RESEARCH PAPER

Development and Validation of RP HPLC Method for Simultaneous Estimation of Amlodipine, Indapamide, and Telmisartan in Pharmaceutical Dosage Form

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Abstract

A simple, precise, accurate, and robust reverse phase high-performance liquid chromatographic (RP-HPLC) method was developed and validated for the simultaneous estimation of Amlodipine (AML), Indapamide (IND), and Telmisartan (TEL) in pharmaceutical dosage form. Chromatographic separation was achieved using optimized RP-HPLC conditions with UV detection at 238 nm. Optimal analysis conditions were determined by employing a HIBAR ODS C18, 250 mm*4.6 mm, Acetonitrile: 0.05 M Potassium dihydrogen phosphate (50:50 v/v), pH 3.0, with a flow rate of 1.0 ml/min. These conditions facilitated excellent with retention times of AML, IND, and TEL were found to be 4.422 min, 6.104 min, and 8.573 min respectively, demonstrating adequate separation with good peak symmetry. The method exhibited excellent linearity over concentration ranges of 1.25–7.5 µg/mL for AML, 0.625–3.75 µg/mL for IND, and 10–60 µg/mL for TEL with correlation coefficients greater than 0.997. Validation of the optimized method adhered to ICH Q2 (R1) guidelines on analytical method validation. The %RSD values for precision were below 2%, indicating high reproducibility of the method. Recovery studies showed results within 99–101%, confirming the accuracy of the developed method. The assay values for AML, IND, and TEL were found to be 99.20%, 99.73%, and 99.20% respectively. The developed RP-HPLC method was found to be reliable and suitable for routine quality control analysis of pharmaceutical formulations containing these drugs.

Keywords: RP-HPLC, Method validation, Amlodipine, Indapamide, Telmisartan, ICH guidelines, Pharmaceutical analysis.

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1. Introduction

Hypertension is one of the most common chronic cardiovascular disorders affecting millions of people worldwide. Persistent elevation of blood pressure significantly increases the risk of heart disease, stroke, and renal complications. According to global health reports, hypertension is responsible for a large proportion of cardiovascular mortality. Effective management of hypertension often requires combination drug therapy to achieve adequate blood pressure control.[1]

Amlodipine, IUPAC name (Benzenesulfonic acid; 3-*O*-ethyl 5-*O*methyl 2-(2-aminoethoxymethyl)-4-(2chlorophenyl)-6-methyl-1,4dihydropyridine-3,5-dicarboxylate) with Molecular weight- 408.9 g/moL is a long-acting dihydropyridine calcium channel blocker widely used for the treatment of hypertension and angina pectoris. It acts by inhibiting the influx of calcium ions into vascular smooth muscle cells, thereby promoting vasodilation and reducing peripheral vascular resistance.[2]

Indapamide, IUPAC name (4-chloro-*N*-(2-methyl-2,3-dihydroindol-1-yl)-3-sulfamoylbenzamide) with Molecular weight - 365.84 g/moL is a thiazide-like diuretic with antihypertensive properties. It exerts its pharmacological effect by inhibiting sodium reabsorption in renal tubules and promoting diuresis.

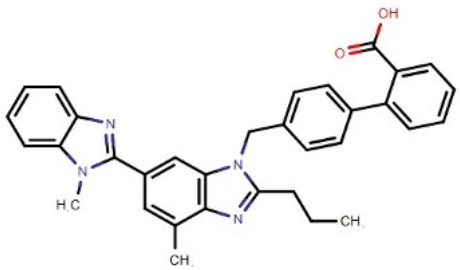
Additionally, Indapamide exhibits vasodilatory activity which contributes to its antihypertensive effect.[3,4]

Telmisartan, IUPAC name (2-[4-[[4-methyl-6-(1-methylbenzimidazol- 2-yl)-2-propylbenzimidazol-1yl]methyl]phenyl]benzoic acid) with Molecular weight- 514.6 g/moL is an angiotensin II receptor blocker (ARB) that selectively inhibits the binding of angiotensin II to AT1 receptors. This inhibition prevents vasoconstriction and aldosterone secretion, resulting in reduced blood pressure.[5,6]

Several analytical methods have been reported for the estimation of antihypertensive drugs individually or in combination using spectrophotometry, HPLC, and other chromatographic techniques. Some researchers have reported methods for the determination of Amlodipine and Telmisartan in combined dosage forms. Similarly, analytical methods for Indapamide alone or in combination with other drugs have also been developed.[7-14] No any studies are available for the simultaneous estimation of Amlodipine, Telmisartan, and Indapamide in a single analytical method. Therefore, there is a need to develop a simple, accurate, and validated RP-HPLC method for the simultaneous determination of these three drugs.

The combination of Amlodipine, Indapamide, and Telmisartan provides a multi-mechanistic therapeutic approach for hypertension management. Fixed-dose combinations of these drugs brand name (Widaplik tablets) offer improved patient compliance and enhanced therapeutic effectiveness.

Reverse phase HPLC (RP-HPLC) is particularly suitable for the simultaneous estimation of multiple drugs in complex pharmaceutical formulations. The objective of the present study was to develop and validate a simple, rapid, and reliable RP-HPLC method for the simultaneous estimation of Amlodipine, Indapamide, and Telmisartan in pharmaceutical dosage form according to ICH Q2 (R1) guidelines.



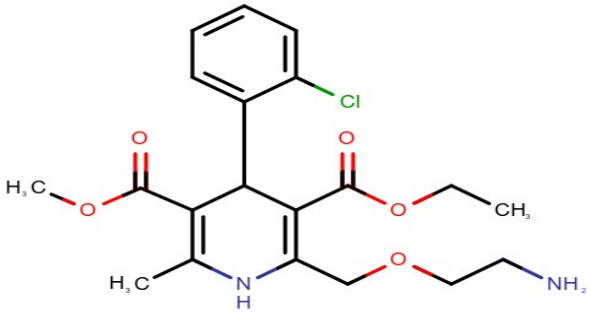


Fig.1 Structure of Telmisartan[5] **Fig.2 Structure of Amlodipine besylate[2]**

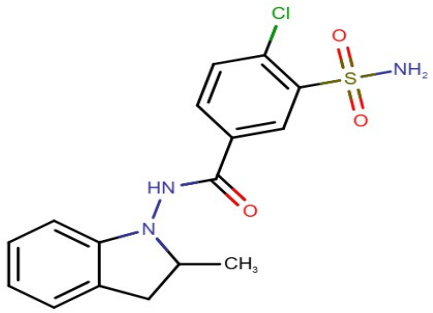


Fig.3 Structure of Idapamide[3]

2. Materials and Methods

2.1 Chemicals and Reagents

Pure samples of Amlodipine, Indapamide, and Telmisartan were obtained as gift samples from a BLD Pharmatech Pvt Ltd. HPLC grade methanol, acetonitrile, and water were used for chromatographic analysis. All chemicals and reagents used in the study were of analytical grade. Water was deionized and purified using a Milli-Q Reagent Grade water system

2.2 Instrumentation

The SHIMADZU (Series 2010) HPLC apparatus, featuring a UV-VIS detector capable of binary gradient operation, was employed to process the samples. Chromatographic analysis was conducted utilizing LC solution software for processing and integration. Employed in the process was a HIBAR ODS C18 measuring 250 mm in length and 4.6 mm in internal diameter. Precise material quantities were determined using a Mettler Toledo weighing scale with a sensitivity of 0.1 mg. pH adjustments were made using the Labman LMPH 10 pH meter.

2.3 Selection of Detection Wavelength

The main problem for detection of multicomponent analysis is adequate selection of analytical wavelength.

When the individual solution, having concentration of 10 µg/ml of TEL and 10 µg/ml of AML and 10 µg/ml of IND were scanned between 200-800 nm, it was observed that at 238 nm, adequate signal of all the components can be generated and hence it was selected as analytical wavelength for further method development.

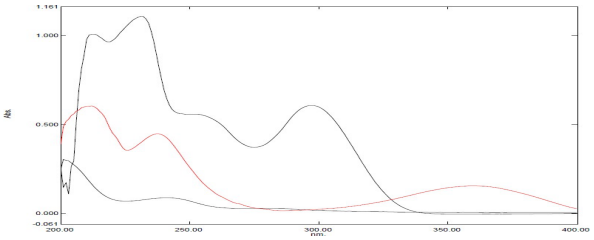


Fig.4 Selection of analytical wavelength for HPLC

2.4 Preparation of Standard Stock Solutions

Standard stock solutions of Telmisartan (TEL), Amlodipine (AML), and Indapamide (IND) were prepared separately using Methyl alcohol as the solvent. Accurately weighed 40 mg of TEL, 5 mg of AML and 2.5 mg of IND was transferred into a 100 mL volumetric flask individually and dissolved in methanol to obtain a master stock solution having a concentration of 400 µg/mL of TEL, 50 µg/mL of AML and 25 µg/mL of IND. From this solution, 1.0 mL was pipetted and diluted up to 10 mL with methanol to obtain a standard solution of 40 µg/mL of TEL, 5 µg/Ml of AML and 2.5µg/mL of IND. These prepared solutions were used for further analytical studies. The solutions were filtered using 0.45 µm membrane filter to remove any particulate matter.

2.5 Preparation of Working Standard Solutions mixture

Weigh accurately about 40 mg of TEL, 5 mg of AML and 2.5 mg of IND and transfer into a 100 ml volumetric flask. Make up the volume of the flask to the mark with Methyl alcohol. (400 µg/ml TEL + 50 µg/ml AML + 25 µg/ml of IND). Withdraw 1.0 ml from Master Stock Solution and make up to 10 ml with methyl alcohol TEL+AML+IND (40+5+2.5 $\mu g.ml^{-1}$

2.6 System Suitability Parameters

Solution of TEL+AML+IND (20+2.5+1.25 $\mu g.ml^{-1}$) was injected 3 times for determination of System suitability parameters which includes Retention time (R_t), Tailing factor (Tf), Resolution (R_S) and number of theoretical plates. System suitability parameters for selected concentration were determined by RSD.

3. Method Validation

The developed RP-HPLC method was validated according to ICH Q2 (R1) guidelines.[15]

3.1 Linearity and Range

Preparation of Solution for linearity studies:

Weigh accurately about 40 mg of TEL, 5 mg of AML and 2.5 mg of IND and transfer into a 100 ml volumetric flask. Make up the volume of the flask to the mark with Methanol. (400 µg/ml TEL + 50 µg/ml AML + 25 µg/ml of IND). Various aliquots were taken and diluted up to 10 ml in order to prepare final solutions for linearity studies as 1.25–7.5 µg/mL for AML, 0.625–3.75 µg/mL for IND, and 10–60 µg/mL for TEL.

3.2 Repeatability

Prepared standard working solution of mixtures having concentration of TEL (10 to 60 µg/mL), AML (1.25 to 7.5 µg/mL) and IND (0.625 to 3.75 µg/mL) were injected at volume of 20 µL into column by employing optimized chromatographic conditions. Each standard mixture was injected 5 time and peak area was monitored. Each concentration was monitored for repeatability by RSD.

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

The **limit of detection (LOD)** and **limit of quantification (LOQ)** were determined to evaluate the sensitivity of the developed RP-HPLC method. LOD represents the lowest concentration of analyte that can be detected but not necessarily quantified under the stated experimental conditions, whereas LOQ represents the lowest concentration that can be quantitatively determined with acceptable precision and accuracy.

LOD and LOQ were calculated based on the standard deviation of the response (σ) and the slope (S) of the calibration curve according to the guidelines of the **ICH Q2(R1)**. The following equations were used:

- **LOD = 3.3 σ / S**
- **LOQ = 10 σ / S**

Where **σ** is the standard deviation of the response and **S** is the slope of the calibration curve.

3.4 Accuracy

Accuracy of the analytical method has been performed by spiking of placebo with the standard. Spiking of the sample was performed at 50, 100 and 150 % of the target concentration. Each solution was chromatographed for 3 time and area obtained was subjected to statistical analysis to get idea about mean % recovery.

3.5 Intra-day and Inter-day Precision

Method precision was determined by performing intraday and interday precision. Mixture that represents overall range (TEL+AML+IND = 10+1.25+0.625, 40+5+2.5 and 60+7.5+3.75 µg/ml) were analysed on same day at different time interval for intraday precision. Mixture that represents overall range (TEL+AML+IND = 10+1.25+0.625, 40+5+2.5 and 60+7.5+3.75 µg/ml) were analyzed on different days for interday precision.

3.6 Robustness

Following parameters were altered one by one for determination of robustness of the method and their effect was observed by comparing with the standard preparation. Mobile phase flowrate (± 0.1 mL/min), optimized flowrate was 1.0 mL/min, Mobile phase composition (± 2 mL), in optimized ratio, pH of mobile phase (± 0.2), 3 determinations of TEL+AML+IND (20+2.5+1.25 µg.ml^{-1}) for each alteration was carried out and RSD was measured.

3.7 Assay

Weigh accurately about 104 mg placebo, 40 mg of TEL, 5 mg of AML and 2.5 mg of IND and transfer into a 100 ml volumetric flask. Make up the volume of the flask to the mark with Methanol. (400 µg/ml TEL + 50 µg/ml AML + 25 µg/ml of IND). Sonicate the solution for 10 minutes and filter through 0.45µ filter. Withdraw 0.5 ml from above filtrate in 10 mL volumetric flask; make up the volume with mobile phase, which contain TEL+AML+IND (20+2.5+1.25 µg.ml-1)

4 Result and Discussion

4.1 Optimized Chromatographic Condition

Chromatographic separation was achieved using RP-HPLC conditions with UV detection at 238 nm. Optimal analysis conditions were determined by employing a HIBAR ODS C18, 250 mm*4.6 mm, Acetonitrile: 0.05 M Potassium dihydrogen phosphate (50:50 v/v), pH 3.0, with a flow rate of 1.0 ml/min was observed in Table 1 and Fig 5.

Tabel 1 Optimized Chromatographic Condition

Stationary Phase	HIBAR ODS C18, 250 mm*4.6 mm
Mobile Phase	Acetonitrile: 0.05 M Potassium dihydrogen phosphate pH adjusted 3 with OPA (50:50 v/v)
Detection wavelength	238 nm
Flow rate	1 ml/minute
Run Time	20 minutes
Retention Time	AML: 4.422 min, IND: 6.104 min, TEL: 8.573 min

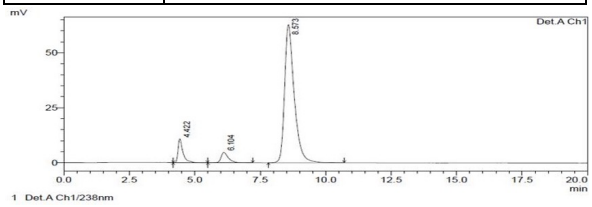


Fig 5. Chromatogram of TEL+AML+IND = 20+2.5+1.25 µg/ml

4.2 System suitability tests

System suitability test reveals the factors such as, theoretical plate(N), capacity factor (k'), resolution (R), separation factor (α), tailing factor (T), Mean±SD and RSD% and found to be in acceptable range for at least 6 successive injections of same analytes, as shown in Fig. 5 and Table 2, represents the system suitability

Table 2 System Suitability Parameter

Parameters	**Data obtained**		
	TEL	**AML**	**IND**
Retention time (Rt)	4.41	6.11	8.53
Resolution (Rs)	4.30		
Theoretical Plates(N)	5711.67	3881.67	7582.00
Tailing factor (T_f)	1.24	1.27	1.34

The retention times indicate adequate chromatographic separation between the three analytes. The peaks were well resolved with symmetrical peak shapes, confirming that the selected chromatographic conditions were suitable for simultaneous analysis.

4.3 Linearity

The method exhibited excellent linearity over concentration ranges of 1.25–7.5 µg/mL for AML, 0.625–3.75 µg/mL for IND, and 10–60 µg/mL for TEL.Calibration curves showed a linear relationship between concentration and peak area is shown in Fig.6 and Table 3. The correlation coefficients greater than 0.997 indicate excellent linearity and confirm that the developed method is suitable for quantitative estimation of the drugs.

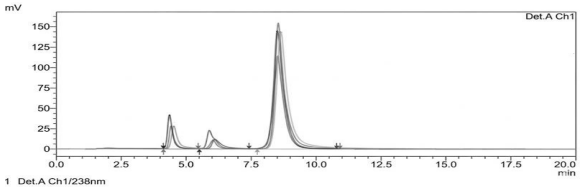


Fig.6 Chromatogram of Linearity Overlain

Table 3 Calibration Curve data

PARAMETERS	TEL	AML	IND
Linear Range (n=3) (µg/mL)	10-60µg/mL	1.25-7.5µg/mL	0.625-3.75µg/mL
Slope	3389.48	7419.34	9228.6
Intercept	5201.5	840.73	1668.6
LOD (µg/ml)	0.249	0.057	0.055
LOQ (µg/ml)	0.754	0.174	0.167
Regression Equation	y = 3389.5x + 5201.5	7419.4x - 840.73	9228.6x - 1668.6
Co-Relation Co-Efficient(r^2)	0.992	0.997	0.998
Recovery (%)	100.22 %	99.67%	99.60%
Repeatability (%RSD)	0.52	1.07	1.40
Intra-day (n=3) (%RSD)	0.53	1.05	1.39
Inter-day (n=3) (%RSD)	0.60	1.10	1.45
Robustness	Robust	Robust	Robust

4.4 Repeatability:

Repeatability was evaluated by analyzing multiple injections (n = 5) of a standard solution containing TEL (40 µg/mL), AML (5 µg/mL), and IND (2.5 µg/mL) under the same operating conditions. All %RSD values are **less than 2%**, Shown in Table 4. which meets the acceptance criteria as per ICH Guidelines. This indicates that the developed RP-HPLC method shows **good repeatability and high precision**, with minimal variation in peak areas for all three drugs.

Table 4: Repeatability Study

Concentration	TEL(40 µg/mL)	AML(5 µg/mL)	IND(2.5 µg/mL)
Area (NMT-2%)	130475	34874	21422
	131484	34762	21893
	130972	34996	21758
	129863	34040	22187
	131428	34721	21521
Mean	130844.4	34678.6	21756.2
± SD	682.93	372.66	304.68
%RSD	0.52	1.07	1.40

4.5 Intra-day and Inter-day study:

For Intra-day and Inter-day Study, %RSD values was found below **2%** shown in Table 5, which complies with the acceptance criteria as per ICH Guidelines. The low %RSD values indicate that the method has good precision and reproducibility both within the same day and across different days.

Table 5: Intra-day and Inter-day study

Drug	Concentration (µg/ml)	Intra-day area mean (n=3) ± SD	%RSD	Inter-day area mean (n=3) ± SD	%RSD
TEL	**10**	41579 ±323.41	0.78	41567.67±341.66	0.82
	40	131052±688.40	0.53	131114±790.51	0.60
	60	210954±679.98	0.32	211146.33±818.56	0.39
AML	**1.25**	8744± 137.50	1.57	8757± 141.38	1.61
	5	34947 ±36.97	1.05	35019 ±386.47	1.10

	7.5	55679.33±459.61	0.83	57767.67±490.32	0.88
IND	**0.625**	4154.67±70.73	1.70	4163.67±73.66	1.77
	2.5	21434±297.18	1.39	21787.67±316.71	1.45
	3.75	32528.67±373.19	1.15	32505±395.74	1.22

4.6 Accuracy:

As Per the results indicated in Table 6 that the method is **accurate and free from interference**, as recoveries are close to 100% and comply with acceptance criteria (98–102%) as per ICH Guidelines.

Table 6: Accuracy

Drug	**% Level of Recovery**	**Amount of drug added(µg/ml)**	**Amount of drug recovered(µg/ml)**	**% Recovery**
TEL	50	20	19.83	99.17
	100	40	40.09	100.22
	150	60	60.23	100.38
AML	50	2.5	2.49	99.93
	100	5	4.98	99.67
	150	7.5	7.49	99.95
IND	50	1.25	1.24	99.47
	100	2.5	2.49	99.60
	150	3.75	3.69	98.40

4.7 Robustness:

The results show in Table 7 indicated minor changes in analytical conditions do not significantly affect the peak area, indicating that the method performance remains consistent. The developed RP-HPLC method is robust, reliable, and unaffected by small variations in experimental conditions, making it suitable for routine quality control analysis.

Table 7: Robustness

Parameter	**Level of change**	**TEL(20µg/ml)**	**AML(2.5µg/ml)**	**IND(1.25µg/ml)**
Flow Rate	**0.8 ml/min**	82146	16395	9399
	1.0 ml/min	82463	16758	9563
	1.2 ml/min	83118	16792	9694
	Mean	82575.67	16648.33	9552.00
	SD	495.70	220.05	147.81
	RSD	0.60	1.32	1.55
pH of mobile phase	**2.8**	82225	16324	9424
	3	82463	16758	9563
	3.2	83147	16625	9717
	Mean	82611.67	16569.00	9568.00
	SD	478.64	222.35	146.56
	RSD	0.58	1.34	1.53
Composition of mobile phase	**52-48**	82316	16429	9411
	50-50	82463	16758	9563
	48-52	83218	16851	9705
	Mean	82665.67	16679.33	9559.67
	SD	483.95	221.73	147.03
	RSD	0.59	1.33	1.54

4.8 Assay

All values are within the acceptable limit of 95–105% as per ICH Guidelines Shown in Table 8. The close agreement between actual and obtained concentrations confirms that excipients (placebo) do not interfere with the estimation of the drugs. The chromatogram (Fig. 7) shows well-resolved peaks without interference,

further proving the specificity of the method. So the developed RP-HPLC method is accurate, precise, and specific in the presence of placebo, and can be successfully applied for routine quality control analysis of combined pharmaceutical dosage forms.

Table 8: Assay

PARAMETERS	TEL	AML	IND
Actual Concentration (µg/mL)	**20µg/mL**	**2.5µg/mL**	**1.25µg/mL**
Concentration Obtained (µg/mL)	19.84µg/mL	2.48µg/mL	1.24µg/mL
% Assay	99.20%	99.20%	99.73%
%RSD	0.83	1.76	1.67
Limit*	95-105%	95-105%	95-105%

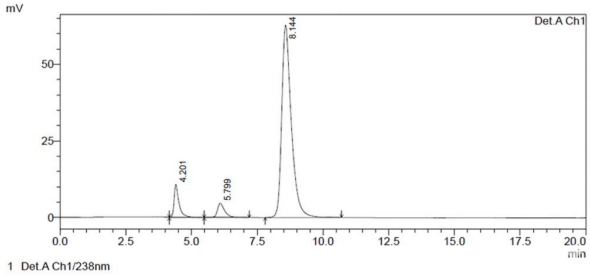


Fig.7 Chromatogram of Assay

5. Conclusion

A simple, rapid, accurate, and reliable RP-HPLC method was successfully developed and validated for the simultaneous estimation of Amlodipine, Indapamide, and Telmisartan in pharmaceutical dosage form. The developed method showed satisfactory results for all validation parameters including linearity, precision, accuracy, robustness, and assay according to ICH guidelines.

Therefore, the proposed RP-HPLC method can be effectively used for routine quality control analysis in pharmaceutical industries.

6. Acknowledgment

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