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Original Article

A New Validated Stability-Indicating HPTLC Method for Simultaneous Determination of Telmisartan, Hydrochlorothiazide and Amlodipine in Oral Pharmaceutical Tablet Dosage Form

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ABSTRACT

Background: The pharmaceutical preparation of Telmisartan, Hydrochlorothiazide, and Amlodipine is commonly employed in an anti-hypertension therapy, requiring dependable analytical techniques for quality evaluation. **Objectives:** This study focused on the development of an easy, fast, and also accurate stability-indicating High-Performance Thin-Layer Chromatography (HPTLC) analytical method for concurrent determination of Telmisartan, Hydrochlorothiazide, and Amlodipine for their bulk and tablet formulations. **Materials and Methods:** Separation was performed using pre-coated Silica gel 60 F254 TLC plates as stationary phase with Toluene: Chloroform: Methanol (2:5:2 v/v/v) as mobile phase. Conducted a Densitometric scanning at the wavelength of 265 nm for identification of spots. Stress testing recommended by the ICH was performed on the standard drugs of Telmisartan, Hydrochlorothiazide, and Amlodipine bulk formulations followed by quantification of the stressed substances with the proposed analytical method. **Results:** Three well-distinguished peaks were obtained for the drugs using the proposed method with retention factor values of 0.63±0.03, 0.32±0.03, and 0.13±0.03 for Telmisartan, Hydrochlorothiazide, and Amlodipine, respectively. Degradation study of the drugs was mainly perceived in acidic, alkaline, hydrolytic, and oxidative environments**.** The planned HPTLC technique was assessed according to the ICH guidelines with validation parameters including calibration behavior, trueness, repeatability, selectivity, and reliability falling within permissible limits. **Conclusion:** The developed HPTLC technique was found to be stability-assessing, making it preferable for the regular analysis as well as stability testing of the studied drugs in fixed dose combinations.

Keywords: Amlodipine, Forced Degradation, High-Performance Thin-Layer Chromatography, Hydrochlorothiazide, Simultaneous estimation, Telmisartan.

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INTRODUCTION

Telmisartan is chemically designated as (4'- [(1,4'-dimethyl-2'-propyl[2,6'-bi-1H-benzimidazol]-1'-yl) methyl]-[1,1'-biphenyl]2-carboxylic acid with a molecular formula of $C_{33}H_{30}N_4O_2$ and a molecular weight of 514.63g/mol [22]. It acts an Angiotensin II Receptor Blocker (ARB) that perform particularly on AT1 receptors for vasodilation and reduces aldosterone synthesis, resulting in decreased blood pressure. Hydrochlorothiazide is chemically designated as 6-chloro-1,1-dioxo-3,4dihydro-2H-1,2,4-benzothiadiazine-7-sulfonamide 1,1-dioxide with a molecular formula of $C_7H_8C_lN_3O_4S_2$ and a molecular weight of 297.74g/mol, a thiazide diuretic which prevents reabsorption of sodium in distal convoluted tubules, enhancing diuresis and decreasing plasma volume. Amlodipine (3-ethyl 5 methyl (2R)-2-[(2R)-3-phenyl-2-propanoylaminopropoxy]-3,6-dihydro-2,6-dimethylpyridine-3,5-dicarboxylate); molecular formula $C_{20}H_{25}C_lN_2O_5$; molecular weight 408.88g/mol, a dihydropyridine calcium channel antagonist that promotes relaxation of vascular smooth muscles by inhibiting calcium influx, decreasing peripheral resistance.[1] This trio synergistically targets multiple hypertension pathways-renin-angiotensin blockade, diuresis, and vasodilation-achieving superior blood pressure control (up to 40-50 mmHg systolic reduction) compared to monotherapies. Benefits include reduced cardiovascular risks (stroke by 30-40%, heart failure by 20-25%), improved renal protection in diabetics, and better adherence via single-pill dosing. Long term use enhances endothelial function and regression of left ventricular hypertrophy, minimizing side effects through complementary

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actions (e.g., ARB counters diuretic-induced renin rise) (Figures 1-3).[2]

On reviewing different literature and ICH stability testing guidelines Q1A (R2) suggested stress studies should be carried out to predict stability problems, identify degradation products and pathway.[3] Stress testing conditions-such as acid, base, hydrolytic, oxidation, photolytic, and thermal degradation-are carried out under more severe environments than accelerated stability testing. Force degradation experiments are carried out to evaluate the intrinsic stability profile of the drug as well as to prove that the proposed analytical procedure is stability-indicating.[4-8] Literature review shows that there are numerous analytical methods for estimation of Telmisartan as an individual component as well as combined with other medicines.[9-20] However, the stability-indicating HPTLC technique has been not established for the quantitative estimation of Telmisartan, Hydrochlorothiazide, and Amlodipine alongside their respective degraded products. Therefore, it becomes necessary for the development of a new, efficient, accurate, quick, efficient and also reproducible HPTLC technique for the concurrent estimation of Telmisartan along with the degradation impurities.

MATERIALS AND METHODS

Materials and Chemicals

Standard bulk drug samples of Telmisartan, Hydrochlorothiazide and Amlodipine were collected from Micro Labs, Bangalore. All additional reagents used for experiment was analytical reagent grade chemicals. Chemicals used in this experiment were Methanol, Chloroform, Toluene, HCl, NaOH, H_2O_2. These chemicals were purchased from MERCK Chemicals, Telma-AMH 40 tablets (label claim 40 mg containing Telmisartan of 40 mg, Hydrochlorothiazide of 12.5 mg, and Amlodipine of 5 mg Batch no. FT114009 Windlass Healthcare (P) Ltd., Uttarakhand.

Instrumentation

The following equipment was employed for this research work: High-Performance Thin-Layer Chromatography (HPTLC) analytical system from CAMAG, Switzerland, which includes partially sample applicator sampler applicator (CAMAG Linomat 5), Hamilton syringe with 100 µL capacity, CAMAG TLC scanner 3 and CAMAG WinCATS software were connected. CAMAG twin-trough chromatographic chambers (10x10 cm), (20x10 cm), UV cabinet with dual wavelength UV lamps, digital weighing balance AUX220 (Shimadzu), ultrasonicator (Spinco tech), digital hot air oven (SV Scientific), and digital water bath (Grant sub-aqua 12) were utilized for this study.

Standard Stock Solutions Preparation

25 mg of each drug was accurately quantified, which is then transferred to three separate 25 mL standard volumetric flasks and diluted with methanol to attain the standard stock solutions of Telmisartan, Hydrochlorothiazide, Amlodipine respectively with each concentration of (1000 mcg/mL).

Preparation of Trinary mixture standard stock solution

A trinary stock solution of the standard drugs was made by transferring 4 mL of Telmisartan, 1mL of Hydrochlorothiazide, along with 0.5 mL of Amlodipine from the prepared stock solution (1000 mcg/mL), into a 10 mL standard volumetric flask where the volume was adjusted to 10 mL using methanol. In the trinary mixture solution, the concentration of the drug substances was as follows: 400 mcg/mL concentration of Telmisartan, 100 mcg/mL concentration of Hydrochlorothiazide and 50mcg/mL concentration of Amlodipine.

Standard solution Preparation for Calibration curve

Various amounts of trinary mixture standard solution, 2 µl, 3 µl, 4 µl, 5 µl, 6 µl, and 7 µl were spotted over the chromatographic plate, which resulted in the formation of various concentrations of Telmisartan in spots of 800, 1200, 1600, 2000, 2400 and 2800 ng/spot of Telmisartan and 200, 300, 400, 500, 600 and 700 ng/spot for Hydrochlorothiazide and 100, 150, 200, 250, 300 and 350 Amlodipine respectively.

Sample solution Preparation

Telma AM tablet samples were weighed accurately and an amount of triturated material equal to the content of a single tablet unit was dissolved in 100 mL of methanol. The mixture was subjected to ultrasonication for 30 min continued by filtration through a 0.45 µ nylon membrane filter.

Determination of Detection Wavelength

Telmisartan, Hydrochlorothiazide, and Amlodipine spectra were recorded separately using a UV spectrophotometer for each drug in the concentration level of 10 mcg/mL within the ranged wavelength of 200 to 400 nm where methanol was used as a blank. The wavelength of the maximum absorption was 265 nm.

Densitometry conditions

Trinary mixture standard solution was applied in band form having the width of 8 mm by means of CAMAG sample syringe (100 µL capacity) onto pre-coated Aluminium plate coated with silica gel 60 F254of size 10 x 10 cm (layer thickness=200 µm) using CAMAG Linomat 5 sampler applicator. The spacing between two adjacent bands was 14mm. The slit-dimensions were set as 6 mm x 0.3 mm while scanning speed was 20 mms^{-1}. To prepare the mobile phase, toluene: chloroform: methanol ratio was kept as 2:5:2 (v/v/v). For ascending linear development procedure, glass twin-trough development chamber which was fully loaded with the mobile phase was used. It was seen that the time taken for full loading of the chamber with mobile phase is 25 min. The size of the chromatogram obtained was 80 mm. With the use of an air

dryer the plates were dried, followed by densitometric scanning using a CAMAG TLC Scanner III operated in absorbance at 265 nm. A deuterium lamp was employed as the light source for the radiation, which produces continuous range of UV rays from 190 to 400 nm.

Forced Degradation Studies Procedure for the Drug substance

The pharmaceutical substances were directly subjected for degradation in thermal stress, photolytic, acidic, alkaline, hydrolytic, and under oxidative conditions. For the degradation of each drug substance under acidic, alkaline, hydrolysis, and oxidative stress condition, a volume of 4 mL of Telmisartan, 1 mL of Hydrochlorothiazide, and 0.5 mL of Amlodipine were put in a 10 mL volumetric flask along with 0.1N hydrochloric acid for acid stress, 0.1N sodium hydroxide for base stress, distilled water for hydrolysis stress, and 1 mL of 3% v/v hydrogen peroxide solution for oxidation stress, diluted up to 10 mL with methanol. The sample was incubated in a heating water bath at 80°C for around 6 hr in case of acid, base, and hydrolysis stress and 60°C for 1 hr in case of oxidative stress. In case of thermal degradation, powdered form of all the standard reference drugs was transferred into three Petri dishes and subjected to heating at 80°C for 24 hr. In case of photo-degradation study, all the standard drugs (about 100 mg) were subjected to ultraviolet light at the wavelengths of 254 nm and 326 nm in a CAMAG UV chamber for 24 hr. Methanolic stock solutions of samples subjected to dry heat as well as those for drugs exposed to UV light have been obtained. From the stock solutions, 4 mL of the Telmisartan standard solution, 1 mL of Hydrochlorothiazide and 0.5 mL of Amlodipine were collected and transferred to a 10 mL standard volumetric flask, continued by dilution with methanol up to 10 mL. Various amounts of the mixture containing Telmisartan, Hydrochlorothiazide and Amlodipine depending upon the type of stress were taken and spots applied onto TLC plates (Table 1).

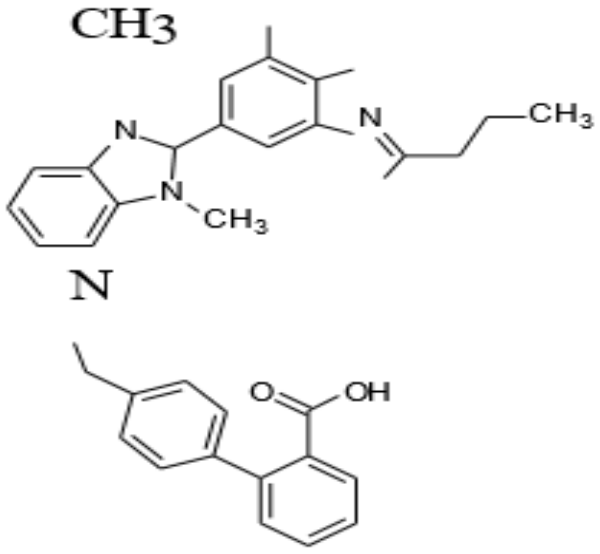

Figure 1: Telmisartan.

Methods Validation

Linearity

Linearity of the developed HPTLC analytical method for Telmisartan, Hydrochlorothiazide, and Amlodipine analysis was established using various amount of the analytes, which served as the standard solutions. The present study involved three different concentrations of the drugs, which contained different amounts of the analytes within the range of 800-2800 ng/spot for Telmisartan, 200-700 ng/spot for Hydrochlorothiazide, and 100-350 ng/spot for Amlodipine.

Precision

Precision was determined by analysis of repeatedly sampled homogenous samples. Reproducibility of the method was verified through precision tests on within-day and between-day variances of the peak areas of the respective drugs. Intra-day precision (in triplicate within a day) and inter-day precision (on three successive days) were conducted at three different concentrations (1200, 2000, 2800 ng/spot for Telmisartan; 300, 500, 700 ng/spot for Hydrochlorothiazide and 150, 250, 750 ng/spot for Amlodipine).

Accuracy

The validity of the method proposed was assured through the use of recovery test on laboratory-prepared trinary mixture utilizing the standard addition method in triplicate at three distinct stages.

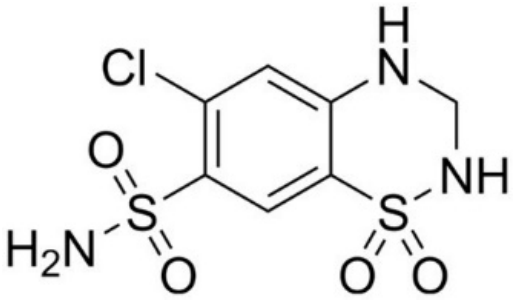

Figure 2: Hydrochlorothiazide.

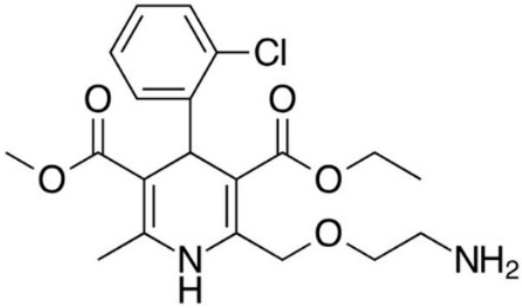

Figure 3: Amlodipine.

Table 1: Degradation Studies under Stress Conditions for Telmisartan, Hydrochlorothiazide, Amlodipine.

Sl. No.	Conditions (Stress Induced)	Concentration TEL (ng spot -1)	Concentration HCTZ (ng spot-1)	Concentration AML (ng spot-1)	Temperature. (°C)	Time (Hours)
1.	Acid (0.1N HCl)	800, 2000, 2800	200, 500, 700	100, 250, 350	80	6
2.	Base (0.1N NaOH)	800, 2000, 2800	200, 500, 700	100, 250, 300	80	6
3.	Water	800, 2000, 2800	200, 500, 700	100, 250, 350	80	6
4.	Hydrogen Peroxide (3% v/v)	800, 2000, 2800	200, 500, 700	100, 250, 350	60	1
5.	Dry Heat	800, 1600, 2400	200, 400, 600	100, 200, 300	80	24
6.	UV light (254 nm and 326 nm)	800, 1600, 2400	200, 400, 600	100, 200, 300	---	24

Limit of Detection (LOD) and Limit of Quantification (LOQ)

To estimate the limit, the concentration of Telmisartan, Hydrochlorothiazide, and Amlodipine at the low end of the standard calibration plot was conducted in triplicate. The number of drugs per spot vs. the average chromatographic peak area of the drugs were plotted in a graph.

$$LOD = 3.3 \times \frac{SD\ (\sigma)}{Slope\ (m)}$$

$$LOQ = 10 \times \frac{SD\ (\sigma)}{Slope\ (m)}$$

Specificity

Method specificity has been demonstrated by the estimation of drug standards and pharmaceutical formulation samples. The occurrence of Telmisartan, Hydrochlorothiazide and Amlodipine in the formulation was confirmed by comparison of their R_f values with spectral data with reference standards.

Robustness

%RSD of the peak area was determined by the composition variation of mobile phase and saturation time at the concentration of 5 µL six times.

RESULTS

Optimum mobile phase Development

Mixtures of the prepared standard solutions of Telmisartan, Hydrochlorothiazide, and Amlodipine were spotted on to the TLC plates of Silica gel 60F254. Many pure solvents having various polarities and mixtures of them were used in order to get an appropriate movement of peaks. After several combinations, the mobile phase comprising of toluene, chloroform, and methanol in a ratio of 2:5:2 gave satisfactory results. The resolution of three components was observed to be very good with the following retention factors: 0.63±0.03, 0.32±0.03 and 0.13±0.03 for the drugs Telmisartan, Hydrochlorothiazide and Amlodipine respectively, as shown in Figure 4.

Degradation Observed

Major degradation of the above three compounds was found during oxidative stress. While in case of Telmisartan major degradation occurred during acidic stress, in case of Amlodipine degradation occurred under neutral and alkaline stress conditions. Minor degradation was observed in case of dry heat and photolytic stress conditions, which have been presented in Table 3 and is shown in Figures 5.1-5.6.

Method Validation

The present developed analytical method validation was carried out based on the guidelines suggested by ICH.[21] The parameters considered while validating the current method include calibration behavior, trueness, repeatability, selectivity, LOD/LOQ and reliability

Linearity

Analysis has been done in triplicates for all concentrations, and the variance in the response of the peak area has been tabulated in Table 4. The area has been plotted against the analyte concentration on a graph. The linearity of the calibration curves has been proved by the correlation coefficient values. These slopes and intercepts are shown in Figures 6-8.

Precision

Results are expressed in % Relative Standard Deviation (%RSD). Results achieved from within-day and between-day analysis experiments lie within an acceptable range, meaning that the developed methods are highly precise Table 2, 5 and Figure 9.

Accuracy

As per the findings of the experiment, the average percent recovery of Telmisartan, Hydrochlorothiazide, and Amlodipine were 100.2%, 100.1%, and 100.4%, respectively. It can be stated from the above-mentioned findings that the developed methodology is of high accuracy (Table 6 and Figure 10).

Limit of Detection (LOD) and Limit of Quantification (LOQ)

For estimation of the detection limit and the quantitation limit, concentration of Telmisartan, Hydrochlorothiazide, and Amlodipine at the low end of calibration curve was performed for three times. These values were represented graphically in a plot of number of active compounds in spots against the average peak area. Regression equation for this graph was estimated. Standard Deviation (SD) of the response was estimated. The value for the detection limit was estimated by the equation (3.3 x SD)/b whereas the value for quantitation limit was thereby estimated from the equation (10 x SD)/b, whereas "b" is the slope value from linearity study. (Table 7).

Specificity

Purity of Telmisartan, Hydrochlorothiazide, and Amlodipine was confirmed by comparing spectra obtained in three distinct positions of the spot as follows:

S: Start of the peak;

M: Apex of the peak; and

E: End of the peak as shown in Figures 11-13, respectively.

Robustness

The low values of %RSD achieved upon the introduction of small intentional changes to the developed HPTLC technique demonstrated the robustness of the technique as evident in Table 8 and Figure 14.

DISCUSSION

The peaks of degradation products were well separated from those of drugs Telmisartan, Hydrochlorothiazide and Amlodipine standard drugs. The Densitogram of the acid degradations of

Table 2: Inter day precision study results of TEL, HCZ and AMD.

Validation Parameter		HPTLC		
Inter day	Conc (ng spot^{-1})	Mean area	SD	%RSD
TEL	1200	6420.58	13.76654	1.140029
	200	7805.36	21.08229	1.049909
	2800	10631.18	15.61792	0.557811
HCZ	300	5339.66	2.005357	0.664041
	500	7672.8	2.086965	0.415797
	700	9947.6	2.446545	0.351088
Amlodipine	150	541.42	2.532941	1.666307
	250	754.16	3.199615	1.274959
	350	971.8	2.755789	0.782481

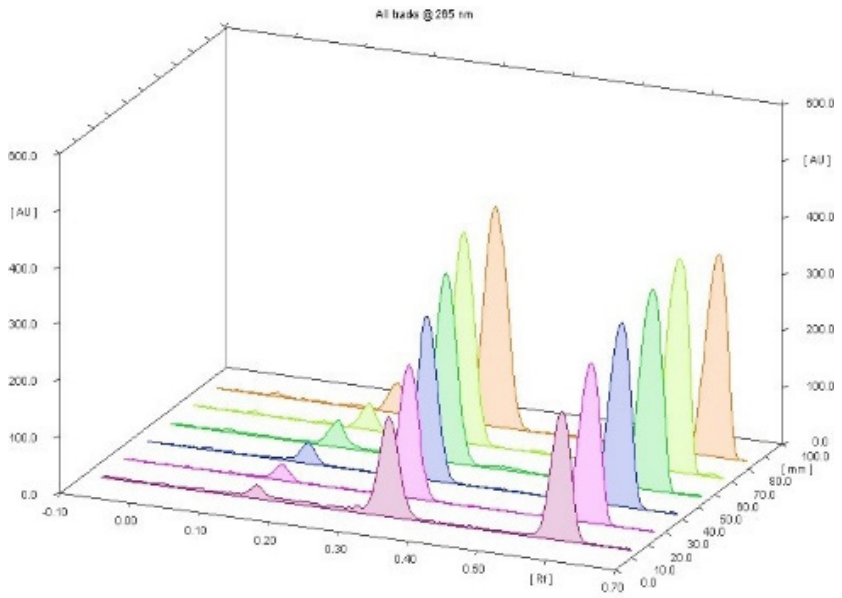

Figure 4: Densitogram of Telmisartan, Hydrochlorothiazide and Amlodipine.

Table 3: Forced degradation study results for Telmisartan, Hydrochlorothiazide, Amlodipine.

Conditions	Degradation in %		
	Telmisartan	Hydrochlorothiazide	Amlodipine
0.1 N HCl, 80°C for 6 hr	18.2	9.7	6.5
0.1 N NaOH, 80°C for 6 hr	3.6	4.2	14.2
Water, 80°C for 6 hr	7.8	11.7	16.3
30% v/v H_2O_2, 60°C for 1 hr	20.7	17.4	15.1
Dry Heat, 80°C for 6 hr	6.5	4.6	5.2
UV light, 254 nm for 4 hr	7.6	6.3	8.4

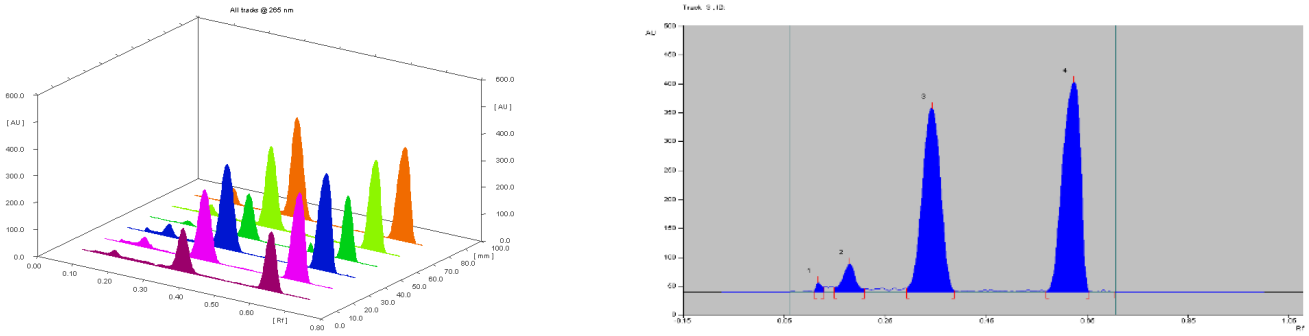

Figure 5.1: Densitogram of acid degradation.

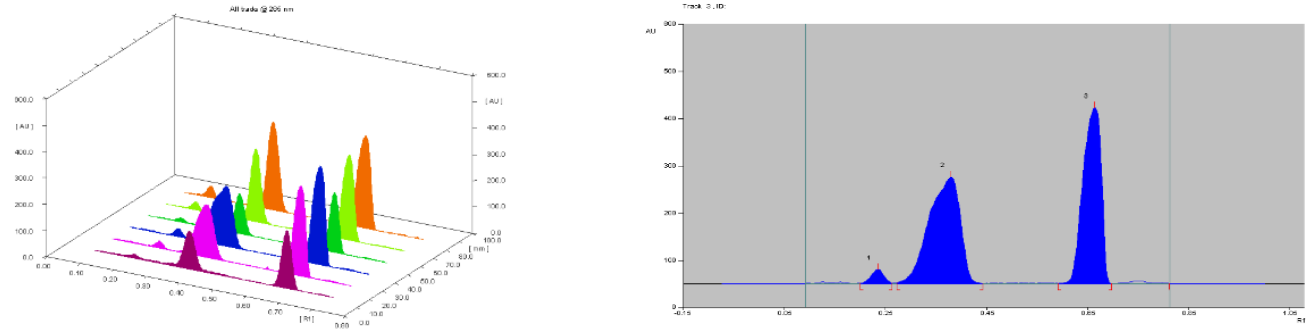

Figure 5.2: Densitogram of Alkali degradation.

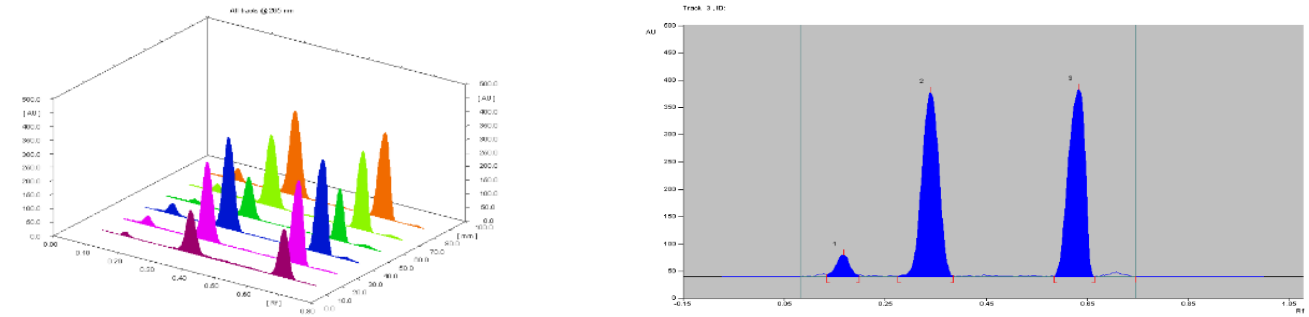

Figure 5.3: Densitogram of neutral Hydrolytic degradation.

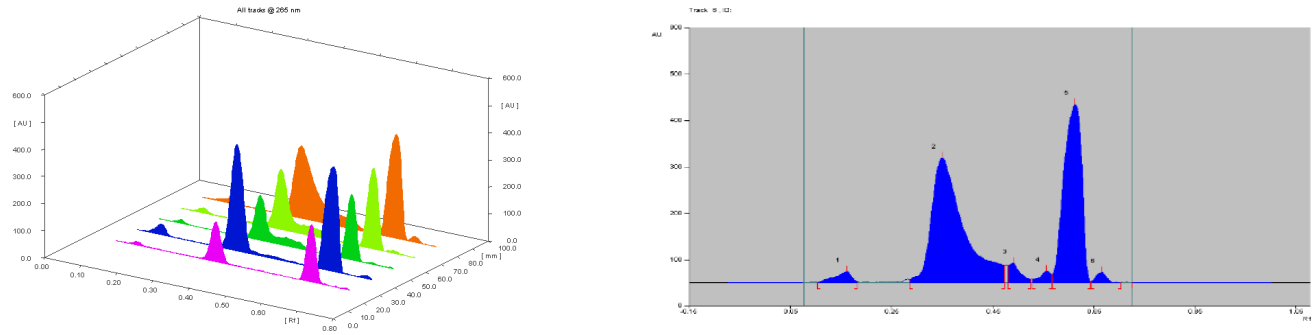

Figure 5.4: Densitogram Degradation under oxidative condition.

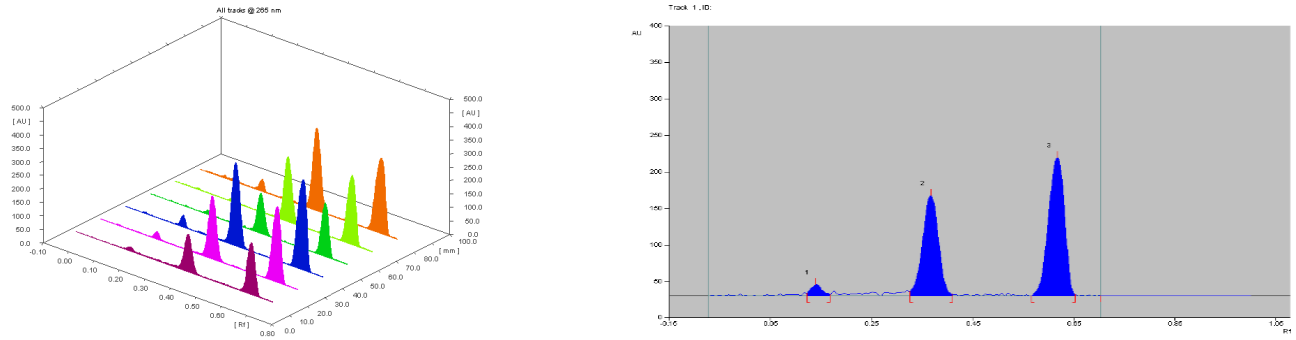

Figure 5.5: Densitogram degradation under dry heat.

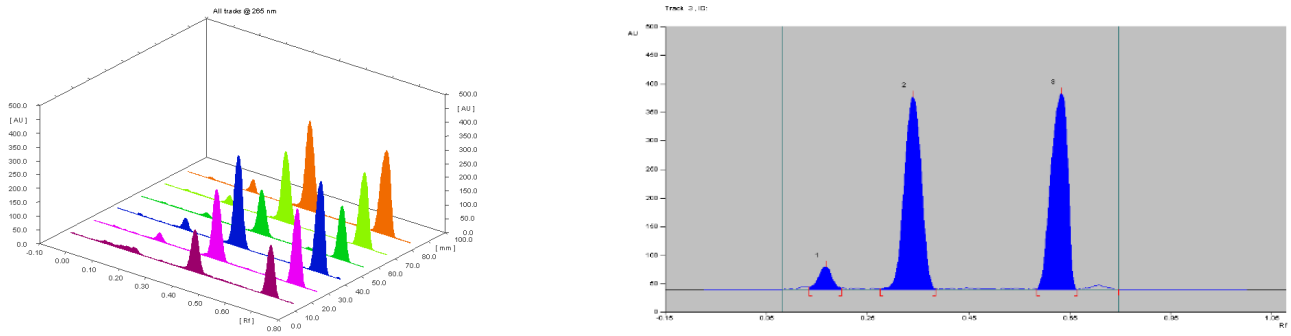

Figure 5.6: Densitogram of Photolytic Degradation.

Table 4: Data of Linearity for Telmisartan, Hydrochlorothiazide and Amlodipine.

Sl. No.	Telmisartan		Hydrochlorothiazide		Amlodipine	
	Conc (ng spot^{-1})	Peak area	Conc (ng spot^{-1})	Peak area	Conc (ng spot^{-1})	Peak area
1.	800	5727.5	200	4160.1	100	429.7
2.	1200	6416.3	300	5353.6	150	538.1
3.	1600	7119.9	400	6533.5	200	645.9
4.	2000	7827.7	500	7645.5	250	755.8
5.	2400	9722.8	600	8800.5	300	861.7
6.	2800	10662.7	700	10105.8	350	968.3
Regression Coefficient	0.9980		0.9999		1	
Slope	2.487		9.41		2.1564	
Intercept	3499.7		18.5.1		214.73	

Table 5: Intra day precision study results of TEL, HCZ and AMD.

Validation Parameter		HPTLC		
Intra day	Conc (ng spot^{-1})	Mean area	SD	%RSD
TEL	1200	6424.9	18.28278	1.511132
	200	7795.76	24.20905	1.208964
	2800	10688.98	28.82465	1.020144
HCZ	300	5368.46	2.6013	0.854395
	500	7652.8	3.593009	0.718306
	700	9941.6	1.660858	0.238515
Amlodipine	150	539.42	1.816754	1.202519
	250	753.76	3.278426	1.307333
	350	970.6	3.446414	0.980131

Table 6: Recovery study results of TEL, HCZ and AMD.

Sl. No.	Conc of TEL	%Recovery of TEL±SD	Conc of HCZ	% Recovery of HCZ±SD	Conc of AMD	% Recovery of AMD±SD
1.	1200	100.4287±6.255607	300	101.0626±1.689002	150	100.2997±1.143404
2.	1600	100.7406±18.33081	400	100.9011±4.080171	200	100.3023±1.796577
3.	2000	101.0491±15.14054	500	99.91545±2.824598	250	100.6884±2.584222
4.	2400	99.84136± 15.35395	600	99.75912±2.532889	300	100.3307±2.380893
5.	Across all Level % Recovery	100.2		100.1		100.4

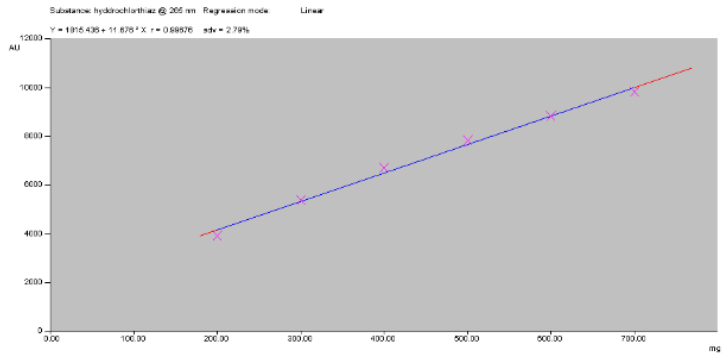

Figure 6: Linearity curve of Tel at 265 nm.

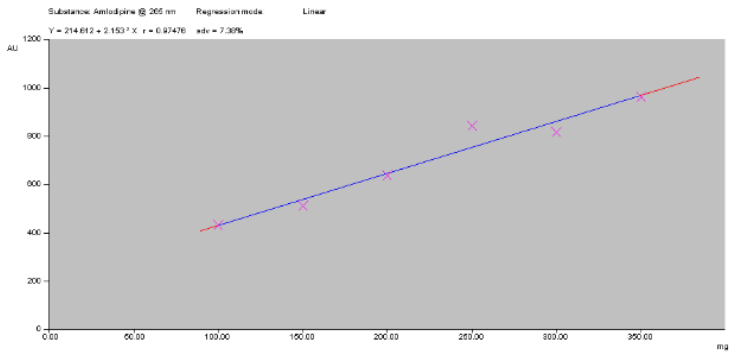

Figure 7: Linearity curve of HCTZ at 265 nm.

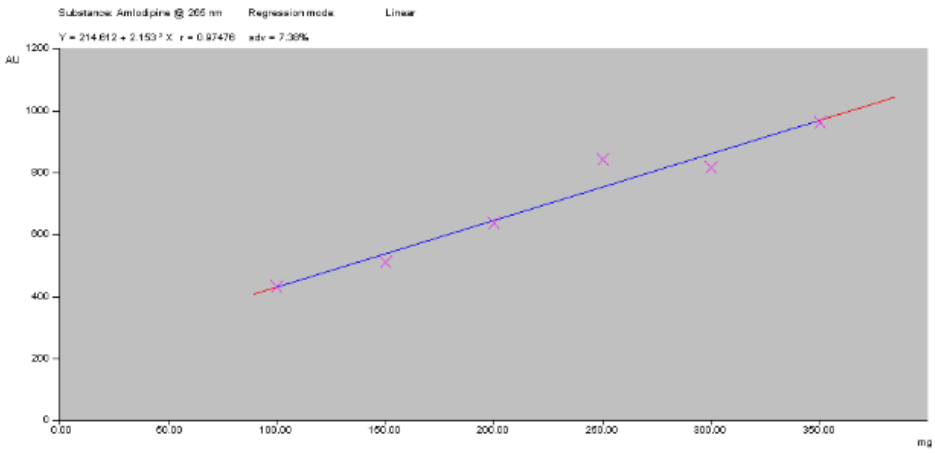

Figure 8: Linearity curve of Tel at 265 nm.

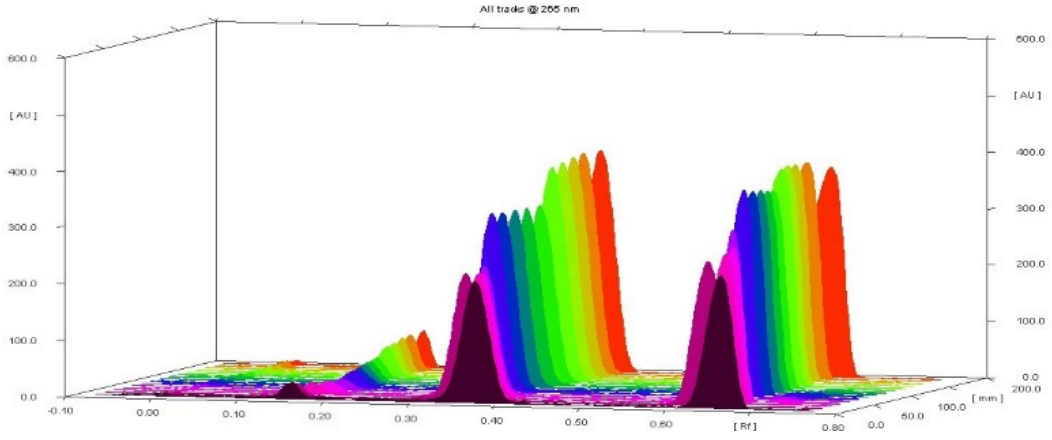

Figure 9: Precision of Tel, HCZ and AMD.

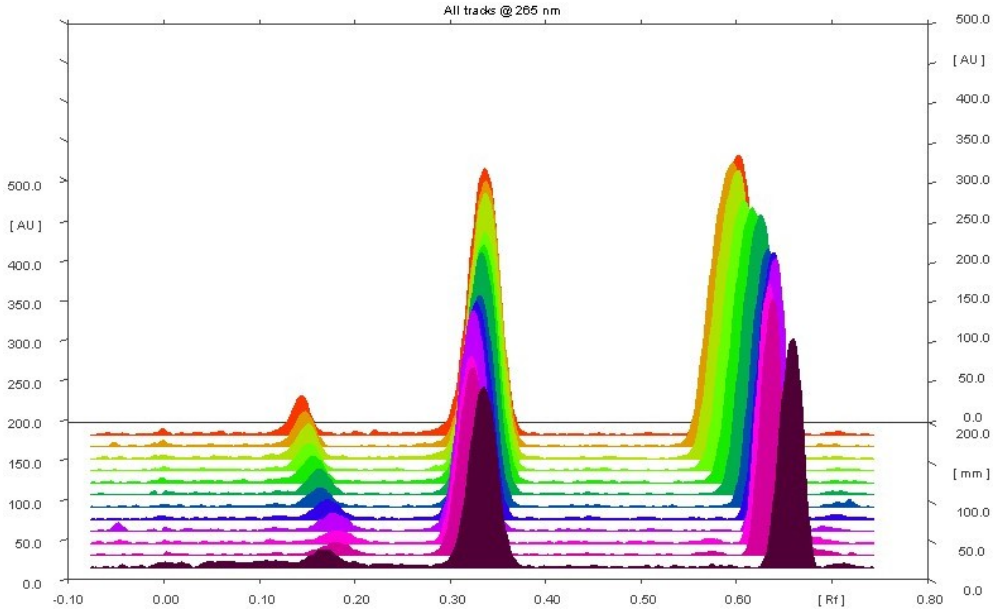

Figure 10: Accuracy of Tel, HCZ and AMD.

Table 7: LOD and LOQ.

Results observed	TEL	HCZ	AMD
*SD	1.705284	0.855626	0.631486
LOD (ng spot^{-1})	3.252854	0.241951	0.969257
LOQ (ng spot^{-1})	9.857133	0.733184	2.937143

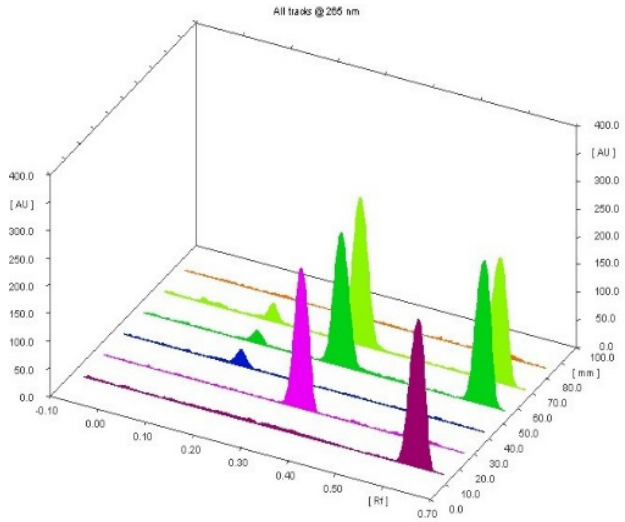

Figure 11: HPTLC Densitogram of Specificity TEL, HCZ and AMD Standard.

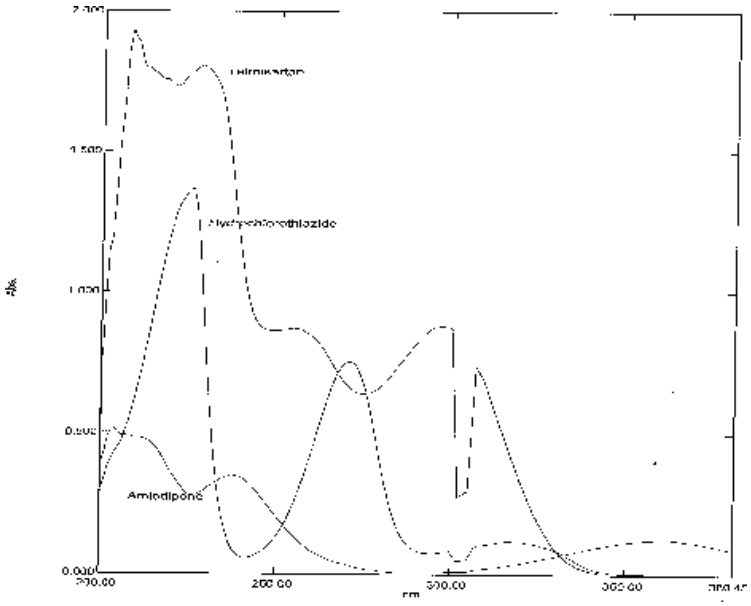

Figure 12: UV Spectra of TEL, HCZ and AMD.

TEL, HCZ and AMD, showed one additional peak at R_f value of 0.07 for AMD drug. For oxidation degradations of TEL, HCZ and AMD, one extra peak was found for HCZ with R_f value of 0.47 while two extra peaks were seen for TEL with R_f values of 0.59 and 0.68. There were no other spots formed from degradations under alkali, neutral, photolytic and dry heat conditions. TEL, HCZ and AMD showed significant degradation only when they were subjected for acidic, alkaline, hydrolytic, and oxidative stress conditions, whereas minimal degradation was seen for these compounds during dry heat and photolytic degradation studies.

For the three-drug combination, calibration curve was established within the range of concentration from 800 to 2800 ng/spot for Telmisartan, 200 to 700 ng/spot for Hydrochlorothiazide, and 100 to 350 ng/spot for Amlodipine based on peak area. Precision study was conducted by calculating %R.S.D., which was less than 2% implying that the developed analytical technique was precise. Accuracy study of the developed analytical technique was also

Table 8: Linearity curve of AMD at 265 nm.

Robustness		Saturation time (in minutes)			Mobile Phase (Toluene: chloroform: methanol)	
		15	25	35	2:5:2(v/v/v)	2:6:2(v/v/v)
Telmisartan	R_f	0.62	0.63	0.64	0.61	0.66
	Area	7756.6	7810.4	7856.6	7798.9	7819.2
	%RSD	1.20	1.22	1.24	1.18	1.21
Hydrochlorothiazide	R_f	0.30	0.32	0.33	0.32	0.34
	Area	7650.3	7693.1	7642.5	7658.2	7688.7
	%RSD	0.85	0.87	0.84	0.85	0.86
Amlodipine	R_f	0.12	0.14	0.14	0.15	0.14
	Area	856.2	858.2	862.7	860.7	859.2
	%RSD	0.58	0.59	0.59	0.72	0.61

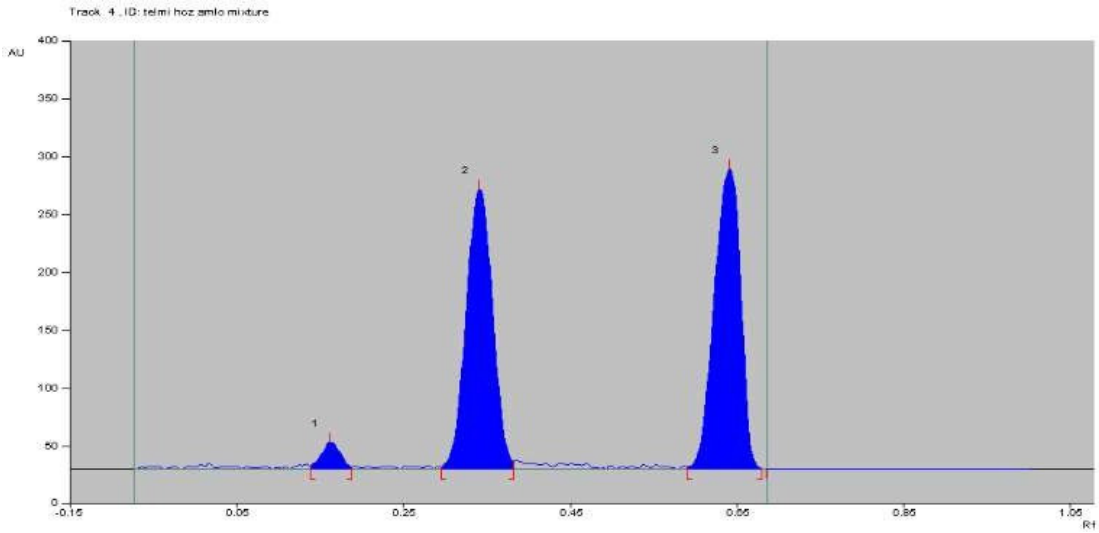

Figure 13: HPTLC Densitogram of TEL, HCZ and AMD in Tablet Formulation.

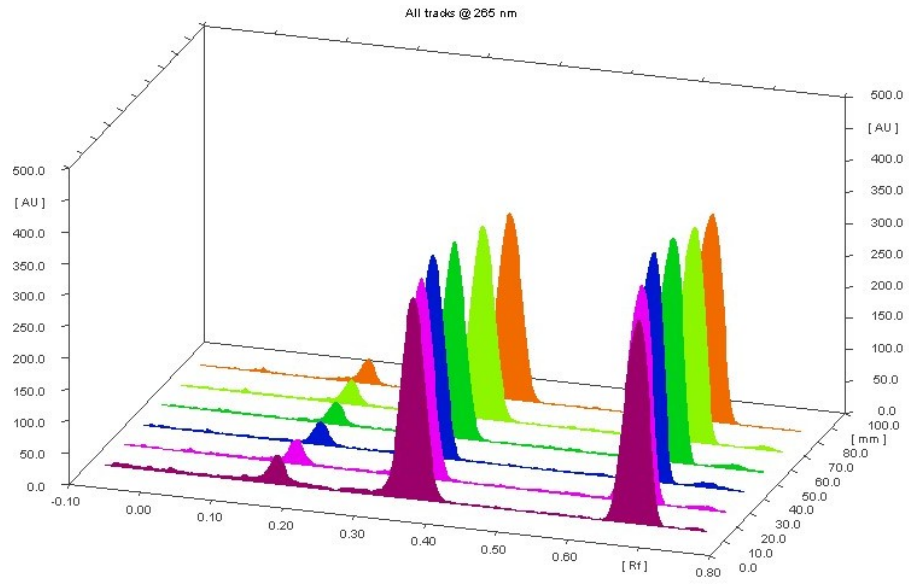

Figure 14: HPTLC Densitogram of Robustness Study for TEL, HCZ and AMD.

assessed, and mean recovery was found to be 100.2%, 100.1% for Telmisartan and Hydrochlorothiazide respectively and 100.4% for Amlodipine. The specificity of the proposed HPTLC technique was confirmed by estimating the band-R_f values and the peak areas of standard sample with those from tablet formulations. It could be seen that there was no interference from any excipient in the Densitogram of tablet formulations. %R.S.D. value was calculated by making some modifications in the HPTLC method developed.

CONCLUSION

From the above study we can conclude that there are various extents of degradation for the drugs such as Telmisartan, Hydrochlorothiazide and Amlodipine under various conditions of stress. As far as the current study is concerned, the products that have been obtained through the forced decomposition studies have been separated from the bulk drug studies. The peak purity profiling studies have also indicated that there is no interference of degradation peak of the drug in drug peak. It has thus been established that the degradation peaks of the drugs can be separated from the drug peaks in present study.

The development of the stability indicating HPTLC method has also been proposed in very few numbers of research papers. This method has been seen to be an accurate, simple, precise, specific and robust.

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ABBREVIATIONS

TEL: Telmisartan; **HCZ:** Hydrochlorothiazide; **AMD:** Amlodipine; **Conc:** concentration; **g:** grams; **HPTLC:** High-Performance Thin-Layer Chromatography; **µL:** microliter; **mcg/mL:** microgram/milliliter; **ng/spot:** nanogram/spot.

CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

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