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Stability indicating HPTLC method for simultaneous determination of Azelnidipine and Telmisartan Combined Tablet Dosage Form

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Abstract: The combination of azelnidipine (AZL) and telmisartan (TLM)is widely used in the treatment of hypertension. A simple, rapid, precise, selective and accurate stability indicating High-Performance Thin-Layer Chromatographic (HPTLC) method was developed and validated for their simultaneous estimation of Azelnidipine and Telmisartanin its combined tablet formulation. Stationary phase used is TLC aluminium plates precoated with silica gel 60F-254.The mobile phase consists of Chloroform: Ethylacetate (5:5 v/v) and 10 ml of mobile phase was used per chromatography run. It provides well defined spots for both azelnidipine (Rf value 0.70) and telmisartan (Rf value 0.17) and the degraded products were clearly separated from pure drugs. Densitometric scanning was performed using a Camag TLC scanner 3 in the reflectance absorbance mode at 254 nm by Wincats software. The calibration plot showed good linearity with r^2 = 0.9967 in the concentration range of 1-6 µg/ml for Azelnidipine and 5 -30 µg/ml for Telmisartan with r^2 =0. 9966.The method was validated for accuracy, precision, recovery and robustness and it was found to be linear, accurate, specific. precise, robust and stability indicating for routine analysis of both the drugs in simultaneous estimation. Percentage assay was found to be 98.87 and 100.17 for Azelnidipine and Telmisartan. The % RSD for intraday studies of AZL and TLM 0.0184 and 0.0068 respectively. The % RSD for interday studies of AZL and TLM was found to be 0.0126and 0. 0068. The LOD for AZL and TLM was found to be 910 µg/ml and 4570µg/ml. The LOQ for AZL and TLM was found to be 276 µg/ml and 13850µg/ml. Drugs were subjected to acid and base hydrolysis, oxidative, photo and thermal degradation as per ICH recommended conditions. The drug undergoes degradation under acidic, base, oxidative and heat degradation but no degradation observed for both the drugs under photo and neutral degradation (water). As the method could effectively separate drug from its degradation products it can be employed as stability indicating one. The reported method is simple, selective, timesaving, and economic compared to other HPLC methods reported.

Keywords: Azelnidipine; Telmisartan; HPTLC; UV-visible spectroscopy; validation; stability.

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INTRODUCTION

Azelnidipine (AZL) is chemically (±)-3-(1-diphenylmethylazetidin3-yl) 5-isopropy12-amino-1, 4-dihydro-6-methyl-4-(3-nitrophenyl) 3,5-pyridinedicarboxylate. It is a dihydropyridine (DHP) type of calcium channel blocker (CCB) used for the treatment of hypertension [1]. Telmisartan (TLM) is chemically 2-[4-[[4-methyl-6-(1-methylbenzimidazol-2-yl)-2-propylbenzimidazol-1-yl] methyl] phenyl] benzoic acid. Telmisartan selectively antagonizes angiotensin II binding to the AT1 subtype receptor, located in vascular smooth muscle and adrenal gland [2]. Fixed Dose Combination (FDC) containing 8 mg of AZL and 40 mg of TLM is available in the market with the brand name of Uniaz t-40 under the therapeutic class of anti-hypertensive agent, calcium channel blocker [3]. High-performance thin layer chromatography (HPTLC) is an enhanced form of thin layer chromatography (TLC). A number of enhancements can be made to the basic method of thin layer chromatography to automate the different steps, to increase the resolution achieved and to allow more accurate quantitative measurements. HPTLC technique is one of the most flexible, reliable, and cost-efficient separation technique ideally suited for the analysis of botanicals and drugs. HPTLC is a vital element in the routine identification of complex fingerprints of plant extracts and pharmaceutical products [4].

Stability testing is a routine procedure performed on API and its formulation. It is employed at various stages of the product development. The major aim of pharmaceutical stability testing is to provide reasonable assurance that the products will remain at an acceptable level of fitness/quality throughout the period during which they are in market place

available for supply to the patients and will be fit for their consumption until the patient uses the last unit of the product. The purpose of stability testing is to provide evidence on how the quality of a drug substance or drug product varies with time under the influence of a variety of environmental factors such as temperature, humidity, and light, and to establish a re-test period for the drug substance or a shelf life for the drug product and recommended storage conditions [5].

Various analytical methods including HPLC, UV, HPTLC UHPLC, LC-MS have been reported for determination of Azelnidipine and Telmisartan individually and in combination with other drugs. Literature survey reveals that there is no stability indicating high-performance thin layer chromatography method for the simultaneous estimation of Azelnidipine and Telmisartan in their combined tablet dosage form so, the present work is to develop a simple, rapid, precise, selective and accurate stability indicating High-Performance Thin-Layer Chromatographic (HPTLC) method for the estimation of Azelnidipine and Telmisartanin its formulation. The aim of the present work is to develop a stability indicating HPTLC method for simultaneous determination of Azelnidipine and Telmisartan in their combined tablet dosage form.

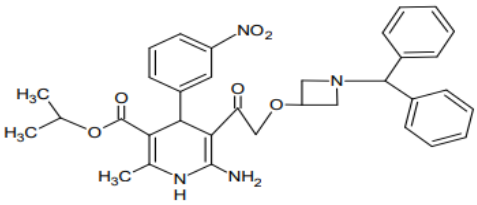

Figure 1. Structure of Azelnidipine

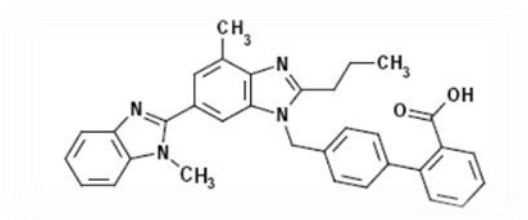

Figure 2. Structure of Telmisartan

EXPERIMENTAL

MATERIALS AND METHODS

Using HPTLC estimation the samples were spotted in the form of bands of width 8 mm with a Camag500 micro litre sample syringe (Hamilton, Switzerland) on a silica gel precoated aluminium plate 60 F 254, (10cm ×10cm, 250 µm thickness) using a CamagLinomat 5 sample applicator. The plates were prewashed with methanol and activated at 60˚C for 5 min prior to chromatography with constant application rate of 150 nl/sec and the space between two bands was 14.5 mm. The slit dimension was kept at 5×0.45 mm and the scanning speed was 20 mm/sec. The monochromatic band width was set at 20 nm and each track was scanned three times and base line correction was adjusted. The mobile phase consists of Chloroform: Ethylacetate (5:5 v/v) and 10 ml of mobile phase was used per chromatography run. Linear ascending development was carried out in 20 ×10cm twin trough glass chamber saturated with a mobile phase. After development of the plate, it was air dried and densitometry scanning was performed using a Camag TLC scanner 3 in the reflectance absorbance mode at 254 nm and operated by Wincats software, the light source used was Deuterium lamp emitting a continuous UV spectrum between 200-400 nm. Concentration of the compound chromatographed was determined from the intensity of diffused light. Evaluation was determined by using peak area with linear regression.

Azelnidipine and Telmisartan working standards were procured from Precise Biopharma Pvt. Ltd, Maharashtra, India. Azelnidipine and Telmisartan tablet formulation (8 mg and 40 mg) were used, marketed by Torrent Pharmaceuticals Ltd., India. Analytical grade methanol, chloroform, ethyl acetate procured from Merck, Darmstadt, Germany. TLC aluminum plate precoated with silica gel 60F-254 (10 × 10 cm, layer thickness 0.2 mm procured from E. Merck KGaA, Darmstadt, Germany.

Preparation of Solutions

Preparation of standard stock solution of Azelnidipineand Telmisartan.

Standard stock solutions of Azelnidipine and Telmisartan were prepared by accurately weighed 50 mg of each drug and transferred in 10 ml standard flask and the volume was made up with methanol to get a concentration of 5000 µg /ml.

Preparation of working standard solution

From the standard stock solutions 1 ml aliquots were taken from AZL and 5 ml aliquot was taken from TLM and diluted up to 10 ml with methanol to get the mixture solution containing the concentration of500 µg/ml AZL and 2500 µg/ml TLM.

Preparation of Sample Solution

For analysis of tablet dosage form, twenty tablets, each containing, 8 mg Azelnidipine and 40 mg Telmisartan, were weighed and their average weight was calculated. The tablets were finely powdered and powder equivalent to 50 mg Telmisartan was accurately weighed and dissolved in 10 ml of methanol. The solution was centrifuged for 5 mins at 600 rpm, filtered through Whatman No. 41 filter paper and the residue was washed with methanol. From the resulting

solution aliquots of 5ml solution was transferred to a 10 ml standard flask and the volume was made up with the methanol to get the same concentration as that of final standard solution.

Selection of Wavelength

In UV-visible spectroscopy, the **s**tandard stock solution of Azelnidipine and telmisartan were scanned in the range of 200-400 nm separately. Data were obtained through overlay spectra of both drugs, AZL and TLM show absorption maxima at 256 nm and 306 nm respectively. The detection of HPTLC was carried out at different wavelengths best response was achieved at 254 nm and 296 nm in Chloroform: Ethyl acetate. Finally, for the detection, the wavelength selected was 254nm.

METHOD VALIDATION

The number of drugs introduced into the market is increasing every year. These drugs may be either new entities or partial structural modifications of the existing one. Very often; there is a time lag from the date of introduction of a drug into the market to the date of its inclusion in pharmacopoeias. This happens because of the possible uncertainties in the continuous and wider usage of these drugs, report of new toxicities, and development of patient resistance and introduction of better drugs by the competitors. Under these conditions, standards and analytical procedures for these drugs may not be available in pharmacopoeias. It becomes necessary, therefore, to develop newer analytical methods for such drugs [6]. Analytical method development and validation was performed as per ICHQ2(R1) guidelines [7]. validated parameters include linearity, accuracy, precision, LOD, LOQ, ruggedness and robustness. Linearity of the method was performed in triplicate using mixed standard solutions at six different concentration ranges. The selected range for linearity was 1-6µg/ml for AZL and 5-30 µg/ml for TLM. By plotting peak area vs concentration, the linear regression equation was obtained. The LOD and LOQ values were calculated from standard deviation of the response and the slope respectively. The precision of the method was performed as intraday and interday for three independent sample solutions at three concentration levels for each. The % RSD was calculated for intraday and interday studies. Accuracy of the method development was established using spiked preanalyzed samples with concentration of know standard solutions with levels of 50%,100% and 150% in triplicates and the % RSD was calculated. The ruggedness of the method assessed by comparison of the intraday and interday assay results for AZL and TLM that has been performed by two analysts. The %RSD values of the intraday and interday assay results for AZL and TLM in the commercial tablet performed in the same laboratory by two analysts. In addition, the robustness of the method was investigated by altering mobile phase ratio, development distance, detection wavelength and slit dimension. The degree of reproducibility of results obtained as a result of a small deliberate variations in the method parameters and by changing analyst values were calculated respectively.

Stability studies

forced degradation studies of tablet formulation

Azelnidipine and telmisartanin combined tablet formulation (Uniaz T-40) were purchased from local market containing 8 mg and 40 mg respectively. The tablets were accurately weighed, crushed and sample powder equivalent to 50 mg of telmisartan (contains 10 mg of Azelnidipine) was transferred into 10 ml standard flask and made up with methanol and filtered thoroughly. From this 5 ml solution was taken and transferred to 10 ml standard flask, made up with methanol and it was exposed to stress conditions. This solution was used for forced degradation to provide an indication of stability indicating property and specificity of the proposed method. In all degradation studies the average peak area of Azelnidipine and telmisartan after application of 1µl of six replicates was obtained and appropriate volume was spotted on to TLC plate

Acid hydrolysis

To 2.5 ml of sample solution, 2.5 ml of 0.1 N HCl was added. The volume was made up with 10 ml methanol. The mixture was refluxed at 60°C for 5 hours. Appropriate volume of resultant solution was applied on TLC plate and densitogram were developed.

Base hydrolysis

To 2.5 ml of sample solution, 2.55 ml of 1 N NaOH was added. The volume was made up with 10 ml methanol. The mixture was refluxed at 60°C for 5 hours. Appropriate volume of resultant solution was applied on TLC plate and densitogram were developed.

Oxidative degradation

To 2.5 ml of sample solution, 2.5 ml of 30% H_2O_2 was added. The mixture was kept in room temperature for 4 hours. Appropriate volume of resultant solution was applied on TLC plate and densitogram were developed.

Neutral hydrolysis

To 2.5 ml of sample solution, 2.5 ml of distilled water was added. The mixture was refluxed at 60°C for 5 hours. Appropriate volume of resultant solution was applied on TLC plate and densitogram were developed.

Photo degradation

In photo-degradation study, the tablets were exposed to UV light in a photo-stability chamber for 7 days. Accurately weighed powder was transferred to the 10 ml container and the volume was made up to the mark with methanol. Appropriate volume of resultant solution was applied on TLC plate and densitogram were developed.

Thermal degradation

Dry heat studies were performed by keeping the drug sample in oven (80°C) for 7 days. accurately weighed powder was transferred to the 10 ml container and the volume was made upto the mark with methanol. Appropriate volume of resultant solution was applied on TLC plate and densitogram were developed.

RESULTS AND DISCUSSION

Method development

An analytical method details the steps necessary to perform an analysis. This may include: preparation of samples, standards and reagents, use of the apparatus; generation of the calibration curve, use of the formulae for the calculation, etc. The objective of validation of an analytical method is to demonstrate that the method is suitable for the intended use [8]. In this estimation the samples were spotted in the form of bands of width 8 mm with a Camag 500 micro liter sample syringe (Hamilton, Switzerland) on a silica gel precoated aluminum plate 60 F 254, (10cm ×10cm, 250 µm thickness) using a Camag Linomat 5 sample applicator. The plates were prewashed with methanol and activated at 60˚C for 5 min prior to chromatography with constant application rate of 150 nl/sec and the space between two bands was 14.5 mm. The slit dimension was kept at 5×0.45 mm and the scanning speed was 20 mm/sec. The monochromator band width was set at 20 nm and each track was scanned three times and base line correction was adjusted. The successful separations were achieved with satisfactory peak parameters using chloroform: ethyl acetate (5:5 v/v) as mobile phase system.10 ml of mobile phase was used per chromatography run. Linear ascending development was carried out in 20 ×10cm twin trough glass chamber saturated with a mobile phase. After development of the plate it was air dried and Densitometric scanning was performed using a Camag TLC scanner 3 in the reflectance absorbance mode at 254 nm and operated by Wincats software, the light source used was Deuterium lamp emitting a continuous UV spectrum between 200-400 nm. Concentration of the compound chromatographed were determined from the intensity of diffused light. Evaluation was determined by using peak area with linear regression.

Method validation

Linearity

Azelnidipine was found to be linear in the range of 1000-2000 ng/spot respectively. The correlation coefficient of Azelnidipine was found to be 0.9967. The linearity range of Azelnidipine was shown in [Table 1]. Telmisartan was found to be linear in the range of 5000-30000 ng/spot respectively. The correlation coefficient of Telmisartan was found to be 0.9966. The linearity range of Telmisartan was shown in [Table 1]. The calibration curves were plotted as peak area vs concentration of the standard solutions [Figure 30(i)].

The calibration curves show that linear response was obtained over the range of concentrations used in the assay procedures.

Table 1. Linearity concentration of Azelnidipine and Telmisartan

Conc.(ng/spot)	Azelnidipine	Conc.(ng/spot)	Telmisartan	
	Rf value peak area*		Rf value*peak area*	
	10000.666421	5000	0.15	5045
	20000.668981	10000	0.15	7537
	30000.7010800	15000	0.19	9879
	40000.7012465	20000	0.19	11814
	50000.7014865	25000	0.18	13930
	60000.7116993	30000	0.19	17015

Accuracy (Recovery studies)

The accuracy of the method was determined by recovery experiments. A known quantity of the pure drug was added to the reanalyzed sample formulations at 50%, 100%, 150 % levels. The recovery studies were carried out 6 times in each level and the percentage recovery and percentage relative standard deviation were calculated and given in Table 2**.** The percentage recovery of Azelnidipine and Telmisartan was found to be in the range of 99.39 and 99.28.

Table: 2 Recovery Study of AZL and TLM

Drug	Label Claim mg/tab	Estimated amount (mg/ml)	Spike Level (%)	Amount of drug added %	Percentage Recovery	%RSD*
AZL	8mg	7.58	50	50	99.68 %	0.41
			100	100	99.47%	0.32
			150	150	99.02%	0.24
TLM	40mg	39.11	50	50	98.99%	0.45
			100	100	99.09%	0.76
			150	150	99.77%	0.49

Precision

The precision was determined by studying reproducibility and repeatability. The area of drug peak and percentage relative standard deviation of intraday and interday were calculated and presented in Table **3** and **4**. The results revealed that the developed method was found to be reproducible in nature.

Table: 3. Results of intraday precision

Drug	Conc.(ng/spot)	Intraday precision		
AZL		peak area*	SD	%RSD
	1000	6422	1.7078	0.0265
	2000	8982	1.5275	0.0170
	3000	10802	1.2909	0.0119
TLM	5000	12465	0.9574	0.0076
	10000	14863	1.3437	0.0090
	15000	16992	0.6871	0.0040

Table 4. Results of interday precision

DRUG	CONC.(NG/SPOT)	INTERDAY PRECISION		
Azelnidipine		Peak area*	SD	%RSD
	1000	6530	1.1055	0.0169
	2000	8892	1.0671	0.0120
	3000	10752	0.9574	0.0089
Telmisartan	5000	12684	1.3743	0.0108
	10000	15014	1.0671	0.0071
	15000	17112	0.7453	0.0043

The results complied with the acceptance criteria since the percentage relative standard deviation of peak area of Azelnidipine and Telmisartan were found to be within the limit i.e., NMT 2%

Repeatability

Repeatability of the sample application was assayed by spotting 1000, 2000,3000 ng/spot of Azelnidipine and 5000, 10000, 15000 ng/spot of Telmisartan drug solution six times on a precoated TLC plate followed by the development and scanning, the percentage RSD was calculated and presented in **Table 5(a).** The results complied with the acceptance criteria since percentage relative standard deviation of Azelnidipine 0.0126 and Telmisartan 0.0222 was found to be within the limit i.e., NMT 2%

Table 5(a). Results of repeatability

DRUG	CONC.(NG/SPOT)	REPEATABILITY		
Azelnidipine		Peak area*	SD	%RSD
	1000	6330	1.1055	0.0169
	2000	8172	1.0671	0.0120
	3000	10742	0.9574	0.0089
Telmisartan	5000	12344	1.3743	0.0108
	10000	14124	1.0671	0.0071
	15000	17182	0.7453	0.0043

Table 6. Optimization of Chromatographic Conditions

Parameter	*Modification*	*Azelnidipine (%recovery)*	*Telmisartan (% recovery)*
Mobile phase ratio	6:4	98.56	98.84
	4:6	97.35	97.56
Development distance	9mm	98.12	91.56
Detection wavelength(nm)	266 nm	98.96	98.52
Slit dimension	5*0.35 m micro	98.65	97.99

LOD & LOQ

In order to estimate the LOD and LOQ, blank methanol alone was spotted six times then the signal to noise ratio was determined. The LOD was found to be 3:1 and the LOQ was 10:1. The LOD and LOQ were experimentally verified for known concentration of standard solution of Azelnidipine and Telmisartan until the average responses approximately 3 or 10 times the standard deviation of the responses for 6 replicate determinations and presented in **Table 7.**

Table 7. Results of LOD and LOQ

parameter	azelnidipine (ng/spot)	telmisartan(ng/spot)
LOD	910.09	4570.74
LOQ	2763.21	13850.74

Ruggedness

The samples were analyzed by different chemists in same instruments on different days. The method is rugged because the percentage relative standard deviation was found to be within limit i.e., NMT 2% and the results presented in **Table 8.**

Table 8. Results of Ruggedness

Drug	Conc.(ng/spot)	Mean peak area	%RSD*
Day-I, Analyst-I			
Azelnidipine	2000	6451	0.5084
Telmisartan	10000	12624	1.0390
Day-II, Analyst-II			
Azelnidipine	2000	6488	0.0494
Telmisartan	10000	12469	0.0011

Robustness

In order to establish the robustness of the method, small deliberated changes were made in the experimental conditions chamber saturation time, volume of mobile phase and distance run by solvent front. In the above changed conditions, stock solution was analyzed and results of robustness studies were expressed in terms of % RSD of peak areas in changed condition. The method was found to be robust because the percentage recovery was within the limit i.e., 2% and the results presented in **Table 9.**

Table 9. Summary of validation parameters

Sl.No	*Parameters*	*Azelnidipine*	*Telmisartan*
1	Linearity range (µg/ml)	1- 6 µg/ml	5 -30 µg/ml
2	Correlation co-efficient (R^2)	0.9967	0.9966
5	Assay (%)	98.87	100.17
6	Accuracy (%)	99.47% ± 0.32	99.09% ± 0.76
7	Intraday(%RSD) *	0.0184	0.0068
8	Interday (%RSD) *	0.0126	0.0074
9	LOD (µg/ml)	910	4570
10	LOQ (µg/ml)	2763	13850
11	Ruggedness(%RSD) *	0.2789	0.5200
12	Rf	0.70	0.17

Forced degradation studies

Acid hydrolysis

In acid hydrolysis, mixture of AZL and TLM were refluxed in acidic condition (0.1 N HCl) at 60°C for 5 hours. For AZL Rf value of 0.78 has been observed without co-eluting peaks. For TLM Rf value of 0.23 has been observed with an additional peak with Rf value of 0.25 has been observed. The rate of hydrolysis of TLM was higher in acid and AZL peak was well resolved from the additional peak.

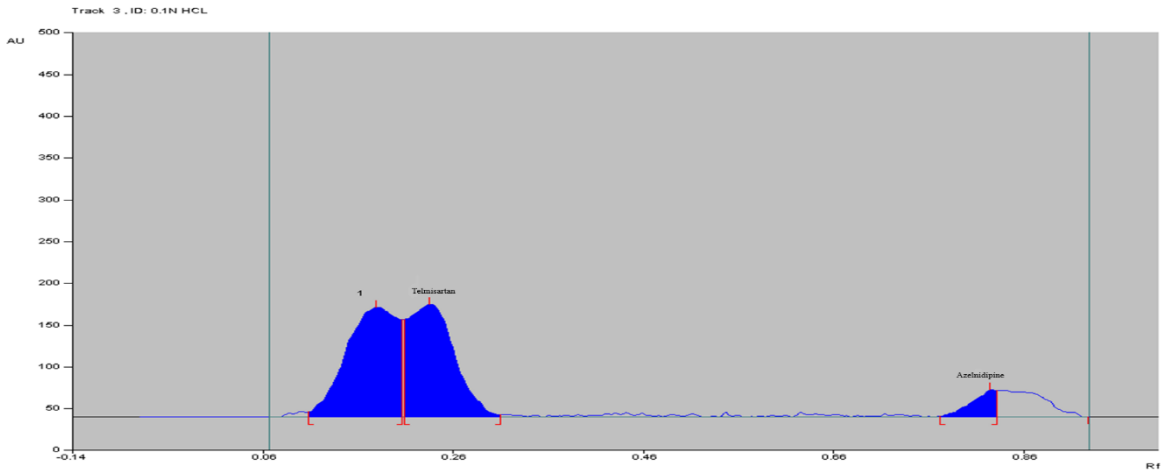

Figure 1. Chromatogram of azelnidipine and telmisartan sample subjected to acid degradation (AZL= 0.78, TLM =0.23, DP 1=0.25)

Base hydrolysis

In base hydrolysis, mixture of AZL and TLM were refluxed in alkaline condition (1N NaOH) at 60°C for 5 hours shows partial degradation of TLM. The degradation product, at Rf value of 0.08 and 0.39 was well resolved from the main TLM peak. For AZL main peak Rf value of 0.80, shows no degradation. For AZL Rf value of 0.25 has been observed

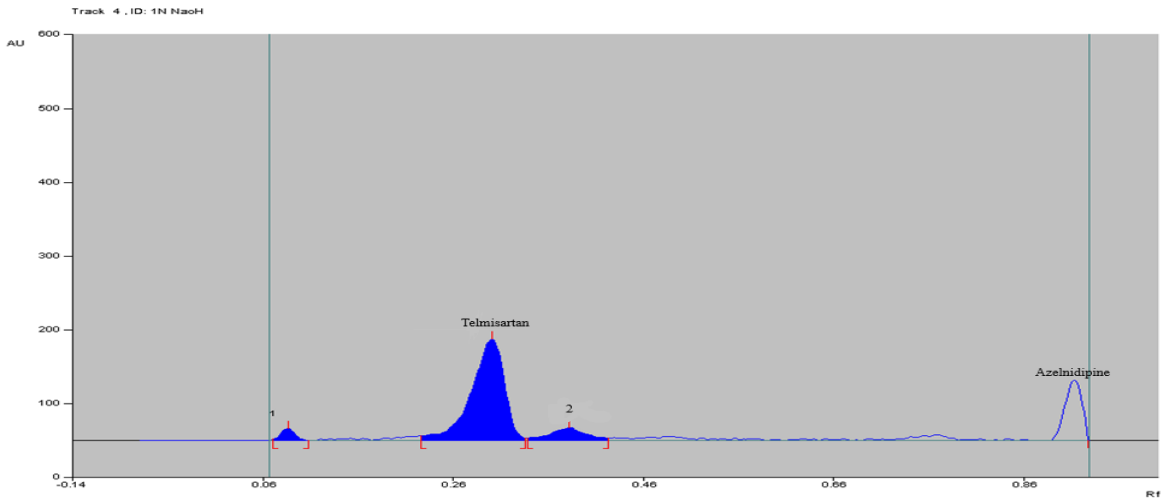

Figure 2. Chromatogram of azelnidipine and telmisartan sample subjected to base degradation (AZL= 0.80, TLM =0.25, DP 1=0.08, DP2= 0.39)

Oxidative degradation

In oxidative degradation, mixture of AZL and TLM were refluxed at 27 °C for 4 hours using H_2O_2 (1.5%) shows complete oxidation of TLM and AZL. TLM was completely oxidized shows degradation products with Rf value of 0.15, 0.19, 0.45, 0.53, 0.57 and AZL shows degradation product with Rf value of 0.91

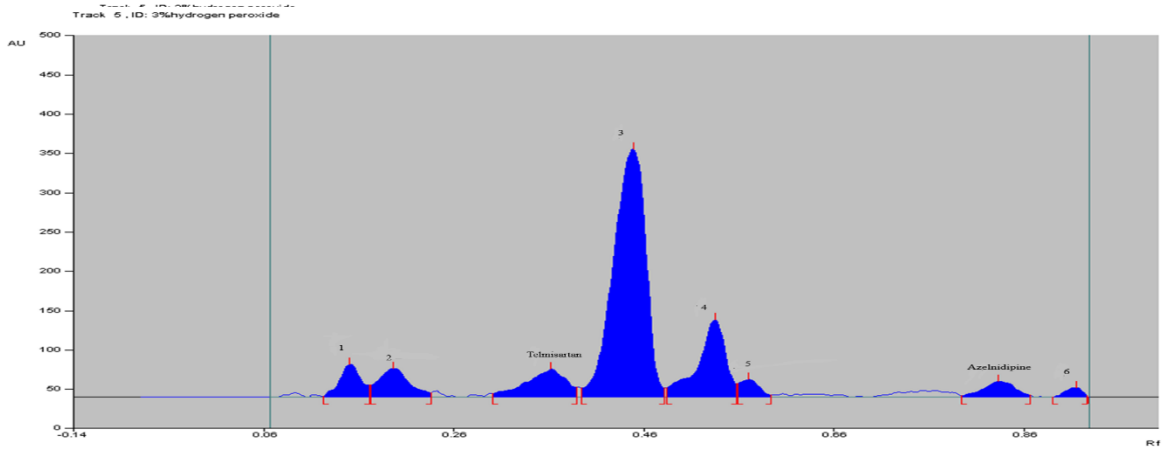

Figure 3. Chromatogram of azelnidipine and Telmisartan sample subjected to oxidative degradation (AZL= 0.80, TLM =0.26, DP 1 =0.15, DP 2= 0.19, DP 3 = 0.45, DP 4 =0.53, DP 5 = 0.57, DP 6 =0.91)

Neutral hydrolysis

In neutral degradation study, mixture of AZL and TLM were refluxed at 80 °C for 3hrs with water. One degradation product peak with Rf value of 0.58 was observed. AZL main peak at Rf value of 0.80 and TLM main peak at Rf value of 0.26 was clearly obtained

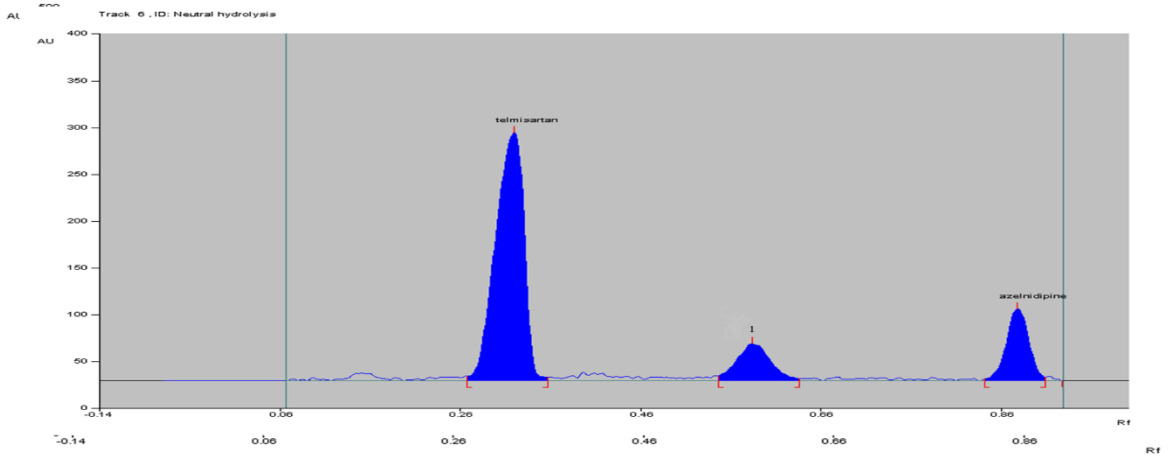

Figure 4. Chromatogram of azelnidipine and telmisartan sample subjected to neutral degradation (AZL= 0.80, TLM =0.26, DP 1= 0.58)

Photo degradation

In photo-degradation study, the tablets were exposed to UV light in a photo-stability chamber for 7 days. No additional peaks of degradation products were observed after photolysis suggesting that there is no degradation occurred in photolysis and the drugs are stable in photolytic degradation. No other co-eluting peak was found with the main peaks, suggesting the specificity of the method for the simultaneous estimation of AZL and TLM in presence of degradation products and impurities.

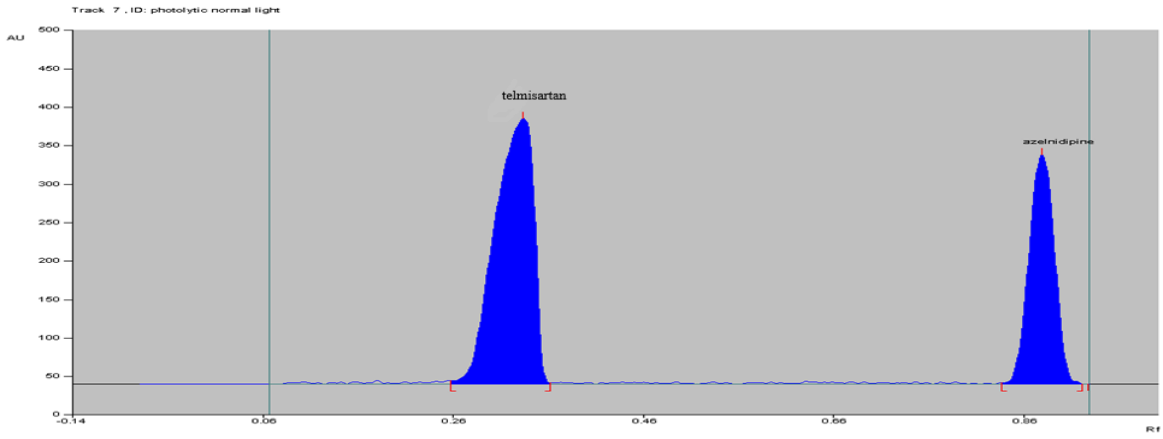

Figure 5. Chromatogram of azelnidipine and telmisartan sample subjected photo degradation (AZL= 0.80, TLM =0.25)

Thermal degradation

For dry heat degradation study, tablets were placed in an oven at 80 °C for 7 days. The solid state studies shows AZL and TLM was not stable to the effect of temperature. Degradation products obtained with Rf value of 0.12 and 0.11. It shows the drugs was unstable, indicating the samples of AZL and TLM cannot be used for 7 days at 120 °C without degradation

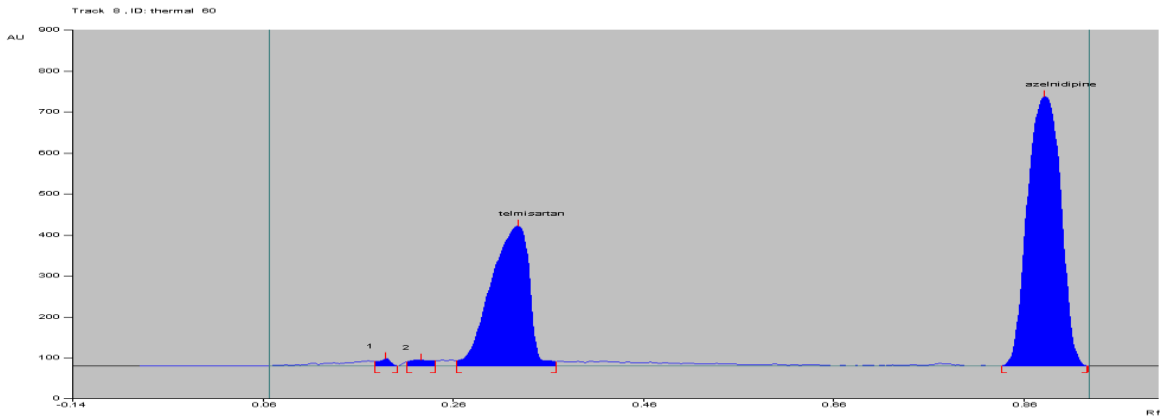

Figure 6. Chromatogram of azelnidipine and telmisartan sample subjected to thermal degradation (AZL= 0.80, TLM =0.25, DP 1 =0.19, DP 2 = 0.22)

Table 10. Results of forced degradation studies on Azelnidipine and Telmisartan samples using the proposed method

Stress condition/Duration/State	**Degradation (%)**	
	Azelnidipine	Telmisartan
None (control sample)	No	No
Acidic/ 0.1 M HCl/5 hrs/solution/80°C	11.74	11.93
Alkaline/ 1 N NaOH /5 hrs./solution/ 80°C	9.13	9.28
Oxidative/ 3 % H2O2 /4hrs/solution/ 30 °C	18.23	17.92
Neutral/H2O/3hrs/solution/80°C	16.91	11.18
Dry heat/120°C/7 days/solid	16.22	4.5
Photo/UV/7 days/solid	No	No

A simple, rapid, precise, selective, accurate and a novel HPTLC method has been developed for routine analysis of Azelnidipine and Telmisartan in fixed-dose tablet combination. The method was validated for linearity, precision, accuracy, robustness and ruggedness. It has the advantage over newly reported HPLC method [9]. The newly developed HPTLC method consumed less than 10 ml of mobile phase per run (8 samples per plate), whereas already reported HPLC methods would consume 75ml mobile phase per runs of similar number of samples. When compared with the reported HPLC method, the developed HPTLC method requires less time per chromatographic run, less sample volume (1µl) and cost effective for the estimation of Azelnidipine and Telmisartan mixtures in bulk and tablet dosage form the calibration

plot show good linearity with correlation coefficient 0.9967 for Azelnidipine and 0.9966 for Telmisartan. The low % RSD values in the precision and recovery studies for HPTLC method shows that there is no interference due to excipients used in the formulation. Hence it was concluded that the developed method is simple, precise, accurate, robust, and specific for routine analysis of Azelnidipine and Telmisartan in combined tablet dosage form. It can also be applied for single component analysis of Azelnidipine and Telmisartan separately in bulk and tablet dosage form.

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