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Validated Stability Indicating RP-HPLC-PDA Method for Simultaneous Quantification of Azelnidipine and Telmisartan in Pharmaceutical Dosage Form

P. Roja[1], M. M. Eswarudu[1]*, P. Siva Krishna[1] P. Ravi sankar[1], P. Srinivasa Babu[2]
Department of Pharmaceutical Analysis, Vignan Pharmacy College, Vadlamudi, Guntur District – 522213, Andhra Pradesh, India.
Department of Pharmaceutics, Vignan Pharmacy College, Vadlamudi, Guntur District – 522213, Andhra Pradesh, India.
***Corresponding Author's** Email: eswarmunnangi@gmail.com

ABSTRACT
For the simultaneous detection of Azelnidipine and telmisartan in bulk and pharmaceutical dose form, a reversed phase high performance liquid chromatographic (RP-HPLC) approach has been designed and validated in the current work. Azelnidipine and Telmisartan were successfully separated by chromatography utilising the Waters Alliance-e2695 system and a Waters X-Bridge Phenyl 150 X 4.6 mm, 3.5 column. The mobile phase used was a 0.1% trifluoroacetic acid and acetonitrile (20:80 v/v) solution given at a flow rate of 1.0 mL/min. Analytes were monitored and measured by PDA detector at 258 nm. Telmisartan and Azelnidipine had retention times of 2.322 minutes and 4.867 minutes, respectively. The current analytical technique was conducted in accordance with ICH standards (ICH, Q2R1). The concentration ranges for Telmisartan and Azelnidipine in the linearity study were found to be 10–60 µg/mL and 2–12 µg/mL, respectively, and their respective coefficients of variance were found to be 0.9997 and 0.9998. For Telmisartan and Azelnidipine, the % Recovery was found to be 100.1% and 100.4%, respectively. LOD and LOQ for Telmisartan were 0.12 µg/mL and 0.4 µg/mL and for Azelnidipine 0.024 µg/mL and 0.08 µg/mL, respectively. To determine the stability, the standard and sample solutions are observed at different degradation studies in laboratory conditions like acidic, alkaline, peroxide, hydrolysis, thermal, reduction, photochemical degradation testing conditions, the results and data was compared with standard chromatograms and drugs was shown to be more stable under hydrolysis and Photochemical degradation testing settings than under acidic, alkaline, peroxide, thermal, reduction degradation conditions. It was concluded that the simultaneous estimation of Telmisartan and Azelnidipine in bulk and its pharmaceutical dosage form was found to be successfully conducted by using method. It could be applied for the regular examination of the investigated pharmaceuticals in quality control laboratories.
Keywords: *RP-HPLC, PDA Detector, Telmisartan, Azelnidipine, Quantification and Method Validation.*

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INTRODUCTION

Hypertension (HT) is a very common disorder, particularly for past middle age. It is not a disease in itself, but is an important risk factor for cardiovascular mortality and morbidity. Hence, Azelnidipine (AZL) and Telmisartan (TEL) fixed dose combination was approved by US-FDA for the treatment of hypertension. When compared to Azelnidipine monotherapy, the fixed dose combination with Telmisartan is safe, well tolerated, and has a lower incidence of side effects.[1]

Azelnidipine (AZL) is a calcium channel blocker of the dihydropyridine class used to treat angina pectoris and hypertension. Chemically it is 3-[1-(Benzyldrylazetidin-3-yl]5-isopropyl-2-amino 6 methyl-4-(3-nitrophenyl)-1,4-dihydropyridine-3, 5 dicarboxylate; It is practically insoluble in water but freely soluble in acetone and acetic acid, methanol, ethanol, and ethyl acetate. It acts by inhibiting trans membrane Ca^{2+} influx through the voltage dependent channels of smooth muscles in vascular walls. [2-6]

Telmisartan (TEL) belongs to Angiotensin receptor blockers with chemical name 2-[4-[[4-methyl-6-(1-methylbenzimidazol-2-yl)-2-propylbenzimidazol-1yl] methyl] phenyl] benzoic acid. It is sparingly soluble in strong acid (except HCL), and completely soluble in strong base and methanol. It binds reversibly and specifically to the receptors in vascular smooth muscle and the adrenal gland, interfering with the binding

of angiotensin II to the angiotensin II AT1-receptor. [7-8]. Telmidoz®-AZ tablets, which contain 8 mg of Azelnidipine and 40 mg of Telmisartan are used for hypertension treatment.
Literature survey revealed a variety of analytical methods UV, RP-HPLC has been reported for estimation of TEL and AZL and individually or in combination with other drugs. The reported methods are Spectrophotometric [9-11], and HPLC [11-15] methods are reported for the simultaneous quantification of TEL and AZL and in combined pharmaceutical formulation. Present study aimed to develop a Stability indicating RP-HPLC method and validation for the determination of AZEL and TEL in bulk and in its pharmaceutical dosage form with good accuracy and precision. According to ICH Q2R1 analytical method validation parameters, the developed method was validated. [16-18]. Figure 1 depicts the AZEL and TEL chemical structures.

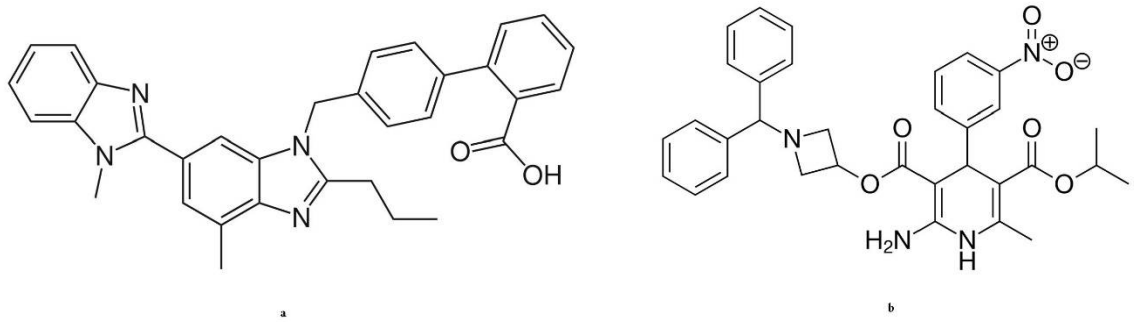

Figure 1: Chemical Structures of (a) Telmisartan and (b) Azelnidipine

MATERIAL AND METHODS

Chemicals and reagents: HPLC graded of Acetonitrile and Analytical grade of Trifluoro acetic acid was procured from Rankem, India. The study made use of water that has been purified using a Milli-Q system. The rest of the chemicals and reagents were procured from standard commercial supplier. Standard drug samples of Azelnidipine (≥98%), was bought from Aavyan Labs, Hyderabad, India. and Telmisartan (≥98%) standard drugs (API) were obtained as gift samples from Dr. Reddy's Laboratories, Hyderabad, India. The commercial formulation of Telmisartan and Azelnidipine (Telmidoz®-AZ) were procured from local Pharmacy store.

Instrumentation: The analysis was performed by using a chromatographic system Alliance Waters e2695 series HPLC comprised of vacuum degas, auto injector, and quaternary gradient pump with Photodiode Array detector. The HPLC system was equipped with Empower 2 software. The absorbance was measured using a double beam UV-Visible spectrophotometer (Shimadzu (UV-1780) with 1 cm matched quartz cells. The samples were weighed using an electronic balance from Shimadzu (AX-200). Ultrasonicator (Citizen) and Class "A" volumetric glassware were employed. and Class 'A' volumetric glassware's were used for the study.

Chromatographic conditions: For chromatographic separation, Waters X-Bridge Phenyl 150 X 4.6 mm, 3.5 µm column was used to analyze TEL and AZL. The mobile phase was made up of a 20:80 v/v combination of acetonitrile and 0.1% TFA. And it was delivered at a flow rate of 1.0 mL/min. Methanol was used as diluent. Analytes detection was done at 258 nm with a PDA detector and sample injection volume of 10 µl. The run time was set at six minutes.

Mobile phase preparation: Accurately transferred 1mL TFA into a 1000 mL of water and filtered through 0.45µm membrane filter paper, pH of the buffer was set at 2.3 and HPLC graded acetonitrile was used and ratio is 20:80 v/v.

Standard stock preparation: Accurately weighed and transferred 5 mg of TEL, 5 mg of AZL working standard into a 10 mL clean dry volumetric flask, further 3 mL of methanol was added and sonicated to dissolve it completely and made volume up to the mark with the methanol as diluent. Further Pipetted 8 mL of the TEL and 1.6 mL of the AZL into two different 10 mL volumetric flasks, and made the volume up to the mark with diluent to get stock solution.

Further pipetted 1 mL of the above stock solution into a 10 mL volumetric flask and diluted up to the mark with diluent to obtained 40 ppm of TEL, 8 ppm of AZL drug solution.

Sample preparation: Accurately weighed and transferred 28.6 mg of tablet powder into a 10 mL volumetric flask and 5 mL of diluent was added, sonicated it up to 10 mins to dissolve completely and made volume up to the mark with the same solvent. Then it was filtered through 0.45-micron filter paper. Further

pipetted 1 mL of the above solution into a 10 mL volumetric flask and diluted up to the mark with diluent to obtained 40 ppm of TEL, 8 ppm of AZL.

Method Validation

The proposed method was validated according to the ICH Q2R1 guidelines which include system suitability, specificity, linearity, accuracy, precision, limit of detection (LOD), limit of quantification (LOQ) and robustness.

The following parameters were studied as part of the validation study.

System Suitability test: HPLC system was optimized as per the chromatographic conditions.

Into the chromatographic system, 10 µL of study drug analytes were injected in triplicate. The characteristics such as retention time, theoretical plates, relative retentions, and tailing factor were calculated and compared with the standard specification of the system to ascertain the system's compatibility for the suggested method.

Specificity: Method was chosen by comparing the chromatograms of blank, standard and sample for Specificity study.

Linearity: Linearity was assessed using visual inspection of plot of signal as a function of analyte concentration. If there is a linear relationship test results are calculated by regression line by method of least squares. Peak area vs. concentration data for TEL and AZL were plotted to create calibration curves, and regression equations were then derived.TEL and AZL calibration curves were plotted over a range of six different concentrations.

Accuracy: The accuracy of the method was evaluated using standard addition method. A known amount of standard drug is added to the fixed amount of pre-analysed injection solution. Percent recovery is calculated by comparing the area before and after addition of the standard drug. The 50%, 100%, and 150% levels are used for the standard addition method. According to the proposed method, the solutions are assessed in triplicate at each level.

Precision: It was expressed by injecting into an HPLC column on the same day in six replicates, known concentrations of TEL (40 µg/mL) and AZL (8 µg/mL) were examined. The intermediate precision was assessed by injecting samples prepared at the same concentrations on two different days by different operators. The standard deviation, percent relative standard deviation (%RSD), was calculated using the peak areas of all injections.

Limit of Detection (LOD) and Limit of Quantification (LOQ): LOD and LOQ of TEL and AZL were calculated using the following equations:

$$LOD = 3.3 \times N / B$$

$$LOQ = 10 \times N / B$$

Where N is residual variance due to regression; B is the slope.

Robustness: The standard and samples of TEL and AZL were injected by changing the chromatographic conditions like flow rate of the mobile phase, pH of the buffer and composition of the mobile phase. The parameters like plate count, resolution, tailing factor, and asymmetric factor did not change significantly.

Degradation studies: Standard and sample solutions are assessed during various degradation studies in a laboratory setting to evaluate stability, and the results and data are compared with standard chromatograms.

Acid degradation studies: One mL of TEL and AZL Stock solution was transferred into 10 mL of volumetric flask, one mL of 2N Hydrochloric acid was then added and thoroughly mixed and refluxed for 30 mins at 60^0C. The resultant solution was diluted to obtain 40 µg/mL, 8 µg/mL solutions and 10 µL solutions were injected into the system and the chromatograms were recorded to assess the stability of sample.

Alkali degradation studies: One mL of stock solution of TEL and AZL solution was transferred into a 10 mL volumetric flask. One mL of 2N Sodium hydroxide was then added, thoroughly mixed, and kept for 30 minutes at 60^0 C. The final solution was diluted to obtain 40 µg/mL, and 8 µg/mL solutions. 10 µL of these solutions were then injected into the system, and chromatograms were obtained to determine the sample's stability.

Oxidative degradation studies: One mL of stock solution TEL and AZL was transferred into a 10 mL of volumetric flask, 1 mL of 20% hydrogen peroxide (H_2O_2) was then added and mixed well and solutions were kept for 30 mins at 60^0C. The resultant solution was diluted to obtain 40 µg/mL and 8 µg/mL solutions. 10 µL of the solutions were injected into the system, and the chromatograms were recorded to measure the stability of sample.

Thermal degradation studies: To evaluate dry heat degradation, one mL of a standard drug solutions that contains TEL and AZL was placed at 105°C for six hours. To determine the stability of the sample, the

resulting solution was diluted to a concentration of 40 µL g/mL, 8 µg/mL solutions, and 10 µL were injected into the HPLC system. Chromatograms then were recorded.

Photo stability studies: The photo chemical stability of the drugs was studied by exposed to UV Light. The 40 µg/mL and 8 µg/mL of TEL and AZL solutions by keeping the flasks in the UV Chamber for 7 days. For HPLC study, the resultant solution 10 µl were injected into the system and the chromatograms were recorded to assess the stability of the sample.

Neutral degradation studies: Stress testing under neutral conditions was studied by refluxing the drug solutions in water for 6 hours at a temperature of 60^0C. For HPLC study, the resultant solution was diluted to get 40 µg/mL 8 µg/mL solutions and 10 µL were injected into the system, and the chromatograms were recorded to assess the stability of the samples.

RESULTS AND DISCUSSION

The HPLC method was optimised for simultaneous determination of TEL and AZL and in pharmaceutical dosage form by using Waters X-Bridge Phenyl 150 X 4.6 mm, 3.5 µm column in isocratic mode with mobile phase made of 0.1% TFA and Acetonitrile in the 20:80 v/v ratio. Mobile phase was pumped at a rate of 1.0 mL/min, and a PDA detector was used to monitor both analytes at 258 nm. Resulted in peaks with good shape and well resolved. The results of optimized HPLC conditions were shown in Table 1. The method was linear in the range of 10-60µg/mL and 2-12µg/mL for TEL and AZL with correlation coefficient 0.9997 for TEL and 0.9998 for AZL. Linear regression data and linearity curves for both analytes were given in Table 2, Figure.4. It was discovered that TEL and AZL had respective mean% recoveries of 100.1% and 100.4%. which demonstrates methods is accurate. In Table 3, the accuracy results were shown. The % RSD values of method and system precision are 0.87 and 0.40 and 0.34 and 0.37 for TEL and AZL respectively. The proposed method is accurate, as shown by the % RSD values of reproducibility for TEL and AZL, which were found to be < 2%. Tables 4 and 5 presented the precision results. TEL and AZL showed retention times (RT) of 2.322 mins and 4.867 mins, with a measured theoretical plate count of 5429, 6671, and a tailing factor of 1.15 and 1.01, respectively, the column appears to be operating effectively. LOD and LOQ for TEL, were 0.12 µg/mL and 0.4 µg/mL and for AZL, 0.024 µg/mL and 0.08 µg/mL, respectively. Which shows the sensitivity of the method. Table 6 illustrates that the method is sufficiently robust because of % RSD values of the robustness studies were found to be < 2%. Table 7 summarizes the results of system suitability and validation parameters for TEL and AZL.

The proposed validated method was applied for the determination of TEL and AZL in commercial formulations. The % assay was found to be 99.85 % and 99.01 % for TEL and AZL respectively. Table 8 and Figure 3 depicts the assay's results.

After subjecting TEL and AZL with varying strengths of acid (2N HCl), alkali (2N NaOH), Hydrogen peroxide (20% H_2O_2), heat (105^0C), photolytic (UV chamber), and water (Hydrolysis), and drugs was shown to be more stable under hydrolysis and Photochemical degradation testing settings than other testing conditions. Table 9 and Figure 5 shown the stability study results. Typical chromatogram of standard TEL and AZL including blank and placebo was depicted in Figure. 3. These outcomes showed that the suggested method is specific and sensitive for quantifying TEL and AZL.

The proposed RP-HPLC method was optimised for simultaneous determination of TEL and AZL and in pharmaceutical dosage form. The resulted in peaks with good shape and well resolved.

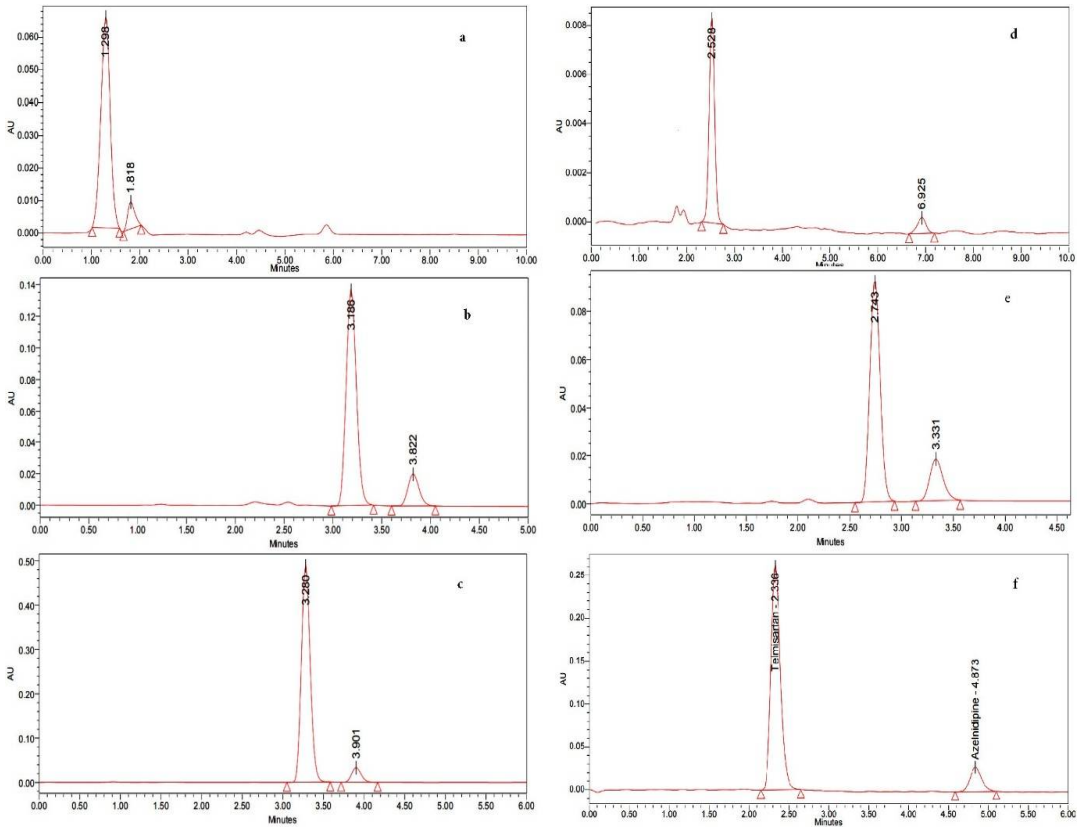

Figure 2: Trails to optimize the method(a-f)

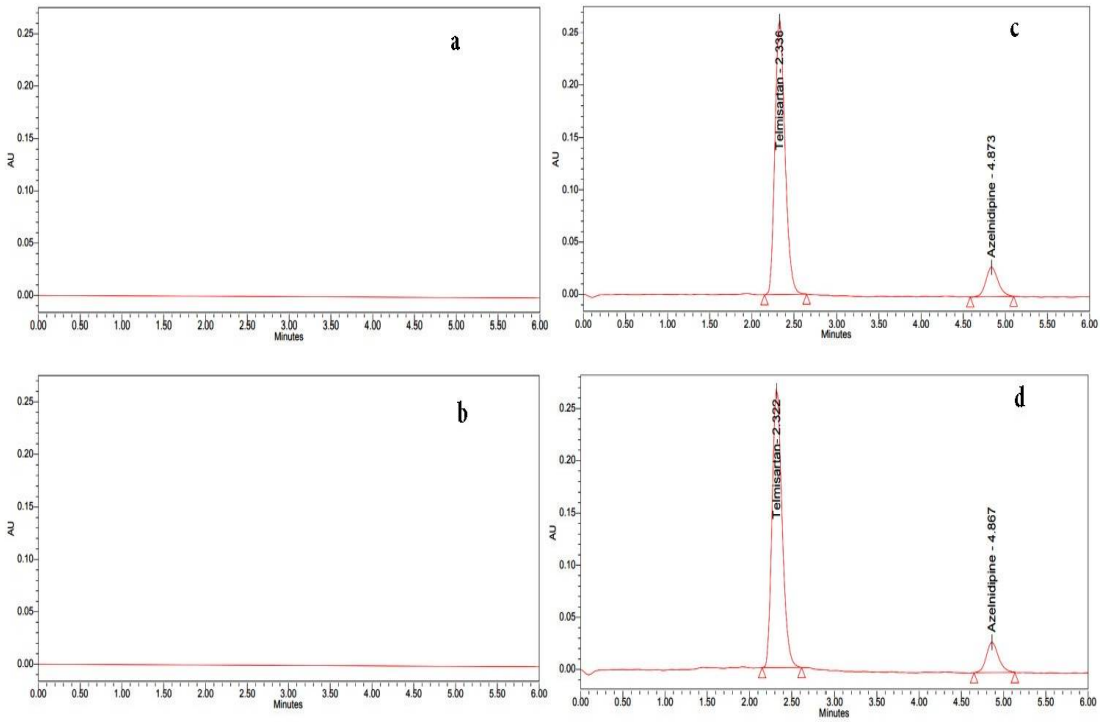

Figure 3: Chromatograms of a. blank, b. placebo, c. Optimized chromatogram, d. Assay of the optimized method

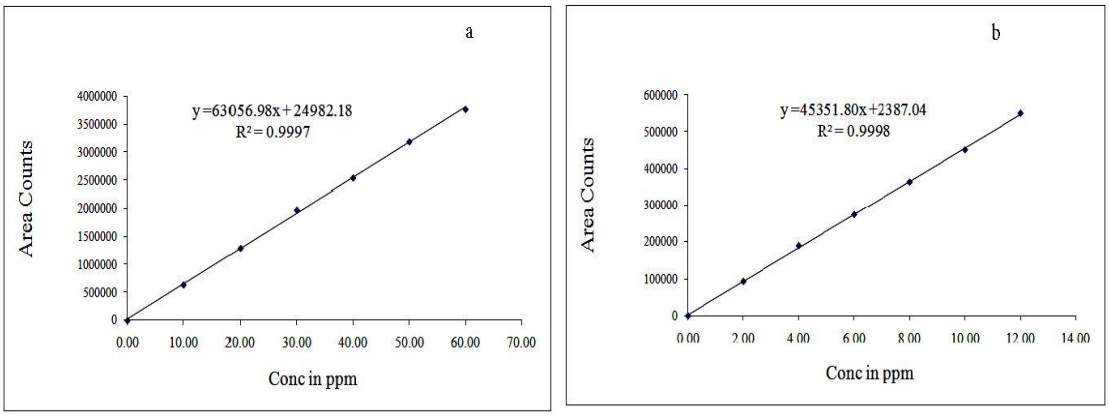

Figure 4: a. Linearity Graph of Telmisartan b. Linearity Graph of Azelnidipine

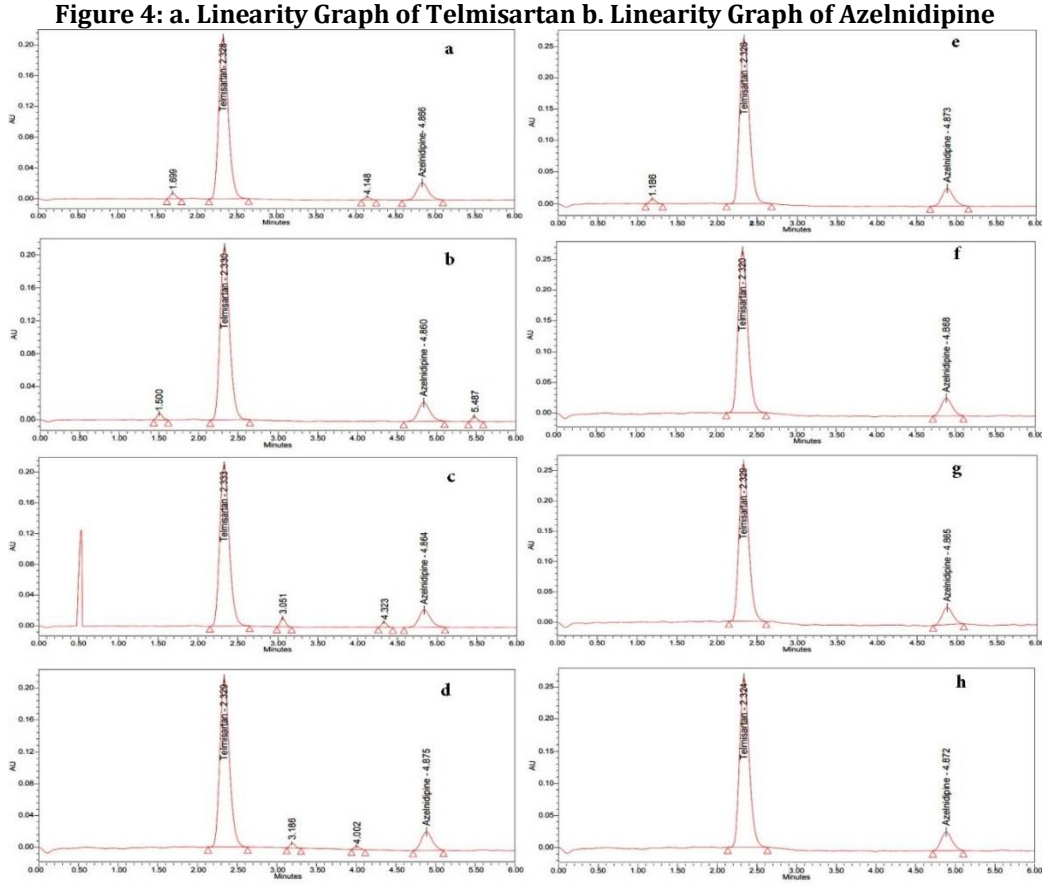

Figure 5: Chromatogram of a. Acid degradation, b. Alkali degradation, c. Peroxide degradation, d. Reduction degradation, e. Thermal degradation, f. Photolytic degradation, g. Hydrolysis degradation, h. Control degradation

Table 1: Optimized Chromatographic Conditions of Telmisartan and Azelnidipine

S.No.	Parameters	Observation
1	Instrument used	Waters HPLC with auto sampler and PDA detector.
2	Injection volume	10 µl
3	Mobile Phase	Acetonitrile and 0.1% TFA (20:80)
4	Column	Waters X-Bridge Phenyl (150 x 4.6 mm, 3.5 µm)
5	Detection Wave Length	258 nm
6	Flow Rate	1 mL/min
7	Runtime	6min
8	Temperature	Ambient (25°C)
9	Mode of separation	Isocratic mode

Table 2: Linearity results of Telmisartan and Azelnidipine

S.NO	Telmisartan		Azelnidipine	
	Conc.(µg/mL)	Peak area	Conc.(µg/mL)	Peak area
1	10.00	639653	2.00	93123
2	20.00	1295299	4.00	189437
3	30.00	1981147	6.00	274437
4	40.00	2541563	8.00	363524
5	50.00	3188539	10.00	451032
6	60.00	3770639	12.00	549932

Table 3: Accuracy result of Telmisartan and Azelnidipine

%Concentration (at specification Level)	Area	Amount Added (mg)	Amount Found (mg)	% Recovery	Mean % Recovery
Telmisartan					
50%	1267441	2	2.01	100.5	100.1
100%	2525921	4	4.0	100.0	
150%	3772308	6	5.98	99.7	
Azelnidipine					
50%	183053	0.4	0.402	100.5	100.4
100%	366406	0.8	0.806	100.8	
150%	545237	1.2	1.199	99.9	

Table 4: Method Precision Results of Telmisartan and Azelnidipine

S. No.	Area for Telmisartan	Area for Azelnidipine
1	2555679	363519
2	2512432	362247
3	2573387	364054
4	2537485	363138
5	2522066	365055
6	2541679	366359
Average	2540455	364062
Standard Deviation	22136.168	1463.227
%RSD	0.87	0.40

Table 5: System Precision Results of Telmisartan and Azelnidipine

S. No	Concentration Telmisartan (µg/mL)	Area of Telmisartan	Concentration Azelnidipine (µg/mL)	Area of Azelnidipine
1.	40	2537472	8	362893
2.	40	2525965	8	364560
3.	40	2512625	8	361950
4.	40	2530410	8	363591
5.	40	2525364	8	365786
6.	40	2520205	8	364268
Mean	2525340		363841	
S. D	8500.83		1343.09	
%RSD	0.34		0.37	

Table 6: Robustness study results for Telmisartan and Azelnidipine

Parameter	Telmisartan					
	Condition	Retention time (min)	Peak area	Resolution	Tailing	Plate count
Flow rate Change (mL/min)	Less flow (0.9 mL)	2.545	2741736	-	1.16	5546
	Actual (1mL)	2.336	2537472	-	1.17	5429
	More flow (1.1mL)	2.088	2242709	-	1.07	5374
	Less Org (18:82)	2.832	2836811	-	1.18	5571
	Actual (20:80)	2.332	2525965	-	1.19	5432

Organic Phase change	More Org (22:78)	1.926	2091340	-	1.11	5359
Azelnidipine						
Flow rate Change (mL/min)	Less flow (0.9mL)	5.056	384210	9.89	1.10	6704
	Actual (1mL)	4.873	362893	10.21	1.04	6615
	More flow (1.1mL)	4.605	321542	10.05	1.00	6548
Organic Phase change	Less Org (18:82)	5.336	404417	9.92	1.13	6718
	Actual (20:80)	4.879	364560	10.38	1.09	6628
	More Org (22:78)	4.324	306259	9.86	1.02	6523

Table 7: Results of System Suitability and Validation Parameters

S. No.	Parameter	Results	
		Telmisartan	Azelnidipine
1	Linearity range (µg/mL)	10-60	2-12
2	Slope (m)	63056.98	45351.80
3	Intercept (c)	24982.18	2387.04
4	Correlation coefficient(R^2)	0.9997	0.9998
5	Retention times (min)	2.332	4.879
6	Plate count	5429	6671
7	Tailing factor	1.15	1.01
8	Repeatability (%RSD)	0.34	0.37
9	LOD (µg/mL)	0.12	0.024
10	LOQ (µg/mL)	0.4	0.08
11	Resolution (Rs)	10.33	

Table 8: Assay table of Benidin T Marketed Formulation

Formulation	Label Claim	Amount Found	% Assay
Telmidoz®-AZ	AZEL- 8 mg/tablet	7.92 mg/tablet	99.01
	TEL- 40 mg/tablet	39.94 mg/tablet	99.85

Table 9: Forced Degradation results for Telmisartan and Azelnidipine

Results: % Degradation results	Telmisartan		Azelnidipine	
	Area	% Degradation	Area	% Degradation
Control	2525530	0	363806	0
Acid	2207963	12.6	321270	11.7
Alkali	2175274	13.9	316563	13.0
Peroxide	2103215	16.7	307113	15.6
Thermal	2266240	10.3	359412	1.2
Photolytic	2490377	1.4	361974	0.5
Hydrolysis	2497941	1.1	361196	0.7

CONCLUSION

For the simultaneous quantification of TEL and AZL in bulk and its pharmaceutical formulations, the proposed method was developed and successfully validated. The method was able to quantify TEL and AZL even at a level of 0.4 µg/mL and 0.08 µg/mL with less run time. The established method was precise and is suitable to determine TEL and AZL simultaneously in tablet dosage form and giving an acceptable recovery of the analytes. This method can be used as better analytical tool for simultaneous estimation of TEL and AZL in bulk and in its pharmaceutical formulations.

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CONFLICT OF INTEREST: Nil

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