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DEVELOPMENT AND VALIDATION OF STABILITY-INDICATING HPTLC ASSAY METHOD OF REMOGLIFLOZIN ETABONATE IN BULK AND MARKETED FORMULATION

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Keywords:

Remogliflozin Etabonate (RE), HPTLC, Validation, Stability indicating assay method

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ABSTRACT: Remogliflozin Etabonate (RE) is the latest addition to the sodium-glucose transport proteins 2 inhibitor class of drugs recently approved in India to manage type 2 Diabetes Mellitus. Literature survey revealed that no high-performance thin-layer chromatographic (HPTLC) method had been reported to date for this drug. The present work describes the development and validation of an HPTLC method for RE. The chromatography was performed on pre-coated silica gel 60 F 254 plates using methanol: toluene: ethyl acetate (1:4:5) v/v/v as mobile phase. A thin layer chromatographic (TLC) scanner set at 228 nm was used to directly evaluate the chromatograms in reflectance/absorbance mode. The drug was satisfactorily resolved with R_f 0.45. The method was validated according to the International Council on Harmonization (ICH) guidelines. The calibration plot was linear between 50–300 ng/b and respectively. The accuracy and precision of the proposed method were evaluated by recovery studies and intra-day and inter-day precision studies, respectively. In stability testing, RE was found to be susceptible to alkaline degradation. Because the method could effectively separate the drugs from their degradation products, it may be used as a stability-indicating method.

INTRODUCTION: Remogliflozin Etabonate (RE) is a pro-drug of remogliflozin. RE is an antidiabetic drug, its chemical name is β-D-Glucopyranoside, 5-methyl-4-[[4-(1-methylethoxy) phenyl] methyl]-1-(1-methylethyl)-1H-pyrazol-3-yl, 6-(ethyl carbonate) [1-2]. Remogliflozin inhibits the sodium-glucose transport proteins (SGLT), which are responsible for glucose reabsorption in the kidney. Due to the blocking of the transporter, blood glucose gets eliminated through the urine. Remogliflozin is selective for SGLT2 [3].

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RE has been recently introduced in the market, and a literature survey reveals that few pharmacokinetic studies, stability-indicating RP-HPLC and UV methods have been reported. There is no high-performance thin-layer chromatographic (HPTLC) method for this drug [4-13].

HPTLC method is useful for simultaneous processing of sample and standard, no need for the internal standard, faster technique and reduced cost per analysis, simple sample preparation, no prior treatment for solvents like filtration and degassing, fresh stationary and mobile phases for each analysis with no contamination, the ability for visual detection with an open system, and to determine non- UV absorbing compounds detected by post chromatographic derivatization. It reveals that the proposed method requires less time and

less solvent for the analysis. So, the proposed method is cost-effective as HPLC grade solvents are too costly.

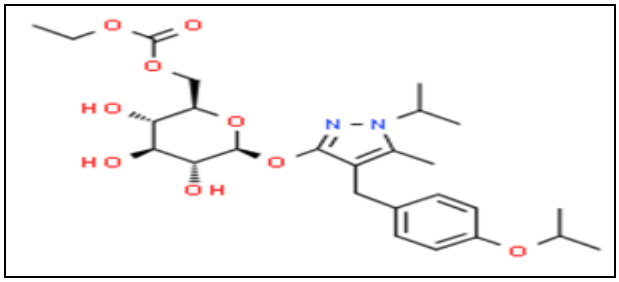

FIG. 1: STRUCTURE OF REMOGLIFLOZIN ETABONATE

MATERIAL AND METHODS:

Chemicals and Reagents: Methanol, Toluene, Ethyl acetate, conc. HCl, Hydrogen peroxide, and NaOH (AR grade) were supplied by Merck Specialities Pvt. Ltd. Mumbai. Double distilled water was used throughout the study.

Reference standard of RE was procured from Glenmark Pharmaceutical Ltd. RE tablets (100mg) were purchased from the local market.

HPTLC Instrumentation: A CAMAG HPTLC system equipped with Linomat 5 autosampler, TLC scanner 3, and win CATS 1.2.2 software was used. The slit dimension was kept at 5.00 × 0.45 mm, and a 20 mm/sec scanning speed was employed. Chromatography was performed on precoated silica gel 60 F254 TLC plates (10 × 10 cm), (Merck, Darmstadt, Germany, Merck Specialities Pvt. Ltd .Mumbai.) using Methanol: Toluene: Ethyl acetate (1: 4: 5, v/v/v) as mobile phase.

The band length was 6 mm, and the distance between bands 15 mm was kept constant throughout the study. The number of applications on the plates was four for standards and two for test samples.

The application speed was 150 nL/sec. Ascending development to a distance of 85 mm was performed on a 20×10 cm twin trough chamber (CAMAG). Chromatograms were evaluated *via* peak area after scanning in absorbance mode at 228nm. The Retention factor (R_f) of Remogliflozin Etabonate was 0.45.

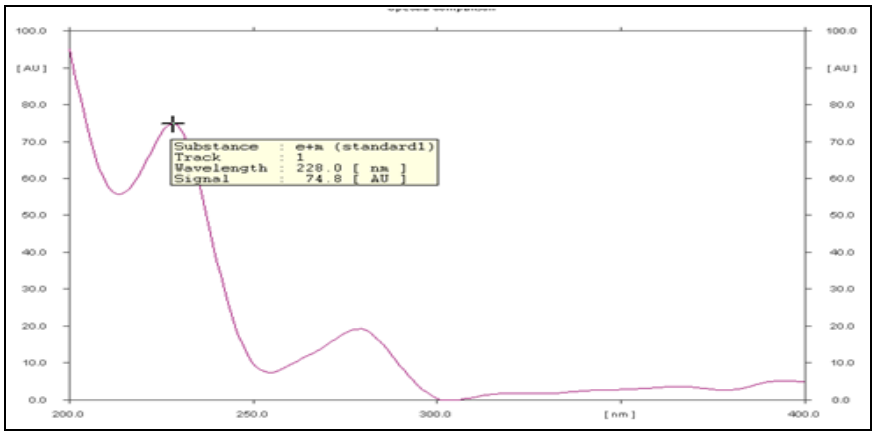

FIG. 2: UV SPECTRUM OF REMOGLIFLOZIN ETABONATE (10 µg/ml)

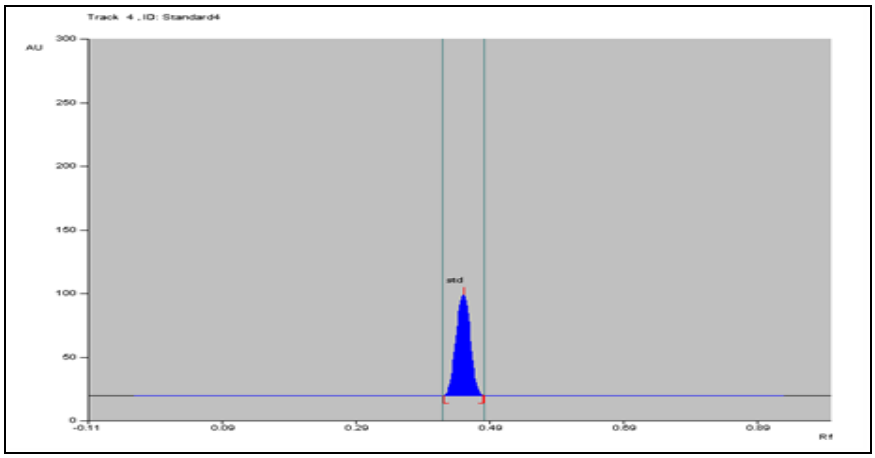

FIG. 3: OPTIMIZED DENSITOGRAM OF REMOGLIFLOZIN ETABONATE

Preparation of Solutions:

Standard Solution: A stock solution of RE was prepared by accurately dissolving about 10 mg of RE with 100 mL methanol. Aliquots of this solution were suitability diluted with methanol to get working standard solutions of RE having a concentration of 1000µg/mL.

Sample Solution: 20 tablets were weighed; the average weight was calculated and crushed to obtain a fine powder. Tablet powder equivalent to about 10 mg RE was transferred to 100 mL volumetric flasks, dissolved, and diluted up to the mark with methanol. From this solution, 10 mL was transferred to a 100 mL volumetric flask and diluted to the mark with methanol (Concentration 10 µg/mL RE).

Procedure: On the TLC plate, two bands of standard and four bands of sample solution, 0.4 µL each, were applied and the plate was developed and scanned under the optimized chromatographic conditions. After scanning, the peaks obtained for standard and sample bands were integrated. The amount of RE present in the applied volume of the standard solution was fed to the computer. The amount of the drugs present in the applied sample solution volume was obtained by comparing the peak area of standard and sample bands. The amount of each drug estimated in average weight of tablet and percent label claim was calculated by using formula.

Optimization of Mobile Phase: Aliquot portions of standard stock solutions (0.4 µL) were applied on TLC plates in the form of a band (band size: 6mm). Different solvents with varying polarity as well as a combination of solvents were tried to get well-separated bands of the drugs. After trying several arrangements and combinations, the solvent system (Methanol: Toluene: Ethyl Acetate (1:4:5; v/v) was most satisfactory as it gave good resolution.

Selection of Wavelength for Densitometric Evaluation of Separated Bands: A standard stock solution was applied on a TLC plate with the help of a CAMAG Linomat-V automatic sample applicator; the plate was developed in a twin-trough glass chamber saturated with mobile phase for 10 min. The plate was removed and air-dried after chromatographic development. The separated bands on the TLC plate were scanned over the wavelength range of 200-700 nm. The wavelength 228nm was selected for the densitometric evaluation of separated bands.

Chromatographic Conditions: The following chromatographic conditions were optimized by trial and error for effective separation and densitometric evaluation of drugs:

TABLE 1: CHROMATOGRAPHIC CONDITIONS

Stationary phase	Aluminum plates precoated with silica gel 60 F254 Merck
Mobile phase	(Methanol:Toluene: Ethyl Acetate) (1:4:5;v/v)
Plate size	10 cm X 10 cm (Thickness: 200µm)
Mode of application	Band
Band size	6 mm (Distance between two bands: 7.7 mm)
Sample volume	0.4 µL
Development chamber	Twin-through glass chamber, 10 cm X 10 cm with stainless steel lid.
Saturation time	10 minutes
Separation technique	Ascending
Migration distance	≈ 80 mm
Temperature	25 ± 5 °C
Scanning mode	Absorbance/Reflectance
Slit dimensions	5 X 0.45 mm
Scanning wavelength	228 nm

Method Validation: The developed HPTLC method was validated according to ICH guidelines. The various validation parameters include linearity, range, accuracy, precision, LOD, LOQ and robustness [14-15].

Linearity and Range: For the establishment of linearity of RE by the proposed method, the calibration curve was obtained at five levels in the concentration range of 0.2-1.2ng/spot. For this, the different increasing amounts of RE working standard (0.4 mg/mL) were spotted three times on individual plates and analyzed as described.

For evaluation of linearity, observed peak area and concentrations were subjected to least square regression analysis to calculate calibration equation and correlation coefficient.

The observed linearity confirms adherence of the system to Beer's law. The regression analysis equation was y =134.956+3.154"X with a correlation coefficient (r) of was 0.99810.

Accuracy: To confirm the accuracy of the proposed method, recovery studies were carried out by standard addition method, as per ICH guidelines. The % mean recovery of each marker in the sample at three levels (80%, 100%, and 120%) was determined. The analysis was performed in triplicates.

Precision:

Intraday Precision: Intraday precision was determined by analyzing tablet sample solutions at different time intervals on the same day. The tablet sample solution was prepared and analyzed similarly as described under the analysis of the tablet formulation.

Inter-day Precision: Inter-day precision was determined by analyzing tablet sample solutions on three different days. The tablet sample solution was prepared and analyzed similarly as described under the analysis of the tablet formulation.

Limit of Detection (LOD) and Limit of Quantitation (LOQ): Separately determined LOD and LOQ were based on the standard deviation of the response of the calibration curve. The standard deviation of y-intercept and slope of the calibration curves were used to calculate the LOD and LOQ.

Robustness: To evaluate the robustness of the proposed method, small but deliberate variations in the optimized method parameters were done.

By introducing small changes in the mobile phase composition, mobile phase volume, and duration of chamber saturation with mobile phase, the effects on the R_f value of drugs were examined.

The composition of the mobile phase was changed slightly (± 0.5 ml for the component). TLC plates with standard and sample bands were run with mobile phases of composition, Methanol: Toluene: Ethyl Acetate (1:4:5; v/v/v) Mobile phase volume and duration of chamber saturation were varied at 10±1ml (9, 10 and 11ml) and 10 ± 5 min (5, 10 and 15 min).

Forced Degradation Study of Remogliflozin Etabonate:

Acidic Stress Degradation: In acidic stress degradation, 10 mg RE was separately transferred to different 10.0 ml volumetric flasks, 10 ml of 0.1 N HCl added to it, then refluxed at room temperature for 45 min. Cooled and neutralized with 10 mL of 0.1 N sodium hydroxide solution and further analyzed by the proposed method.

Alkaline Stress Degradation: In alkaline stress degradation, 10 mg RE was separately transferred to different 10.0 ml volumetric flasks, 10 ml of 0.1 N NaOH added to it, then refluxed at room temperature for 45 min.

Cooled and neutralized with 10 mL of 0.1 N HCl solutions and further analyzed by the proposed method.

Oxidative Stress Degradation: In oxidative stress degradation, 10 mg RE was separately transferred to different 10.0 ml volumetric flasks, 10 ml 3% H_2O_2 is added and kept at dark for 45 min and after that heated to remove H_2O_2 and further analyzed by the proposed method.

Photolytic Stress Degradation: In photolytic stress degradation, 10 ml of RE stock solution was exposed to ultraviolet radiations at 254 nm for 24 hrs in a UV- chamber.

Thermal Stress Degradation: In thermal stress degradation, 10 ml of RE stock solution was kept at 60 °C for 45 minutes to study heat's effect on the drug sample.

Neutral Stress Degradation: In Neutral stress degradation, 10 mg RE was separately transferred to different 10.0 ml volumetric flasks, 10 ml of H_2O added to it, then refluxed at room temperature for 45 min. Cooled and further analyzed by the proposed method.

RESULTS AND DISCUSSION: Validation was done concerning various parameters required under ICH guideline Q2 (R1).

The calibration curve for RE was obtained at five levels in the concentration range of 0.2-1.2 ng/spot. The regression analysis equation was y =134.956+3.154"X with a correlation coefficient (r) was 0.9981.

The Spectra of RE using Win cats software is shown in **Fig. 2** & **3**. The result of linearity studies is shown for RE in **Fig. 4, 5,** and **Table 2.**

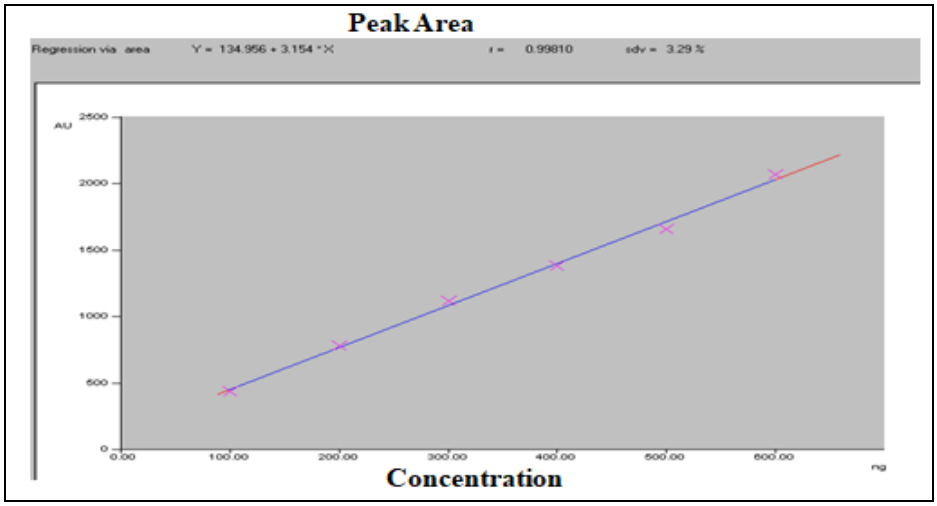

FIG. 4: CALIBRATION CURVE OF REMOGLIFLOZIN ETABONATE BY HPTLC

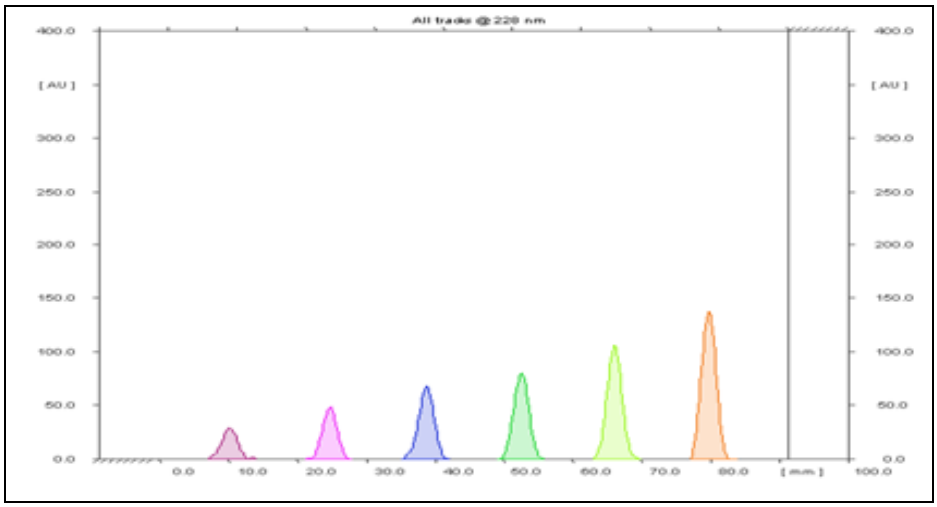

FIG. 5: CALIBRATION DENSITOGRAMS OF REMOGLIFLOZIN ETABONATE USING WINCATS SOFTWARE

TABLE 2: CALIBRATION DATA OF REMOGLIFLOZIN ETABONATE BY HPTLC

S. no.	Concentration (ng/band) Remogliflozin Etabonate	Rf value	Area of peak
1	100	0.45	436.65
2	200	0.45	779.78
3	300	0.45	1117.47
4	400	0.45	1376.58
5	500	0.45	1657.12
6	600	0.44	2066.58

TABLE 3: LINEARITY DATA OF REMOGLIFLOZIN ETABONATE BY HPTLC

S. no.	Parameters	Results
1	Linearity range	150-900 ng/band
2	Regression equation	y =134.956+3.154*X
3	Correlation of coefficient	0.998
4	Slope	3.154
5	Intercept	144.9037
6	LOD	0.2590 ng/band
7	LOQ	0.7850ng/band

Accuracy (% Recovery): The method's accuracy was determined by calculating the recovery of RE by the standard addition method at three concentration levels (80%, 100%, and 120%). The percentage recoveries of RE were found to be in the range of 102.36-104.20%. The Accuracy results of RE are shown in **Table 4.** The weight of the tablet powder taken is 10mg.

TABLE 4: ACCURACY RESULTS OF REMOGLIFLOZIN ETABONATE BY HPTLC

Level of recovery (%)	Amount of drug added (mg)	Amount of drug recovered (mg)	% Recovery	% Recovery Mean	SD	%RSD
	8	10.18	101.84			
80	8	10.17	101.77	101.75	40.48	1.6
	8	10.16	101.64			
	10	10.26	102.69			
100	10	10.28	102.89	102.89	37.906	1.2
	10	10.30	103.09			
	12	10.27	102.76			
120	12	10.24	102.44	102.53	31.085	1.1
	12	10.23	102.39			

Repeatability: In the repeatability studies, six replicates of one concentration of RE were prepared and spotted on an HPTLC plate. From the obtained data, %RSD of RE was found to be less than 2%. The results of repeatability studies for RE are shown in **Table 5.**

TABLE 5: REPEATABILITY RESULT OF REMOGLIFLOZIN ETABONATE

Drug	Amount of drug taken	% Mean estimated	SD.	%RSD
Remogliflozin	8mg	99.85	1.6141	1.612%
Etabonate	10 mg	101.86	1.2834	1.256%
	12 mg	103.19	1.2412	1.201%

Intermediate Precision (Ruggedness): In the intermediate precision studies, six replicates of one concentration were prepared and spotted on an HPTLC plate for 3 consecutive days. From the obtained data, % RSD of RE was found to be less than 2%. The intermediate precision results of RE are shown in **Table 6.**

TABLE 6: INTERMEDIATE PRECISION OF REMOGLIFLOZIN ETABONATE

Drug	Amount of drug taken	% Mean estimated	SD	%RSD
Remogliflozin	8 mg	99.90	1.620	1.621%
Etabonate	10 mg	102.56	1.334	1.300%
	12 mg	100.22	1.045	1.042%

Limit of Detection (LOD) and Limit of Quantitation (LOQ): For RE, LOD and LOQ were calculated from the formula.

$$LOD = 3.3\sigma/S, LOQ=10\sigma/S$$

Where, σ = Standard deviation of the response, S = slope of the calibration curve.

Robustness: To evaluate the robustness of the proposed method, small but deliberate variations in the optimized method parameters such as a change in chamber saturation time, change in the composition of the mobile phase. This was studied to find out the robustness of the proposed method % RSD was found to be less than 2%. The Robustness result of a change in saturation time (±5min) of RE is shown in the table. Change in Mobile phase composition (±1ml) of RE shown in **Table 7.**

TABLE 7: CHROMATOGRAPHIC CHANGES FOR REMOGLIFLOZIN ETABONATE

Chromatographic Changes		
Factor	**Level**	**Rf values**
Mobile phase composition (Methanol: Toluene: Ethyl Acetate (1:4:5; v/v/v)		Remogliflozin Etabonate
1:5:4.5	±0.5	0.44
1:4:5	0	0.45
1: 4.5 :5	±0.5	0.41
Amount of mobile phase (±1ml)		Remogliflozin Etabonate
9	-1	0.44
10	0	0.45
11	+1	0.41
Duration of the chamber (±5min)		Remogliflozin Etabonate
5 min	-5 min	0.43
10 min	0 min	0.45
15 min	+5 min	0.46

Analysis of Marketed Tablet Formulation: Brand Name: Remo 100mg Tablet Label Claim: 100 mg, Tablet Weight: 323.2mg. The % label claim of Remogliflozin Etabonate tablet was found to be 106.2 %.

TABLE 8: % LABEL CLAIM OF REMOGLIFLOZIN ETABONATE IN TABLET BY HPTLC

Weight of tablet powder (mg)	Amount Found (mg/tab)	% Label claim	S.D.	% RSD
324.9	100.25	106.70	1.7551	1.6448

TABLE 9: SUMMARY OF METHOD VALIDATION RESULT BY HPTLC

S. no.	Parameters	Results
1	Linearity (n=6)	150-900 ng/band
2	Correlation coefficient (R^2)	0.998
3	**Precision (%RSD)**	
	Intraday Pression(n=9)	0.43
	Intermediate precision (n=9)	0.44
4	Accuracy (%Recovery) (n=9)	101.75-102.89
5	Limit of Detection (LOD)	0.2590
6	Limit of Quantitation (LOQ)	0.7850
7	Robustness (%RSD)	
	a) Change in saturation time (±5min) (n=3)	
	+5min	0.41
	-5min	0.43
	b) Change in the mobile phase composition	
	1.5:4.5:4	0.65
	2:4:4	0.70
	c) Change in mobile phase (±1ml) (n=3)	
	9	0.43
	11	0.46
8	% label claim of Marketed Tabletformulation	106.2%

Forced Degradation Study of Remogliflozin Etabonate:

Acidic Stress Degradation: In acidic stress degradation, RE showed 8.8 % degradation on exposure to 0.1N HCl at room temperature for 20 min **Fig. 6.**

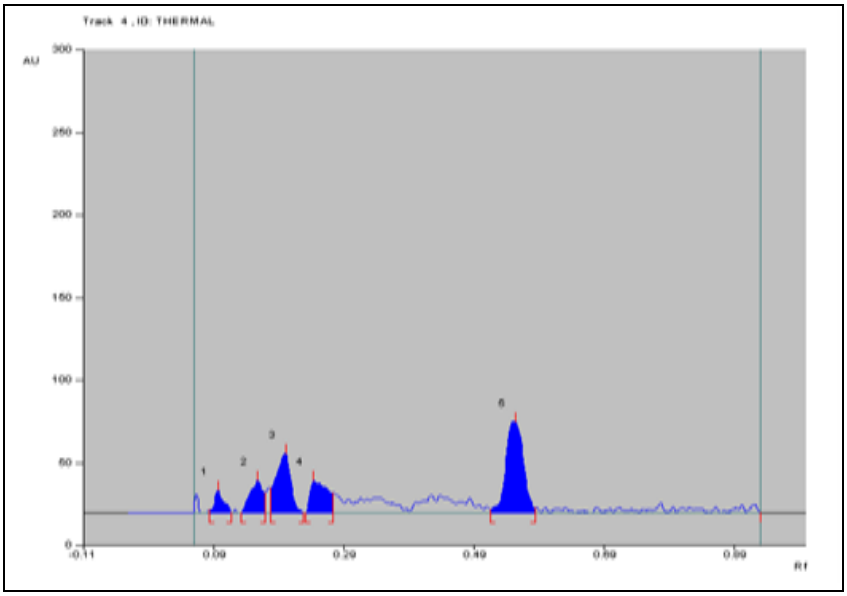

FIG. 6: HPTLC DENSITOGRAM OF ACID DEGRADATION OF REMOGLIFLOZIN ETABONATE IN 0.1N HCL AT ROOM TEMPERATURE AFTER 45 MIN

Alkaline Stress Degradation: In alkaline stress degradation. RE showed 9.0% degradation in 0.1N NaOH at room temp for 45 min **Fig. 7.**

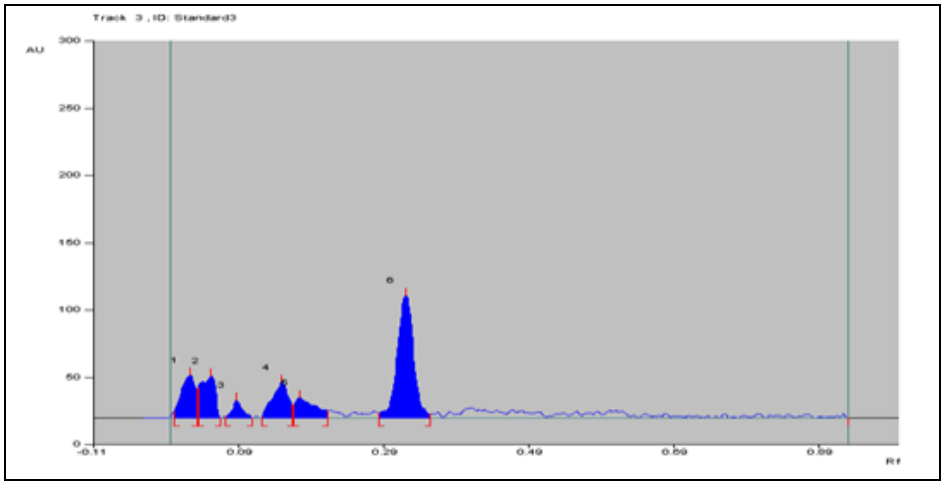

FIG. 7: HPTLC DENSITOGRAM OF ALKALINE DEGRADATION OF REMOGLIFLOZIN ETABONATE IN 0.1N NAOH AT ROOM TEMPERATURE AFTER 45 MIN

Oxidative Stress Degradation: In oxidative stress degradation. RE showed 8.9% degradation in 3% H_2O_2 at room temperature for 45 min **Fig. 8.**

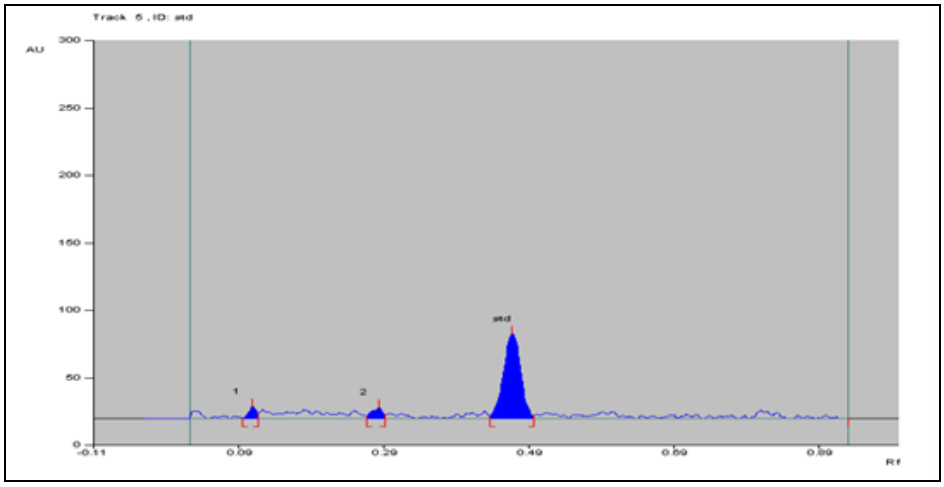

FIG. 8: HPTLC DENSITOGRAM OF OXIDATIVE DEGRADATION OF REMOGLIFLOZIN ETABONATE IN 3% H_2O_2 AT ROOM TEMPERATURE AFTER 45 MIN

Photolytic Stress Degradation: In photolytic stress degradation. RE showed 8.6% degradation on exposure to UV light (254 nm) for 24 h **Fig. 9.**

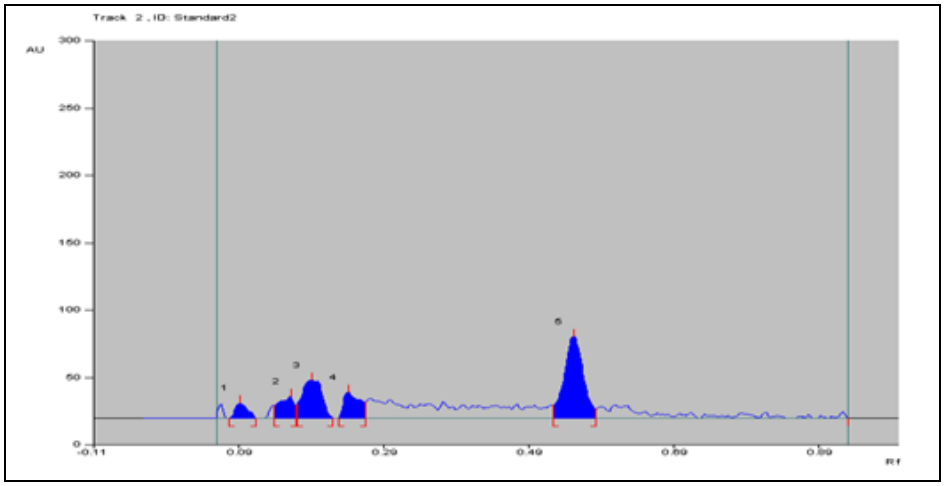

FIG. 9: HPTLC DENSITOGRAM OF PHOTOLYTIC DEGRADATION OF REMOGLIFLOZIN ETABONATE ON EXPOSURE TO UV LIGHT FOR 24 H

Thermal Stress Degradation: In thermal stress degradation. RE showed 8.8% degradation on exposed to 60 °C for 45 min **Fig. 10.**

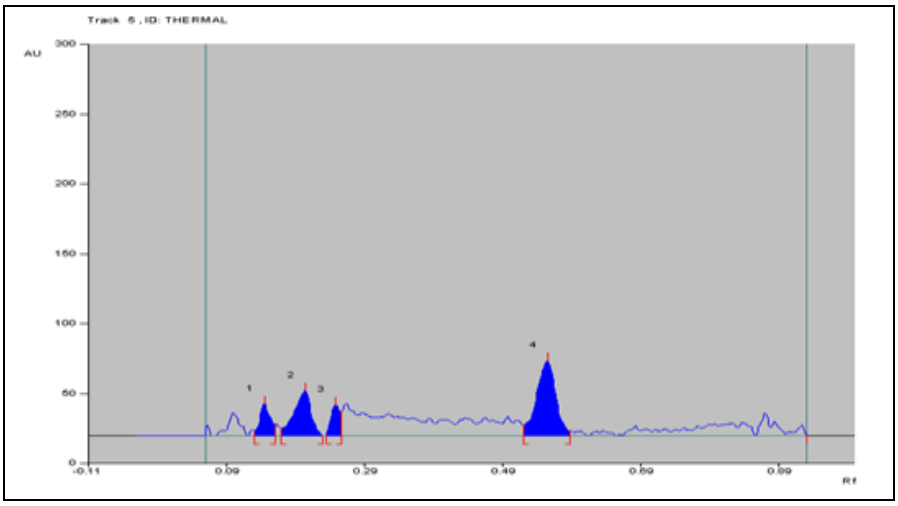

FIG. 10: HPTLC DENSITOGRAM OF THERMAL DEGRADATION OF REMOGLIFLOZIN ETABONATE ON EXPOSURE TO 60 °C FOR 30 MIN

Neutral Stress Degradation: In Neutral stress degradation. RE showed 8.6% degradation in Distilled Water at room temperature for 45 min **Fig. 11.**

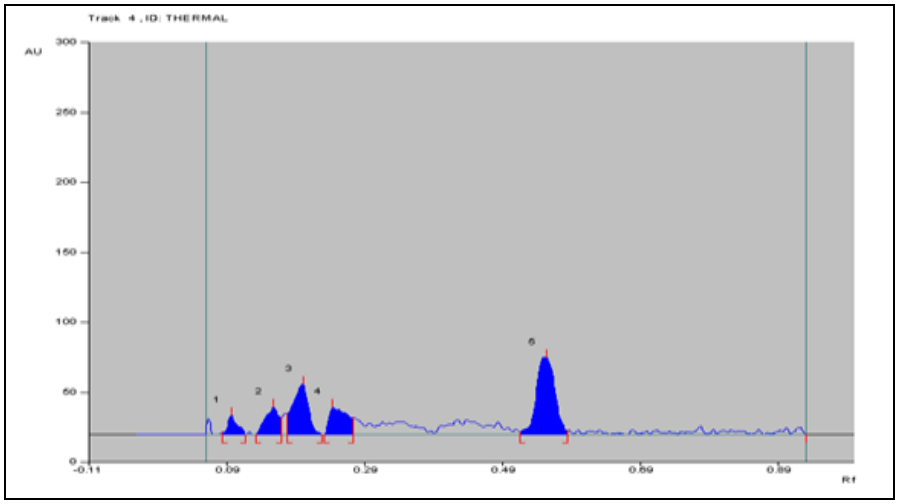

FIG. 11: HPTLC DENSITOGRAM OF HYDROLYTIC DEGRADATION OF REMOGLIFLOZIN ETABONATE IN DISTILLED WATER AT ROOM TEMPERATURE AFTER 45 MIN

TABLE 10: THE RESULTS OF THE STRESS DEGRADATION STUDIES OF REMOGLIFLOZIN ETABONATE BY HPTLC

S. no.	Stress Condition	Temp and Time	Percent Degradation	Rf Value of degraded product
		Remogliflozin Etabonate	Remogliflozin Etabonate	
1	Acid (0.1 N HCl)	Room temp for 45 min	8.8 %	0.58
2	Alkali (0.1 N NaOH)	Room temp for 45min	9.0 %	0.35
3	Neutral (H_2O)	Room temp for 45 min	8.6 %	0.65
4	Thermal	60°C for 45 min	8.8%	0.59
5	Oxide (3 %H_2O_2)	Room temp for 45min	8.9%	0.50
6	Photolytic Degradation	24 hr	8.6%	0.55

CONCLUSION: A new, simple, sensitive, precise, accurate, and specific HPTLC method for the determination and quantification of Remogliflozin Etabonate in pharmaceutical tablet formulation has been developed. ICH guidelines were followed throughout method validation, and it suggested that this method can be applied for routine quality control analysis of Remogliflozin Etabonate in

pharmaceutical formulation. In forced degradation studies, RE was found to be susceptible to alkaline degradation. Because the method could effectively separate the drugs from their degradation products, it may be used as a stability-indicating method.

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CONFLICTS OF INTEREST: This research does not have any conflict of interest with anyone or any institute.

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