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SIMULTANEOUS ESTIMATION OF AMLODIPINE AND TELMISARTAN INCLUDING METHOD DEVELOPMENT AND METHOD VALIDATION BY RP-HPLC IN SOLID DOSAGE FORM

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ABSTRACT

Validation entails a systematic approach to ensure that processes, systems, procedures, and equipment consistently execute their intended functions and provide dependable outcomes. Validation is critical for ensuring quality, adhering to regulatory standards, and reducing production and operational risks. The developed method was novel and simple for the simultaneous estimation of Amlodipine & Telmisartan by RP-HPLC. The two peaks were well resolved at 254nm in isocratic mode at retention times 7.625 and 11.531 min for Amlodipine and Telmisartan respectively at a run time of 20 min and flow rate 1.0 ml/min with 250mm x 4.6mm, 5µm column & Ammonium acetate buffer: methanol (20:80) as mobile phase. % Assay values for Amlodipine and Telmisartan were found to be 98.59% & 99.17% respectively. Linearity was obtained in the range of 16-48 ppm & 20-60 ppm and linearity correlation coefficient was found to be 0.9925 & 0.9955 for Amlodipine and Telmisartan respectively. This new approach was verified using ICH guidelines and found to be specific, sensitive, precise, accurate, and linear.

KEYWORDS: Method development and validation, ICH guidelines, Amlodipine, Telmisartan, and RP-HPLC.

1. INTRODUCTION

1.1 DRUG PROFILE OF AMLODIPINE

Amlodipine, first approved by the FDA in 1987, is a widely used antihypertensive medication that belongs to the class of dihydropyridine calcium channel blockers. These blockers are known for their selectivity towards peripheral blood vessels, resulting in a reduced risk of myocardial depression and cardiac conduction issues compared to other types of calcium channel blockers. Amlodipine is frequently prescribed for the management of high blood pressure and angina. In addition to its primary effects, amlodipine exhibits antioxidant properties and can stimulate the production of nitric oxide (NO), a vital vasodilator that helps lower blood pressure. IUPAC name of Amlodipine is 3-ethyl 5-methyl 2-[(2-aminoethoxy)methyl]-4-(2-chlorophenyl)-6-methyl-1,4-dihydropyridine-3,5-dicarboxylate and molecular formula is $C_{20}H_{25}C_lN_2O_5$. Amlodopine has the molecuar mass of 408.879 g/mol.[1-9]

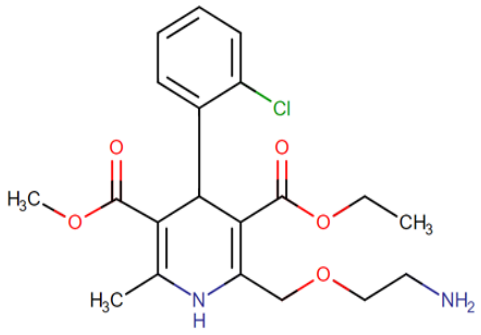


Figure 1: Chemical Structure of Amlodipine.

1.2 DRUG PROFILE OF TELMISARTAN

Telmisartan is an angiotensin II receptor blocker (ARB) commonly used to manage hypertension. ARBs like telmisartan bind with high affinity to angiotensin II type 1 (AT1) receptors, preventing angiotensin II from acting on vascular smooth muscle, which results in a decrease in arterial blood pressure. Additionally, recent research suggests that Telmisartan may possess PPAR-gamma agonistic properties, potentially offering beneficial effects on metabolism. The IUPAC designation for Telmisartan is 4'-{[4-methyl-6-(1-methyl-1H-1,3-benzodiazol-2-yl)-2-propyl-1H-1,3-benzodiazol-1-yl]methyl}-[1,1'-biphenyl]-2-carboxylic acid. Its molecular weight is 514.63 g/mol and molecular formula $C_{33}H_{30}N_4O_2$.[10-17]

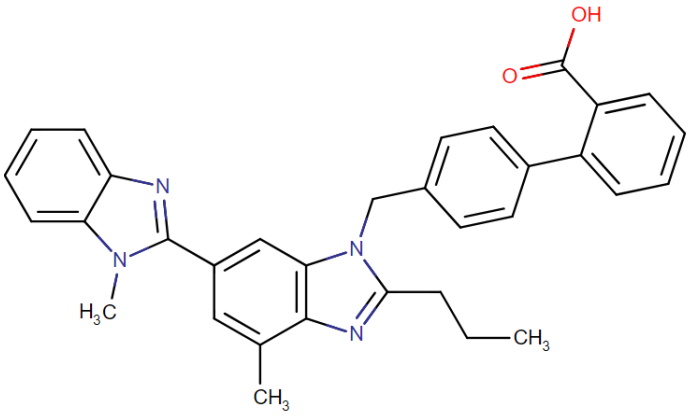


Figure 2: Chemical Structure of Telmisartan.

After an exhaustive literature study[18-26], the authors concluded that a very few methods for simultaneous quantification of Amlodipine and Telmisartan have been assessed using spectroscopy and liquid chromatography. Therefore, there is a need to design an innovative, fast, exact, sensitive, and selective approach for simultaneous estimation of Amlodipine and Telmisartan by RP-HPLC in its tablet dosage forms.

2. MATERIALS AND METHODS

2.1 APPARATUS & CHEMICALS

Table 1: List of apparatus.

S.no	Name	Model	Manufacturer
1	HPLC	Waters 2690	ALLIANCE
2	Weighing Balance	SAB 203 L	Scale tech
3	Pipettes, Beakers and Burettes	NA	Borosil Class-A
4	Ultra Sonicator	PSA-10A	DIGITAL PRO

Table 2: List of chemicals.

S.no	Name	Grade	Batch No
1	Water (Milli Q / HPLC Grade water)	HPLC	P24E100596
2	Ammonium acetate	HPLC	J058A24
3	Methanol	HPLC	R276G24
4	Acetonitrile	HPLC	R14C24

2.2 PREPARATION OF SOLUTIONS

Mobile phase: Ammonium acetate buffer and methanol was mixed and sonicated well and prepared in the ratio of 20:80.

Buffer preparation: Ammonium acetate buffer: 4.0 grams of ammonium acetate was properly weighed and put into a 1000 ml volumetric flask. Water was added to fill the flask and filtered through a 0.45 µm membrane filter.

Diluent preparation: Water and Acetonitrile (70: 30) used as diluent throughout the study.

Standard preparation: 40.00 mg of Amlodipine and 50.00 mg of Telmisartan were precisely weighed and transferred to two separate 100 ml volumetric flasks. 60 mL of diluent was added and sonicated for 5 minutes. The volume was increased to the mark using diluent. Then, 4ml of each solution was put into a 50ml volumetric flask, and the volume was adjusted to the mark using the same diluent.

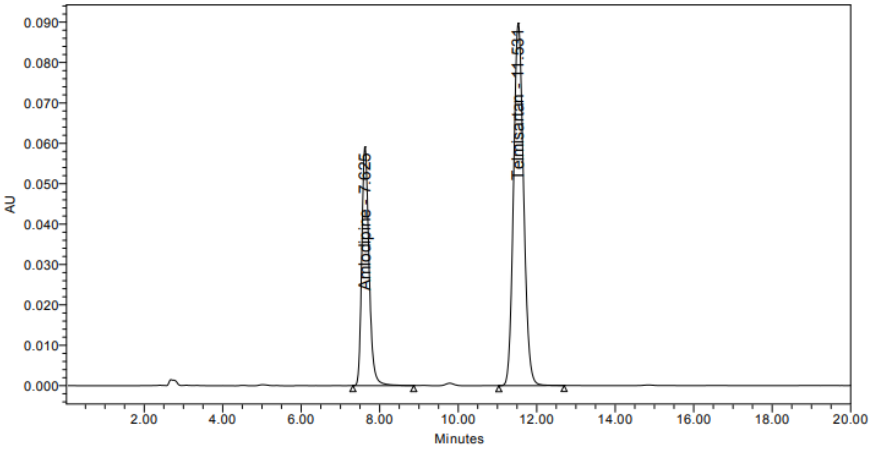
Sample preparation: Equivalent powder from 20 tablets was accurately taken from UZITEL-A containing Amlodipine 40mg and Telmisartan 50 mg respectively and transferred to 100 ml volumetric flask. 60 mL of diluent was added and sonicated for 5 minutes. The volume was made up to the mark using diluent. Then, 4ml of solution was placed into a 50ml volumetric flask, and the final volume was produced to the mark using the same diluent.

Optimized chromatographic conditions: After performing various trials in isocratic mode, the optimized chromatogram was obtained at 254nm with 1.0 ml/min flow rate using Ammonium acetate buffer: methanol (20:80). The Sample temperature was maintained at 20°± 5°C. Peaks were well resolved using Welchrom 250mm x 4.6mm, 5µm column at an ambient temperature for 20 min run time.

3. RESULTS AND DISCUSSION

3.1 SYSTEM SUITABILITY

System suitability in chromatography involves performing a series of tests to verify that all components of the chromatographic system—such as equipment, electronics, analytical procedures, and samples—are working correctly before the analysis begins. These evaluations are essential to ensure that the system meets established standards for the intended application, thereby ensuring both the reliability and accuracy of the analytical outcomes. Validation is done as per ICH requirements.[27]



	Peak Name	RT	Area	% Area	Height	USP Plate Count
1	Amlodipine	7.625	765348	32.40	59408	8275
2	Telmisartan	11.531	1596665	67.60	89781	9610

	USP Tailing
1	1.3
2	1.1

Figure 3: System suitability for standard chromatogram.

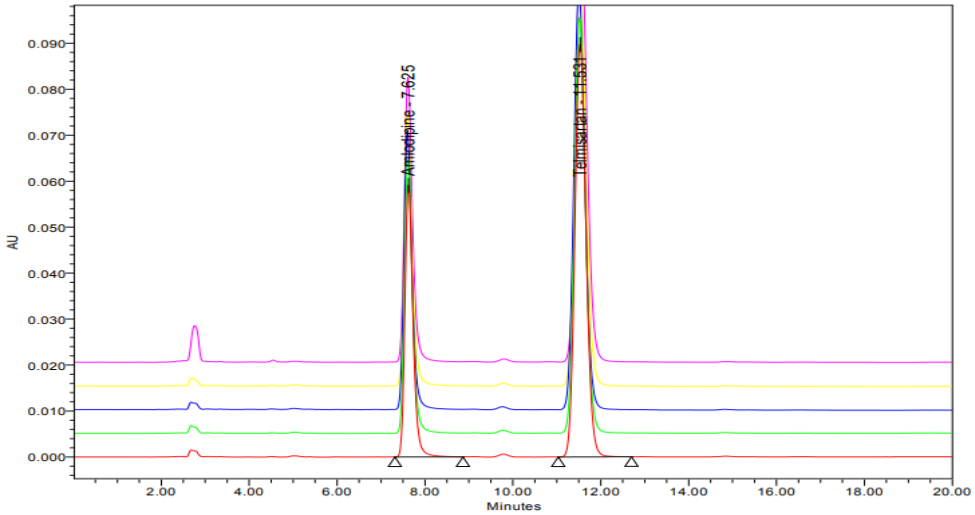


Figure 4: Overlay of System suitability for standard chromatograms.

Table 3: System suitability results.

		Amlodipine	Telmisartan
		Retention Time	Retention Time
1	Mean*	7.612	11.528
2	Std. Dev	0.009	0.017
3	% RSD	0.12	0.15

***** Average of five replicate injections

Discussion: The developed method successfully passed the system suitability criteria, as evidenced by a theoretical plate value exceeding 2000, tailing factor not exceeding 2.0, and % RSD remaining below 2.0%.

3.2 SPECIFICITY

The chromatographic method's capability to distinguish and quantify the target analyte in the presence of other substances, such as impurities, degradation products, matrix components, or additional analytes, is referred to as its specificity. High specificity means that the method can effectively and accurately separate and detect the target compound without interference from other substances within the sample.

Blank

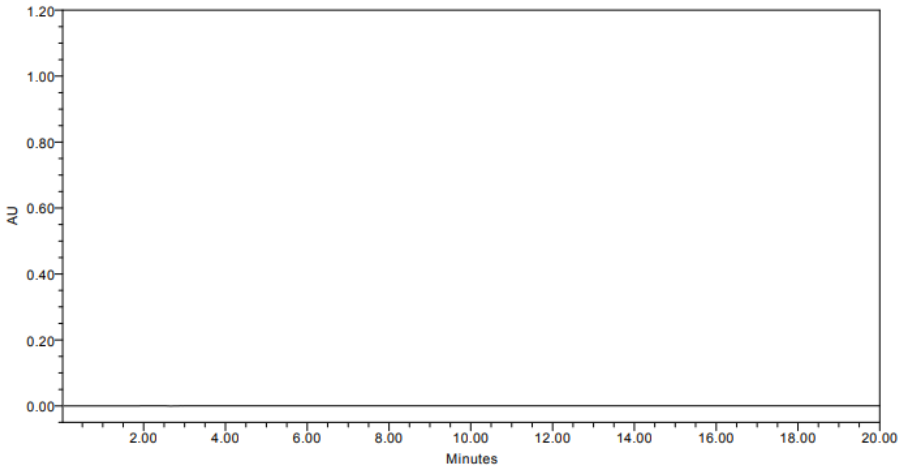


Figure 5: Blank chromatogram.

Discussion: The specificity chromatogram for the blank showed no interference with the primary peak, indicating that the technique is specific.

3.3 ACCURACY

Accuracy in an analytical method describes how well the test results correspond to the actual or reference value. To assess accuracy, sample solutions at concentration levels of 50%, 100%, and 150% are introduced into the system, and the percentage recovery is calculated to evaluate the method's precision.

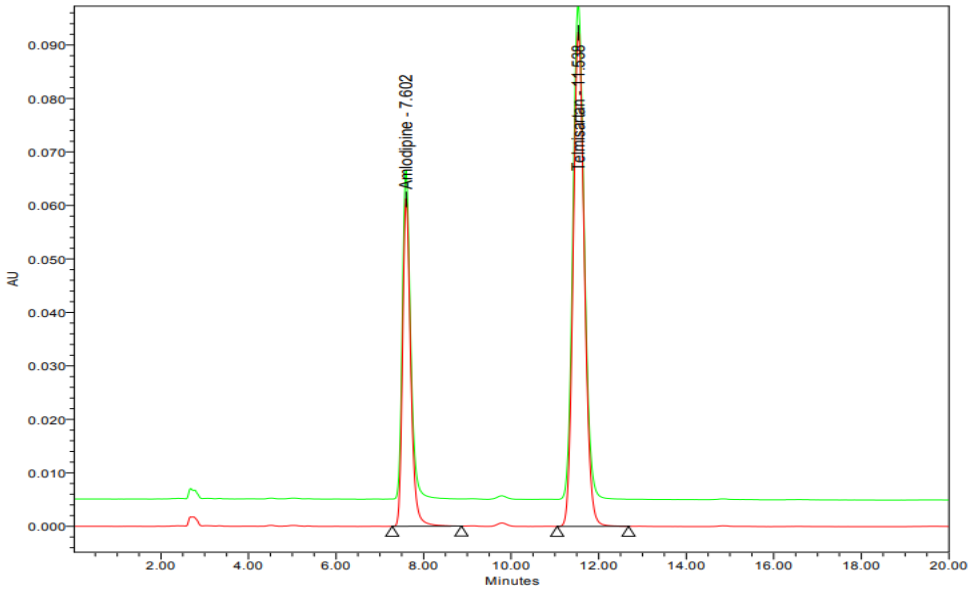


Figure 6: Sample solution chromatogram.

Table 4: Results for Accuracy.

S.No	Sample solution concentration*	Amlodipine		Telmisartan	
		% RSD	Recovery %	% RSD	Recovery %
1	50% sample solution	1.05	99.55%	0.53	99.20%
2	100% sample solution	0.34		0.18	
3	150% sample solution	0.06		0.26	

***** Average of three replicate injections

Discussion: The RSD percentage does not exceed 2.0%. The approach is considered accurate because the percentage recovery acceptability criterion for Amlodipine and Telmisartan ranges between 98.0% and 102.0%.

3.4 PRECISION

Precision indicates how consistently the method can produce similar results under normal conditions. Precision, however, measures the extent of variation or dispersion in these results and is typically expressed through statistical tools such as standard deviation, relative standard deviation (RSD), or coefficient of variation (CV).

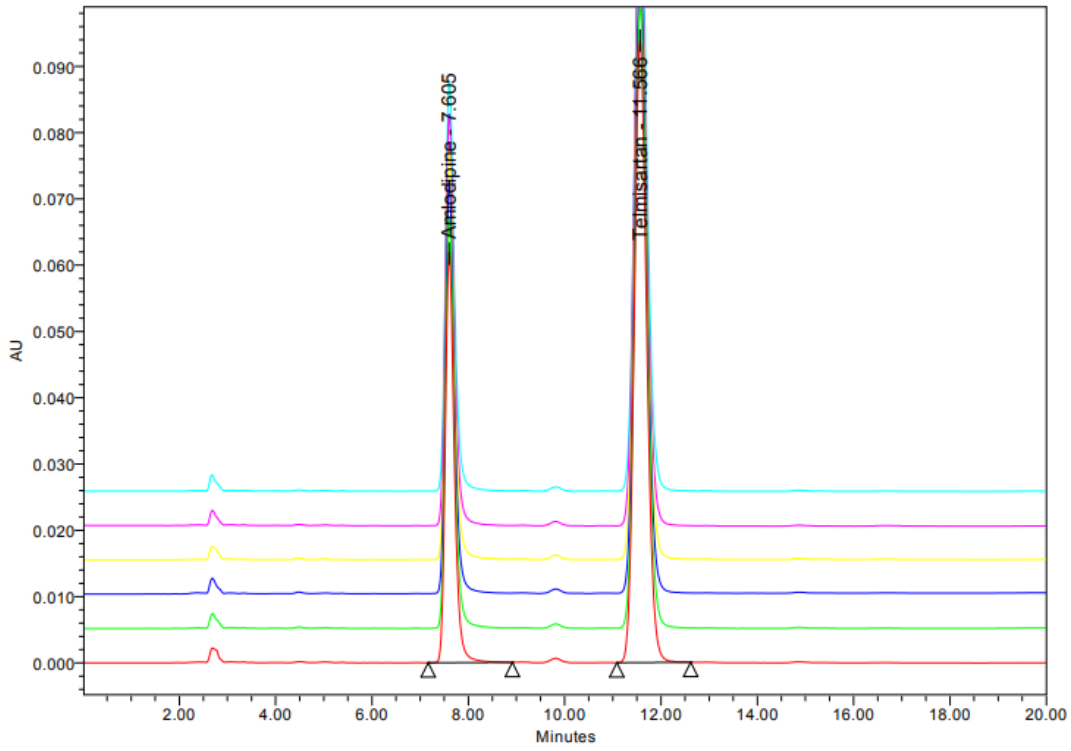


Figure 6: Precision chromatograms overlay of Amlodipine and Telmisartan.

Table 5: Method precision results for Amlodipine and Telmisartan.

S. No	Peak Name*	Average	SD	% RSD
1	Amlodipine	819184	0.24	0.2
2	Telmisartan	1704973	0.15	0.2

***** Average of six replicate injections

Discussion: The RSD percentage does not exceed 2.0%. The approach is regarded as precise since the precision values are within the acceptable range for Amlodipine and Telmisartan.

3.5 LINEARITY

In chromatography, linearity refers to the relationship between the concentration or quantity of an analyte injected and the detector's response. It assesses how accurately the detector response reflects changes in analyte concentration over a specified range. When linearity is present, the detector response, such as peak height or area, will increase or decrease in direct proportion to the analyte concentration. This property is crucial for ensuring accurate and consistent quantification of substances during chromatographic

analysis. Amlodipine and Telmisartan were made in five concentrations, and each concentration was injected three times to test linearity. A graph was plotted taking concentration of analyte on x-axis and peak area on y-axis.

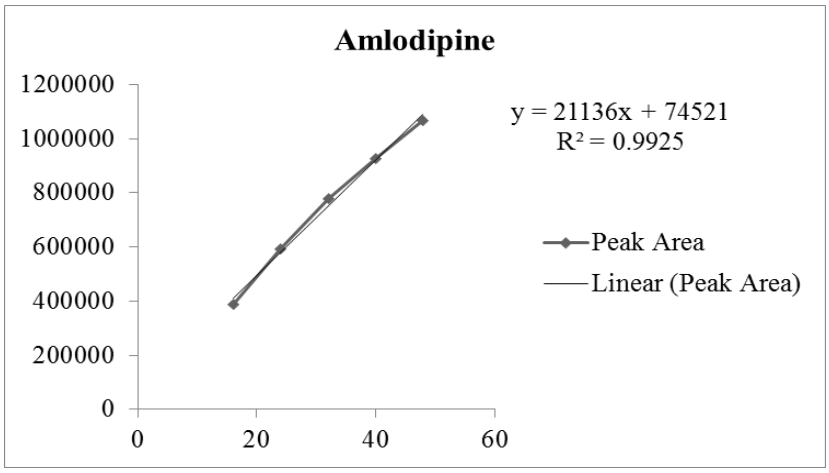


Figure 7: Linearity graph for Amlodipine.

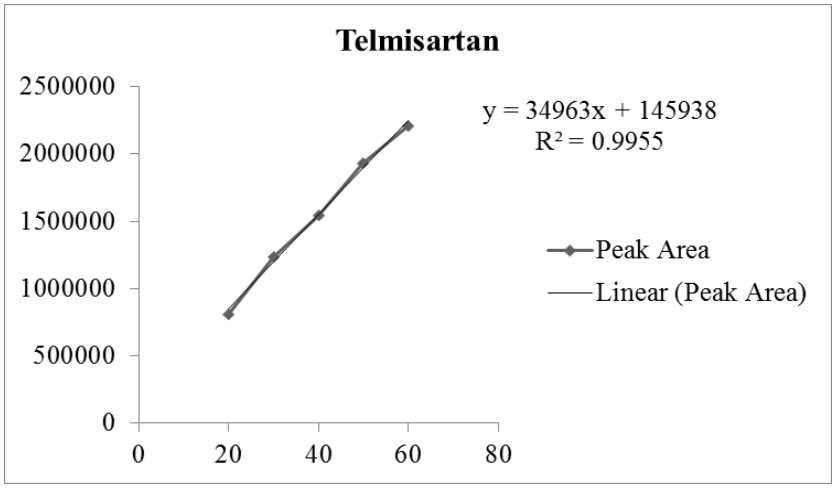


Figure 8: Linearity graph for Telmisartan.

Table 6: Results for linearity.

Amlodipine		Telmisartan	
Conc. in PPM*	**Peak Area**	**Conc. in PPM***	**Peak Area**
16	387748	20	806176
24	593504	30	1233387
32	778985	40	1547878
40	928457	50	1927678
48	1065725	60	2207183
Regression Equation	y = 21136x + 74521	Regression Equation	y = 34963x + 145938
Linearity Correlation Coefficient (R^2)	0.9925	Linearity Correlation Coefficient (R^2)	0.9955

***** Average of three replicate injections

Discussion: The R^2 values are within the acceptability standards, i.e. NLT 0.99 for Amlodipine and Telmisartan, indicating that the method is linear.

3.6 RANGE

The range is the interval between the highest and lowest analyte concentrations in the sample across which the technique has been demonstrated to be exact, accurate, and linear.

Table 7: Range values for Amlodipine & Telmisartan.

Percentage of solution	% RSD for Amlodipine	% RSD for Telmisartan
50%	0.08%	0.08%
100%	0.39%	0.39%
150%	0.06%	0.09%

Bracketing standard

Bracketing is an analytical approach in which samples are evaluated at the higher and lower limits of a specified range to ensure accuracy and precision over the whole range.

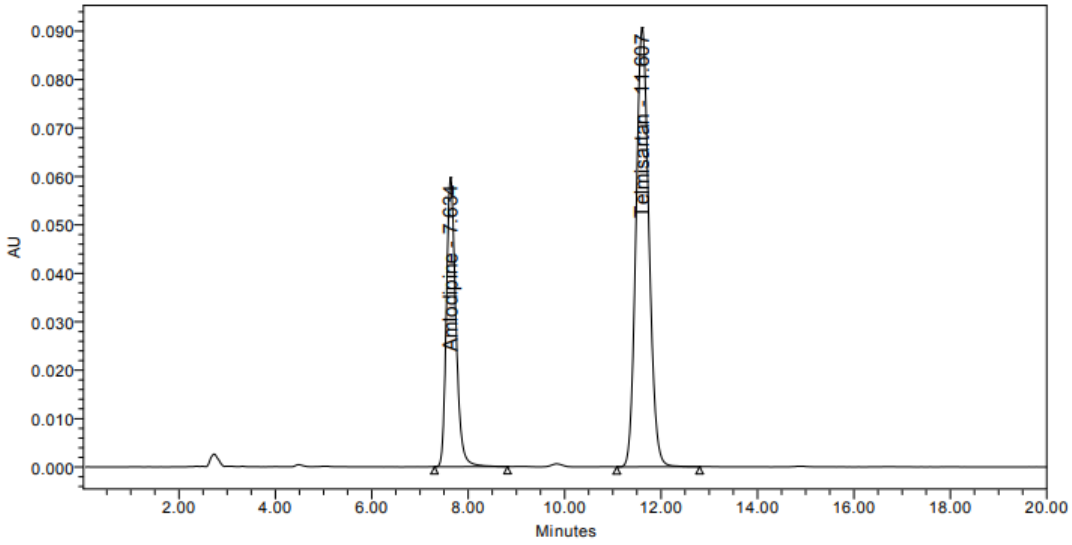


Figure 9: Sample solution Bracketing Standard chromatograms

METHOD APPLICATION TO THE ANALYSIS OF AMLODIPINE AND TELMISARTAN

The proposed and verified technique was used to simultaneously determine Amlodipine and Telmisartan in commercially available tablet dosage form UZITEL-A. The assay findings are reported in the table below. It was discovered that no dosage form excipients interfered with their analysis, indicating that the approach is suitable for routine quality control work.

Table 8: %Assay of Amlodipine and Telmisartan.

UZITEL-A Tablets		
Name of the drug	**Labeled claim (mg)**	**%Assay***
Amlodipine	5	98.59
Telmisartan	40	99.17

***Average of six replicate injections

SUMMARY AND CONCLUSION

The study successfully established and validated a particular, new, and accurate RP-HPLC technique for simultaneously estimating Amlodipine and Telmisartan in Tablet Dosage Forms.

Parameters	Amlodipine	Telmisartan
% Recovery in Accuracy	99.55%	99.20%
% RSD in Precision	0.20%	0.20%
Linearity Correlation coefficient	0.9925	0.9955
% Assay	98.59%	99.17%

The key objectives included optimizing the HPLC method for effective separation and quantification of the two drugs, while ensuring accuracy, precision, specificity, linearity, and range. The method's application to commercial product analysis, routine quality control, and stability testing was also assessed. The mobile phase consisted of ammonium acetate buffer and methanol (20:80). The chromatography was conducted under isocratic conditions with a UV detector set at 254 nm, a flow rate of 1 ml/min, and a run time of 20 minutes. The retention times for Amlodipine and Telmisartan were observed at approximately 7.6 and 11.5 minutes,

respectively. System suitability tests confirmed that theoretical plate counts exceeded 2000, and tailing factors were within acceptable limits. Precision was excellent, with the relative standard deviation (RSD) below 2%. Specificity tests verified the method's ability to accurately distinguish and quantify the drugs without interference. The method's accuracy was validated through recovery studies at different concentration levels, with RSD values below the 2% acceptance threshold. Linearity was demonstrated across various concentration levels. The method proved reliable for quantifying both drugs, with low RSD values further supporting its suitability for pharmaceutical analysis. In conclusion, the developed HPLC method was found to be accurate, precise, specific, and linear, making it suitable for the simultaneous determination of Amlodipine and Telmisartan in pharmaceutical formulations. It is well-suited for routine quality control and stability testing of combined dosage forms

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