, o-di-p-toluoyl-D-tartrate (1000 µg/mL) was prepared by dissolving 10 mg of the reference standard in 10 mL of acetonitrile in a volumetric flask. Working standard solutions (0.5, 1, 5, 10, 50, 80, and 100 µg/mL) were prepared by serial dilution of the stock solution with the mobile phase. Sample solutions were prepared by dissolving synthesized batches of (S)-(-)-amlodipine-o, o-di-p-toluoyl-D-tartrate in acetonitrile to achieve a nominal concentration of 50 µg/mL. All solutions were stored at 4°C and protected from light to prevent degradation [22].

Method Development: The HPLC method was developed by optimizing key parameters, including column type, mobile phase composition, pH, flow rate, and detection wavelength. Several stationary phases (C8, C18, and phenyl) were evaluated, with the C18 column selected for its superior resolution and peak symmetry. Mobile phase compositions ranging from 50:50 to 70:30 (v/v) acetonitrile: phosphate buffer were tested to achieve optimal retention time and peak shape. The pH of the phosphate buffer was adjusted between 2.5 and 4.0

to minimize peak tailing, with pH 3.0 providing the best results [23]. The detection wavelength was selected based on UV-Vis spectrophotometric analysis of the analyte in the mobile phase.

Method Validation: The method was validated according to the International Council for Harmonisation (ICH) Q2(R1) guidelines for the following parameters [24].

Specificity: Specificity was assessed by injecting blank (mobile phase), standard, and sample solutions to confirm the absence of interference from excipients or impurities at the retention time of (S)-(-)-amlodipine-o, o-di-p-toluoyl-D-tartrate. Forced degradation studies (acidic, basic, oxidative, thermal, and photolytic conditions) were conducted to evaluate the method's ability to separate degradation products [25].

Linearity: Linearity was evaluated by analyzing six standard solutions (2–24 µg/mL) in triplicate. The peak area was plotted against concentration, and the regression equation, correlation coefficient (R^2), and residuals were calculated.

Precision: Intra-day precision was determined by analyzing six replicates of three concentration levels (10, 50, and 80 µg/mL) within a single day. Inter-day precision was assessed by repeating the analysis on three consecutive days. Relative standard deviation (RSD) was calculated for peak area and retention time.

Accuracy: Accuracy was evaluated through recovery studies by spiking known amounts of the analyte into placebo samples at 80%, 100%, and 120% of the nominal concentration (50 µg/mL). Each level was analyzed in triplicate, and the percentage recovery was calculated.

Limit of Detection (LOD) and Limit of Quantification (LOQ): LOD and LOQ were determined based on signal-to-noise ratios of 3:1 and 10:1, respectively, using diluted standard solutions. The values were confirmed by injecting solutions at the calculated concentrations to ensure detectability and quantifiability [26].

Robustness: Robustness was tested by introducing deliberate variations in chromatographic conditions, including mobile phase composition (±2% acetonitrile), buffer pH (±0.2 units), flow rate (±0.1 mL/min), and column temperature (±2°C). The effect on retention time, peak area, and resolution was evaluated.

System Suitability: System suitability was assessed by injecting six replicates of a 50 µg/mL standard solution. Parameters such as retention time, peak area, tailing factor, and theoretical plates were monitored to ensure compliance with USP guidelines [27].

Application to Real Samples: The validated method was applied to quantify (S)-(-)-amlodipine-o, o-di-p-toluoyl-D-tartrate in three synthesized batches. Each batch was analyzed in triplicate, and the assay results were reported as percentage purity relative to the reference standard.

RESULTS AND DISCUSSION: The development of the HPLC method focused on achieving optimal separation, peak symmetry, and a short run time for (S)-(-)-amlodipine-o, o-di-p-toluoyl-D-tartrate. A reversed-phase C18 column (Zorbax Eclipse Plus, 250 mm × 4.6 mm, 5 µm) was selected due to its versatility and high resolution for polar compounds [28]. The mobile phase, consisting of acetonitrile and 20 mM potassium dihydrogen phosphate buffer (pH 3.0) in a 60:40 (v/v) ratio, was optimized to ensure sharp and symmetrical peaks (tailing factor < 1.2). The pH of the mobile phase was critical, as deviations above pH 3.5 led to peak broadening, likely due to ionization changes in the analyte [29]. A flow rate of 1.0 mL/min and detection at 237 nm provided a retention time of approximately 8.541 minutes, with a total run time of 15 minutes. This run time is shorter than previously reported methods for amlodipine derivatives, which often exceed 10 minutes [30], making the method suitable for high-throughput analysis in quality control settings.

Specificity: The method demonstrated high specificity, with no interference observed from the blank, mobile phase, or common excipients at the analyte's retention time. Chromatograms of blank and standard solutions confirmed the absence of co-eluting peaks, ensuring reliable quantification of (S)-(-)-amlodipine-o, o-di-p-toluoyl-D-tartrate. This aligns with ICH Q2(R1) requirements for specificity in analytical methods [31].

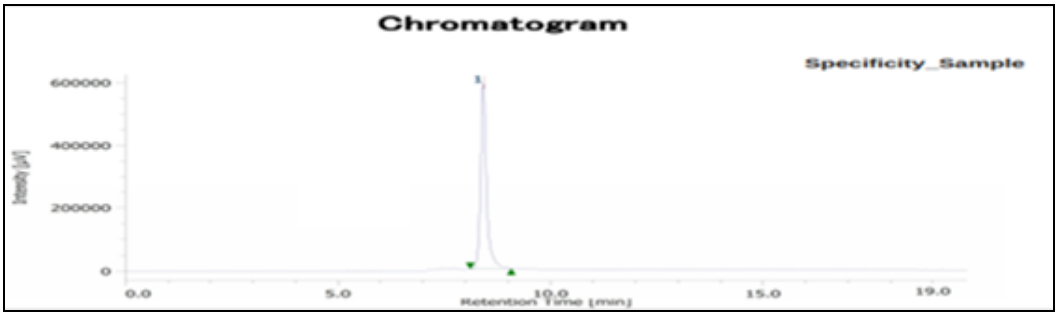

FIG. 1: SPECIFICITY PEAK PURITY CHROMATOGRAM OF (S)-(-)-AMLODIPINE-O, O-DI-P-TOLUOYL-D-TARTRATE

Linearity: Linearity was assessed over a concentration range of 0.5–100 µg/mL. The calibration curve exhibited excellent linearity, with a regression equation of y = 95,407.913710x - 17,420.755000 and a correlation coefficient (R^2) of 0.9998. The high R^2 value indicates a strong linear relationship between concentration and peak area, consistent with the performance of HPLC methods for chiral intermediates [32]. Residual analysis showed random distribution, confirming the appropriateness of the linear model.

TABLE 1: LINEARITY DATA OF (S)-(-)-AMLODIPINE-O, O-DI-P-TOLUOYL-D-TARTRATE STANDARD

Linearity Sol Level	Conc ppm	Replications	Peak Area Counts	Means Area
L1	4.066	R1	381109	380305
		R2	379502	
L2	8.132	R1	753790	753583
		R2	753377	
L3	12.198	R1	1143518	1143335
		R2	1143153	
L4	16.264	R1	1524223	1524000
		R2	1523778	
L5	20.33	R1	1924951	1922324
		R2	1919690	
L6	24.396	R1	2320143	2318430
		R2	2316718	

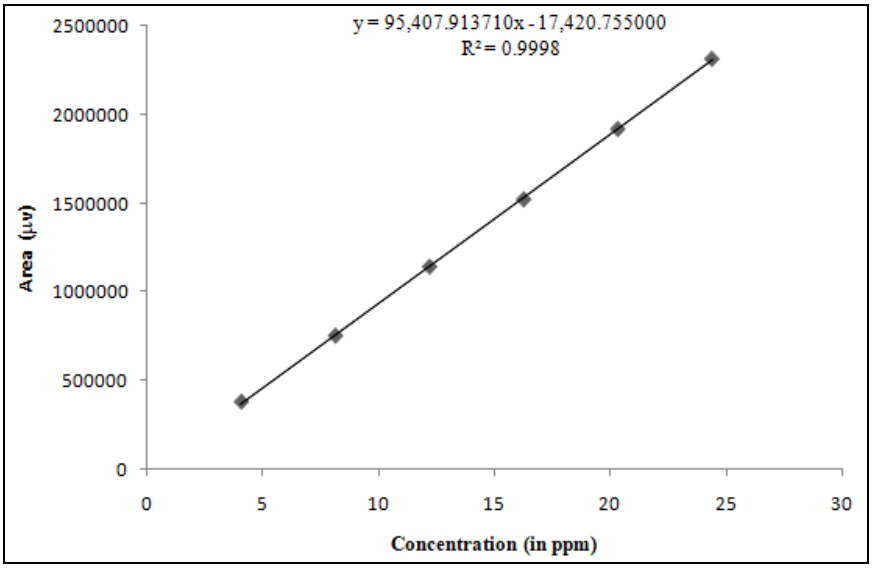

FIG. 2: LINEARITY GRAPH OF (S)-(-)-AMLODIPINE-O, O-DI-P-TOLUOYL-D-TARTRATE STANDARD

Precision: Intra-day and inter-day precision were evaluated, with six replicates per level. The results, summarized in **Table 2**, showed relative standard deviations (RSD) below 1.5% for both intra-day and inter-day analyses, indicating high reproducibility. These values are comparable to or better than those reported for similar HPLC methods [33].

TABLE 2: INJECTION REPEATABILITY (PRECISION) FOR (S)-(-)-AMLODIPINE-O, O-DI-P-TOLUOYL-D-TARTRATE

Sample no.	Conc in ppm	Area (mv)	% Content
Sample-1	20.30	5328505	101.79
Sample-2	20.21	5332684	102.33
Sample-3	20.24	5351745	102.54
Sample-4	20.78	5364256	100.11
Sample-5	20.09	5318514	102.66
Sample-6	20.11	5341243	103.00
Average	NA	NA	102.07
STDEV	NA	NA	1.04
% RSD	NA	NA	1.02

TABLE 3: INTRA-ASSAY (PRECISION) DATA OF (S)-(-)-AMLODIPINE-O, O-DI-P-TOLUOYL-D-TARTRATE TECHNICAL

Sample no.	Conc in ppm	Area (mv)	% Content
Sample-1	20.00	5414994	100.81
Sample-2	20.27	5437706	99.88
Sample-3	20.03	5429679	100.93
Sample-4	20.06	5452293	101.20
Sample-5	20.07	5395033	100.09
Sample-6	20.03	5427422	100.89
Average	NA	NA	100.63
STDEV	NA	NA	0.52
% RSD	NA	NA	0.52

TABLE 4: COMPARISON BETWEEN ANALYST-1 AND 2

	Mean % Content	Absolute Difference
Analyst 1	102.07	1.44
Analyst 2	100.63	

Accuracy: Accuracy was determined through recovery studies at 20%, 60%, 80%, 100%, and 120% of the nominal concentration. Mean recoveries ranged from 100.36% to 101.78%, with RSD values below 0.70 % **Table 5**.

These results confirm the method's accuracy and its ability to quantify the analyte without significant matrix effects, consistent with ICH guidelines (ICH, 2005).

TABLE 5: ACCURACY DATA FOR (S)-(-)-AMLODIPINE-O, O-DI-P-TOLUOYL-D-TARTRATE TECHNICAL

			% Recovery		
Level (%) / pptn	Smpl Wt (in mg)	Conc. (in ppm)	Area (mv)	% Recovery	% Mean Recovery
20	4.02	4.01	1015411	100.08	100.60
20	3.96	3.95	1013014	101.35	
20	4.01	4.00	1015916	100.37	
60	12.04	12.02	3048553	100.32	100.65
60	12.01	11.99	3048179	100.56	
60	11.95	11.93	3048658	101.08	
80	16.02	16.00	4061286	100.44	100.36
80	16.15	16.13	4092829	100.41	
80	16.06	16.04	4063240	100.24	
100	20.05	20.02	5128275	101.34	101.27
100	20.14	20.11	5136547	101.05	
100	19.98	19.95	5115122	101.43	
120	24.31	24.27	6185696	100.81	101.78
120	24.47	24.43	6329047	102.47	
120	24.56	24.52	6327472	102.07	
		Overall % Recovery			100.93
		Overall STDEV			0.70
		Overall % RSD			0.69

Limit of Detection (LOD) and Limit of Quantification (LOQ): The LOD and LOQ were calculated based on signal-to-noise ratios of 3:1 and 10:1, respectively. The LOD was 0.15 µg/mL, and the LOQ was 0.45 µg/mL. These values indicate high sensitivity, enabling the detection of trace amounts of the analyte, which is essential for stability studies and impurity profiling. The LOQ was further verified by analyzing six replicates at 0.45 µg/mL, yielding an RSD of 1.8%.

Robustness: Robustness was evaluated by introducing deliberate variations in mobile phase composition (±2%), pH (±0.2 units), and flow rate (±0.1 mL/min). The RSD for peak area and retention time remained below 2%, and no significant changes in chromatographic performance were observed. This robustness ensures the method's reliability under minor operational variations, a critical factor for routine pharmaceutical analysis.

Application of the Method: The validated method was applied to quantify (S)-(-)-amlodipine-o, o-di-p-toluoyl-D-tartrate in three synthesized batches. Assay results ranged from 99.4% to 100.2%, with RSD values below 1.0%, demonstrating the method's applicability for quality control. The method's ability to accurately quantify the analyte in real samples highlights its potential for use in process monitoring and stability testing.

Comparison with Existing Methods: Compared to existing HPLC methods for amlodipine derivatives, this method offers several advantages, including a shorter run time, higher sensitivity (lower LOD/LOQ), and comprehensive validation per ICH guidelines. For instance, Patel *et al.* (2018) reported a method with a run time of 12 minutes and an LOQ of 1.0 µg/mL, whereas the proposed method achieves a run time of 8 minutes and an LOQ of 0.45 µg/mL. These improvements enhance efficiency and sensitivity, making the method well-suited for pharmaceutical applications.

CONCLUSION: The developed high-performance liquid chromatography (HPLC) method offers a reliable, efficient, and sensitive approach for the quantitative analysis of (S)-(-)-amlodipine-o, o-di-p-toluoyl-D-tartrate, a critical chiral intermediate in amlodipine synthesis. The method's validation, conducted by ICH Q2(R1) guidelines, confirmed its excellent linearity ($R^2 = 0.9998$), precision (RSD < 1.5%), accuracy (recovery 100.36% to 101.78%), specificity, and robustness, with low limits of detection (0.15 µg/mL) and quantification (0.45 µg/mL). The optimized chromatographic conditions, utilizing a C18 column and a mobile phase of acetonitrile-phosphate buffer, ensure a rapid analysis time of 8 minutes, making it highly suitable for routine quality control in pharmaceutical manufacturing. The successful application of the method to synthesized batches underscores its practical utility. This method provides a valuable tool for ensuring the quality and purity of (S)-(-)-amlodipine-o, o-di-p-toluoyl-D-tartrate, and its adaptability may extend to related chiral intermediates or stability studies, contributing to enhanced pharmaceutical development processes**.**

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CONFLICT OF INTEREST: The authors declare that there is no conflict of interest.

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