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STABILITY INDICATING METHOD DEVELOPMENT AND VALIDATION OF REMOGLIFLOZIN ETABONATE IN BULK AND PHARMACEUTICAL DOSAGE FORM BY RP-HPLC

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Keywords:

Remogliflozin Etabonate, RP-HPLC, C18 Column, Validation and ICH guidelines

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ABSTRACT: An accurate, precise, and simple stability-indicating and RP-HPLC method was developed and validated for the estimation of Remogliflozin Etabonate in bulk and pharmaceutical dosage forms. Primacel C_{18} (150 × 4.6mm, 5µm) column, with mobile phase Acetonitrile: Water (70:30, v/v) at isocratic mode, was used for the development of this method. At wavelength 280nm, and flow rate of 1ml/min was maintained. The retention time for remogliflozin etabonate was about 2.6 min. This method was validated with respect to ICH guidelines for linearity, the limit of detection, the limit of quantification, precision, accuracy, robustness, solution stability, and forced degradation studies. Linearity was performed in the concentration range of 25µg/ml to 150µg/ml with a correlation coefficient of 0.999. The percentage recovery for Remogliflozin Etabonate was found to be within limits of 98% - 102%. The %RSD was also found to be less than 2% which is within limits. Forced degradation studies result in maximum degradation occurred in alkali, acid, and peroxide degradation studies. There was no degradation occurred in photolytic and thermal degradation studies.

INTRODUCTION: Remogliflozin Etabonate is an anti-diabetic drug, chemically known as 5-Methyl-4-[4-(1-methyl ethoxy) benzyl]-1-(1-methylethyl)-1H-pyrazol-3-yl-6-O-(ethoxycarbonyl)-β-D-glucopyranoside. It inhibits the sodium-glucose transport proteins (SGLT), which are responsible for glucose reabsorption in the kidney. Blocking this transporter causes blood glucose to be eliminated through the urine. The structural formula is as shown in **Fig. 1** [1-3].

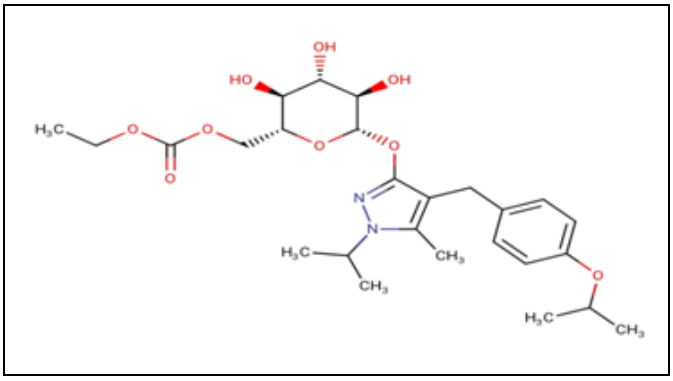

FIG. 1: CHEMICAL STRUCTURE OF REMOGLIFLOZIN ETABONATE

In the literature survey, it was found that there is no published literature for Remogliflozin Etabonate, but we found some articles for dapagliflozin, empagliflozin, and canagliflozin, which belong to the family of Remogliflozin [4-17]. In the present

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work, efforts are made to develop a simple, accurate, and precise RP-HPLC and solution stability method for Remogliflozin Etabonate in bulk and pharmaceutical dosage form and to validate it in accordance with ICH guidelines [18, 19].

MATERIALS AND METHODS: Remogliflozin Etabonate is a gift sample from Metrochem Pvt Ltd, Hyderabad, India. REMO®-ZEN 100mg (Formulation was manufactured by Glenmark Pharma limited). HPLC grade chemicals were preferred for the development of the method; this was obtained for Merck, Hyderabad, India. The method development conditions are described in **Table 1**.

Selection of Wavelength: Wavelength was fixed at 280nm by performing UV Spectroscopy **Fig. 2**.

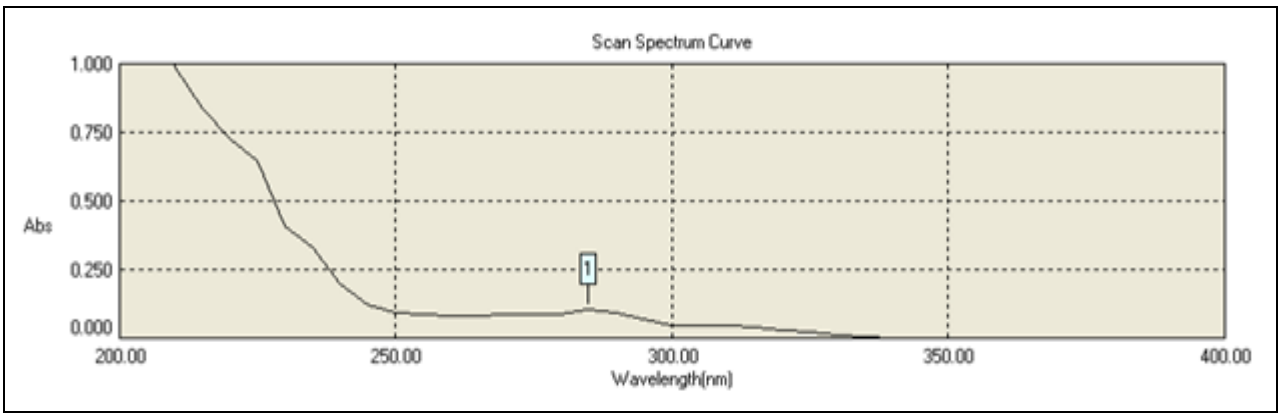

FIG. 2: WAVELENGTH SPECTRA

Chromatographic Conditions: Shimadzu HPLC with spinchrom software and UV/VIS detector with variable wavelength programme was used for the method development. Primacel C_{18} (150 × 4.6mm, 5µm) column. Acetonitrile: Water (70:30, v/v) is used as mobile phase at a flow rate of 1 ml/min Rheodyne injector with 25 µl loop was used for injecting the sample, and the sample was analyzed at 280nm.

Preparation of Mobile Phase: 70ml of HPLC grade Acetonitrile is taken into a mobile phase reservoir, and 30ml of HPLC grade water is added to it, and then it is kept for sonication for 15 mins, sonicated, and degassed.

Preparation of Standard Solution of Remogliflozin Etabonate: 100mg API of Remogliflozin Etabonate is dissolved in 100ml solvent (ACN) and the concentration is 1000µg/ml.

Preparation of Sample Solution: Estimation of Remogliflozin Etabonate (REMO®-ZEN) in dosage form, 20 tablets were weighed individually, and an average weight of the tablets was calculated and triturated into fine powder. 100mg equivalent powder is weighed and transferred it into a 100ml volumetric flask, then dissolve it using 30ml of a suitable solvent (ACN) and sonicated it for 15 min, then make up the volume of the contents in volumetric flask up to the mark using same solvent (ACN) and filter it using Whatman filter paper (No. 1) the concentration obtained is 1000µg/ml. from this solution various sample solutions are prepared and validated according to ICH guidelines.

Preparation of Calibration Curve: From the standard solution pipette out 0.25ml, 0.5ml, 0.75ml, 1ml, 1.25ml & 1.5ml into respective 10ml volumetric flasks and make up the volume up to the mark using suitable solvent (ACN) the concentrations are 25µg/ml, 50µg/ml, 75µg/ml, 100µg/ml, 125µg/ml and 150µg/ml. then the solutions were injected thrice using 25µl injector at the flow rate 1ml/min, at 280nm the chromatograms are recorded and calibration curve was plotted by taking concentration on X-axis and peak area on Y-axis.

Method Development:

Trail 1: Theoretical plates are very less.

Trail 2: Theoretical plates are not within the limits.

Optimized chromatographic conditions: Theoretical plates are more than 2000 which are acceptable and within the limits and the retention time is 2.6 min.

TABLE 1: CHROMATOGRAPHIC CONDITIONS FOR METHOD DEVELOPMENT

Parameters	Trail 1	Trail 2	Optimized Conditions
Column	PRIMACEL C18 (150*4.6mm,5µm)	PRIMACEL C18 (150*4.6mm,5µm)	PRIMACEL C18 (150*4.6mm,5µm)
Mobile Phase	ACN : Water (50:50,v/v)	ACN : Water (60:40,v/v)	ACN : Water (70:30,v/v)
Flow Rate	1ml/min	1ml/min	1ml/min
Injection Volume	25µl	25µl	25µl
Wavelength	280nm	280nm	280nm
Temperature	Ambient	Ambient	Ambient
Retention time	2.6 min	2.6 min	2.6 min
Run time	10 min	10 min	10 min
Theoretical Plates	1842	1973	2139

Assay Procedure: Remogliflozin Etabonate is available in the local pharmacy with the brand name of REMO®-ZEN (100mg, Glenmark Pharma limited). 1000µg/ml of sample solution was prepared and diluted to 50µg/ml and was injected into the HPLC system, and its obtained peak areas were noted down, and its % Assay was calculated as shown in **Table 2**.

TABLE 2: ASSAY OF FORMULATION

Drug	REMO®-ZEN Tablet Label Claim (mg)	Amount Found (mg)	% Label Claim ± % RSD (n=3)
Remogliflozin Etabonate	100	100.27	100.27±0.11

RESULTS AND DISCUSSION:

Specificity: The blank preparation from the formulation, which consists of excipients, was injected. Peaks were not detected in the retention time of analyte peak; this indicates that there is no interference of excipients of the formulation with the pure drug (API); this indicates that this method has specificity. The chromatogram is given in **Fig. 3**.

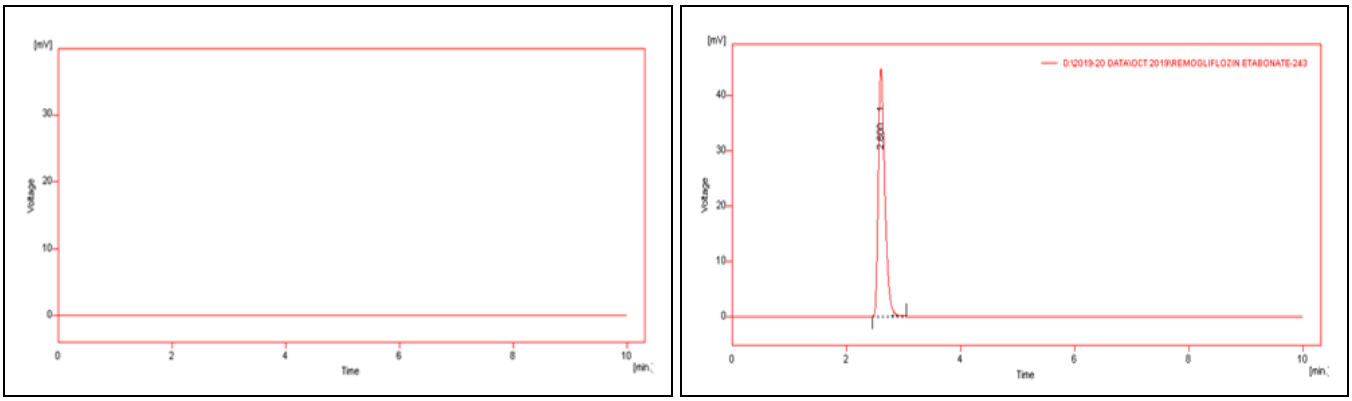

FIG. 3: BLANK AND STANDARD CHROMATOGRAM OF REMOGLIFLOZIN ETABONATE

Linearity: From the standard solution, a series of concentrations in the range of 25-125 µg/ml was prepared and injected thrice. The calibration curve was plotted by taking concentration on X Peak area on Y-axis. The obtained linearity has r^2=0.999, as shown in **Table 3** and **Fig. 4**.

TABLE 3: PEAK AREAS OF REMOGLIFLOZIN ETABONATE

Concentration (µg/ml)	Peak Area (mV)
25	75.633
50	147.02
75	221.147
100	295.687
125	369.122
150	444.654
Correlation Coefficient (r^2)	0.9999

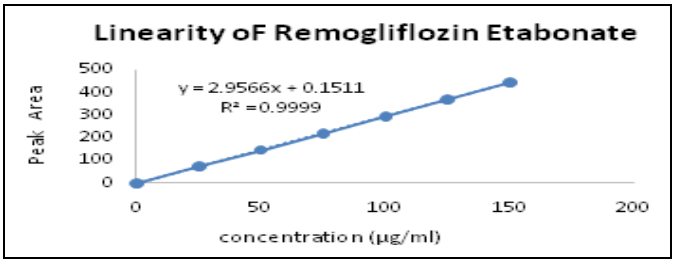

FIG. 4: CALIBRATION CURVE OF REMOGLIFLOZIN ETABONATE

LOD: The limit of detection (LOD) was calculated according to the following formula results are discussed below.

LOD = 3.3 × Standard deviation /Slope

LOD = 0.12µg/ml

LOQ: The limit of quantification was calculated according to the following formula results are discussed below.

LOQ = 10 ×Standard deviation / Slope

LOQ = 0.35µg/ml

Accuracy: Accuracy is described as an aggregate between the true value and the measured value. Accuracy was performed by injecting 50%, 100% & 150% levels thrice, and then its Amount found, Amount added, %Recovery, Mean recovery, and %RSD were calculated and are discussed in **Table 4**.

TABLE 4: ACCURACY RESULTS OF REMOGLIFLOZIN ETABONATE

Level	Amount Added (µg/ml)	Amount Found (µg/ml)	% Recovery	% Avg. Recovery	% SD	%RSD
50%	25	25.12	100.48	100.81	0.870	0.863
50%	25	25.45	101.80			
50%	25	25.03	100.15			
100%	50	49.10	98.21	99.74	1.550	1.554
100%	50	49.89	99.70			
100%	50	50.65	101.31			
150%	75	74.43	99.33	100.20	0.805	0.803
150%	75	75.27	100.36			
150%	75	75.69	100.92			

Precision: Repeatability:

System Precision: It was performed by injecting 50µg/ml of standard solution six times and its peak areas were noted and its average, SD, % RSD was calculated as shown in **Fig. 5** and **Table 5**.

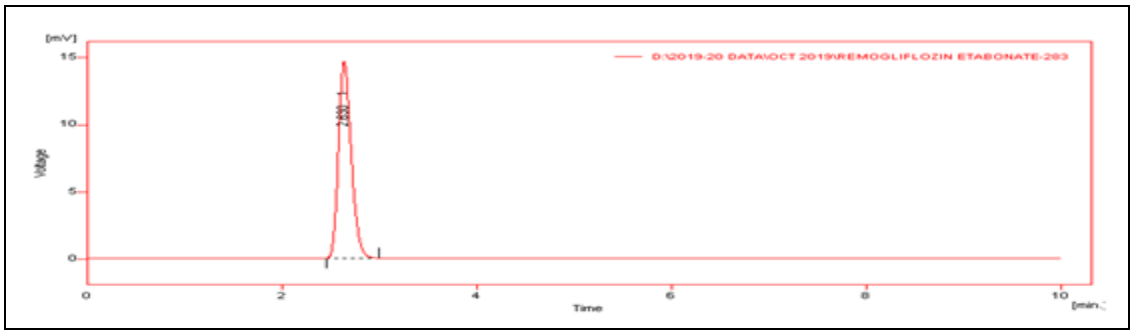

FIG. 5: CHROMATOGRAM FOR SYSTEM PRECISION OF REMOGLIFLOZIN ETABONATE

TABLE 5: RESULTS FOR SYSTEM PRECISION OF REMOGLIFLOZIN ETABONATE

Concentration (µg/ml)	Retention Time	Peak Area (mV)	Average	S. D	%RSD
50	2.6	152.892	152.649	1.479	0.96
50	2.6	154.435			
50	2.6	152.739			
50	2.6	153.691			
50	2.6	151.964			
50	2.6	150.173			

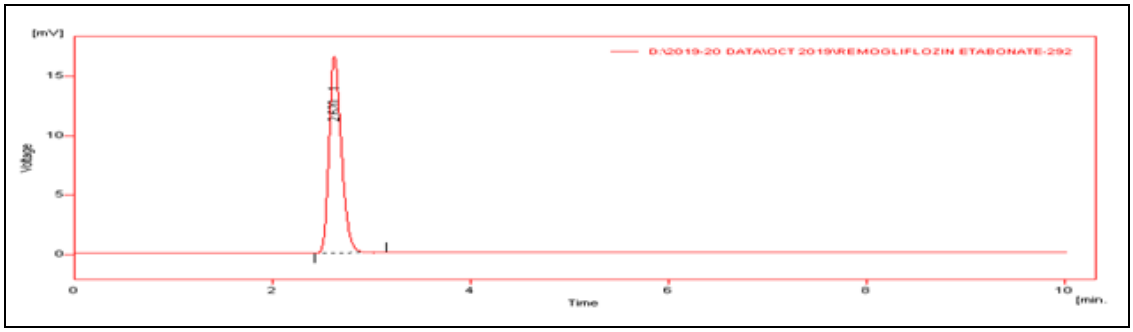

FIG. 6: CHROMATOGRAM FOR METHOD PRECISION OF REMOGLIFLOZIN ETABONATE

Method Precision: It was performed by injecting 50µg/ml of sample solution six times, and its peak areas were noted, and its % Assay, Average, S. D & %RSD were calculated as shown in **Fig. 6** and **Table 6**.

TABLE 6: RESULTS FOR METHOD PRECISION OF REMOGLIFLOZIN ETABONATE

Concentration (µg/ml)	Retention Time	Peak Area (mV)	%Assay	Average %Assay	S. D	%RSD
50	2.6	146.588	99.35	100.11	0.689	0.688
50	2.6	149.378	100.65			
50	2.6	147.942	100.27			
50	2.6	146.843	99.45			
50	2.6	149.295	101.10			
50	2.6	147.404	99.85			

Ruggedness / Intermediate Precision: Ruggedness was performed on two different days by two different analysts in two different labs by maintained the same laboratory conditions. On Day 1, Analyst 1 and Analyst 2 injected 100% concentration of the sample (50µg/ml) six times and noted its peak area values, and calculated its S. D & % RSD. Similarly, on Day 2, Analyst 1 and Analyst 2 injected 100% concentration of the sample (50µg/ml) for six times, and its peak areas were noted and calculated for S. D & %RSD. The results are discussed in **Table 7** and **Fig. 7.**

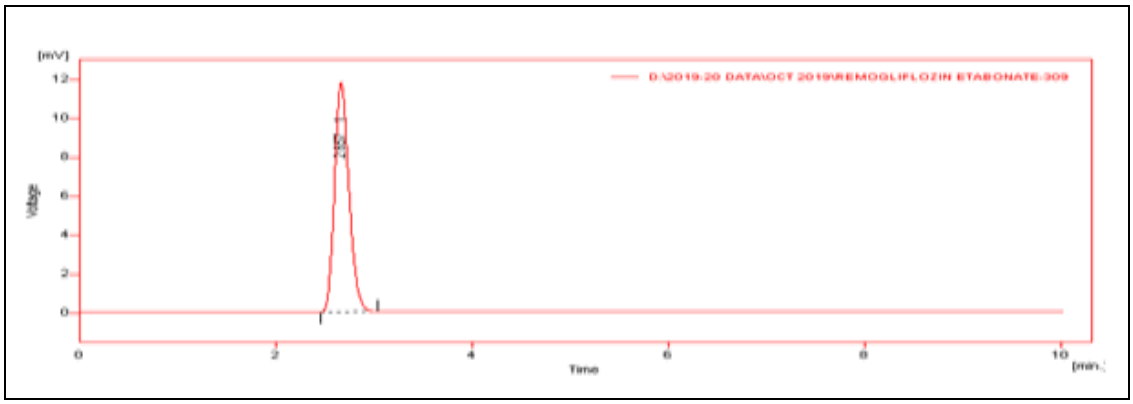

FIG. 7: CHROMATOGRAM FOR INTERMEDIATE PRECISION OF REMOGLIFLOZIN ETABONATE

TABLE 7: RESULTS FOR INTERMEDIATE PRECISION OF REMOGLIFLOZIN ETABONATE

	Lab-1 (%Assay)				Lab-2 (%Assay)			
Concentration(µg/ml)	Day-1		Day-2		Day-1		Day-2	
	A-1	A-2	A-1	A-2	A-1	A-2	A-1	A-2
50	100.32	99.72	99.08	99.12	101.84	99.80	102.08	98.57
50	101.82	100.36	98.45	100.43	101.10	100.43	100.44	102.17
50	100.82	99.75	99.83	102.32	99.43	99.48	101.96	99.71
50	101.42	100.72	99.02	100.84	100.41	101.02	98.42	101.30
50	101.12	100.30	100.65	102.23	99.08	102.19	98.86	100.16
50	102.22	102.42	98.42	100.34	99.29	101.64	99.79	99.02
Average	101.22	100.54	99.241	100.88	100.19	100.76	100.25	100.15
SD	0.64	0.99	0.86	1.22	1.11	1.05	1.53	1.36
%RSD	0.63	0.99	0.86	1.21	1.11	1.04	1.53	1.36
INTERMEDIATE PRECISION WITHIN LABORATORY VARIATIONS (N=6)								
Average			100.47		Average		100.34	
SD			0.865		SD		0.282	
%RSD			0.861		%RSD		0.281	

Reproducibility: Precision between the laboratories is known as Reproducibility. The procedure was carried out by injecting the 100% concentration of the sample (50µg/ml) for six times in two different laboratories into two different HPLC system. The peak areas were noted and its SD & %RSD was calculated which is discussed in **Table 8** and **Fig. 8**.

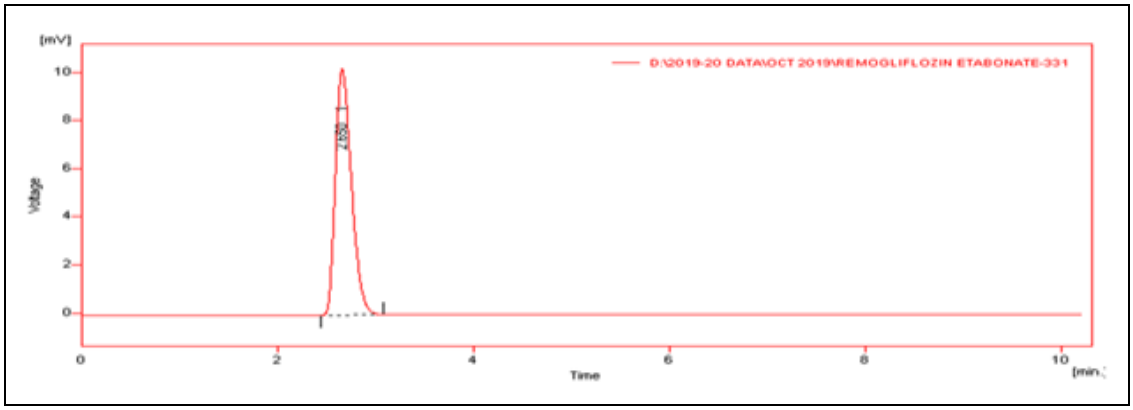

FIG. 8: CHROMATOGRAM FOR REPRODUCIBILITY OF REMOGLIFLOZIN ETABONATE

TABLE 8: RESULTS FOR REPRODUCIBILITY OF REMOGLIFLOZIN ETABONATE

Lab-1 (%Assay)		Lab-2 (%Assay)	
Average	100.47	Average	100.34
SD	0.865	SD	0.282
%RSD	0.861	%RSD	0.281
REPRODUCIBILITY BETWEEN LABORATORIES (N=48)			
Average	100.40		
SD	0.092		
%RSD	0.091		

Robustness: Robustness is known as changes in conditions of the parameters that should not affect any method. So, robustness was performed by small changes in the parameter conditions of the mobile phase (±10%) and Flow rate (±10%).

Change in Mobile Phase: This procedure was carried out by changing the Mobile phase proportion ±10% (*i.e.*, 77:23, v/v and 63:37, v/v). 100% concentration (50µg/ml) of sample solution was injected six times by varying the mobile phase proportions of ACN: water, *i.e.*, 77:23, v/v and 63:37, v/v, its peak areas were noted and calculated for its % Assay, Average, SD & %RSD as shown in **Fig. 9** and **10 and Table 9** and **10.**

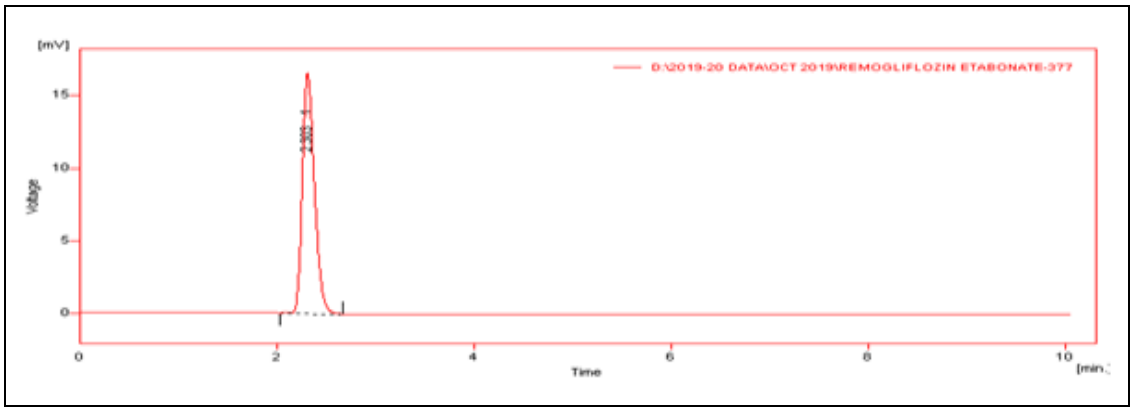

FIG. 9: CHROMATOGRAM FOR ROBUSTNESS AT +10% OF MOBILE PHASE

TABLE 9: RESULTS FOR ROBUSTNESS +10% OF MOBILE PHASE

Concentration (µg/ml)	Retention Time (min)	Peak Area (mV)	% Assay	Mean	SD	%RSD
50	2.2	147.170	99.92	100.54	1.369	1.361
50	2.2	145.665	98.90			
50	2.2	149.777	101.69			
50	2.2	148.516	100.82			
50	2.2	146.586	99.53			
50	2.2	150.985	102.51			

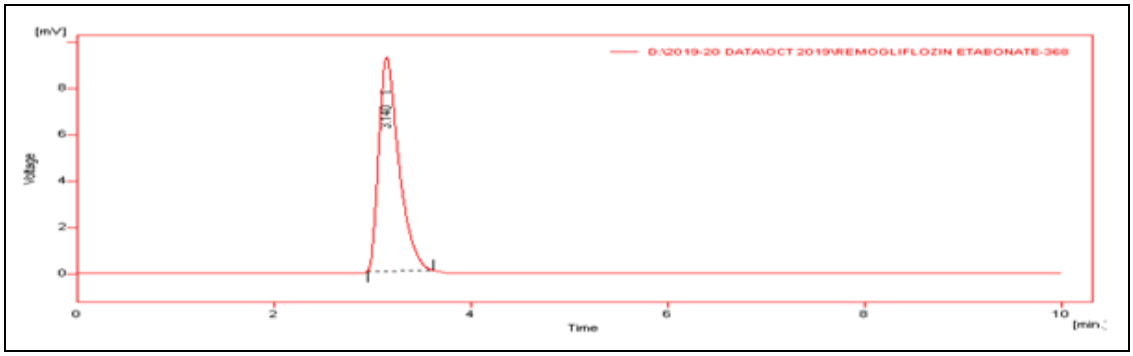

FIG. 10: CHROMATOGRAM FOR ROBUSTNESS AT -10% OF MOBILE PHASE

TABLE 10: RESULTS FOR ROBUSTNESS AT -10% OF MOBILE PHASE

Concentration (µg/ml)	Retention Time (min)	Peak Area (mV)	% Assay	Mean	SD	%RSD
50	3.1	148.157	100.59	99.89	0.718	0.719
50	3.1	147.572	100.20			
50	3.1	146.197	99.26			
50	3.1	146.880	99.73			
50	3.1	148.225	100.66			
50	3.1	145.666	98.90			

Change in Flow Rate: This procedure was carried out by changing the flow rate proportion ±10% (0.9ml/min & 1.1ml/min) 100% concentration (50µg/ml) of sample solution was injected six times by varying the Flow rate conditions i.e., 0.9ml/min and 1.1ml/min, its peak areas were noted and calculated for its %Assay, Average, SD & %RSD as shown in **Fig. 11** and **12, Table 11** and **12.**

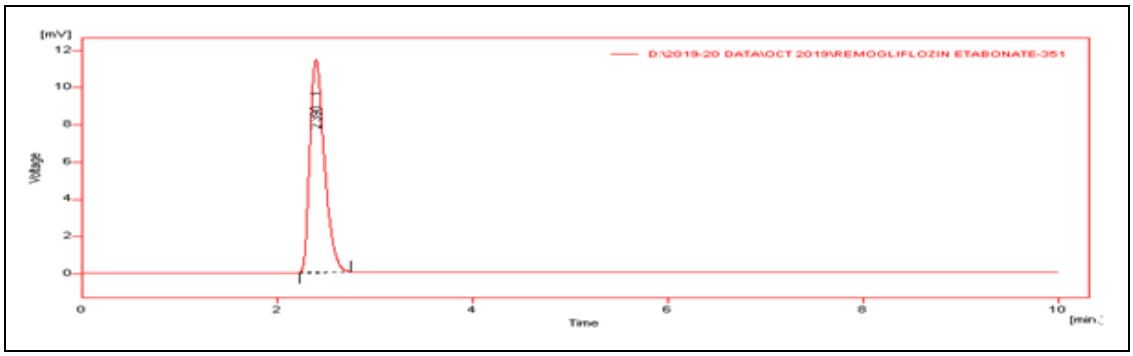

FIG. 11: PEAK ELUTED FOR ROBUSTNESS AT 1.1ml/min OF FLOW RATE

TABLE 11: RESULTS FOR ROBUSTNESS AT 1.1ml/min OF FLOW RATE

Concentration (µg/ml)	Retention Time (min)	Peak Area (mV)	% Assay	Mean	SD	%RSD
50	2.3	146.221	99.28	100.22	1.08	1.08
50	2.3	148.649	100.92			
50	2.3	149.567	101.55			
50	2.3	147.964	100.46			
50	2.3	148.059	100.53			
50	2.3	145.235	98.61			

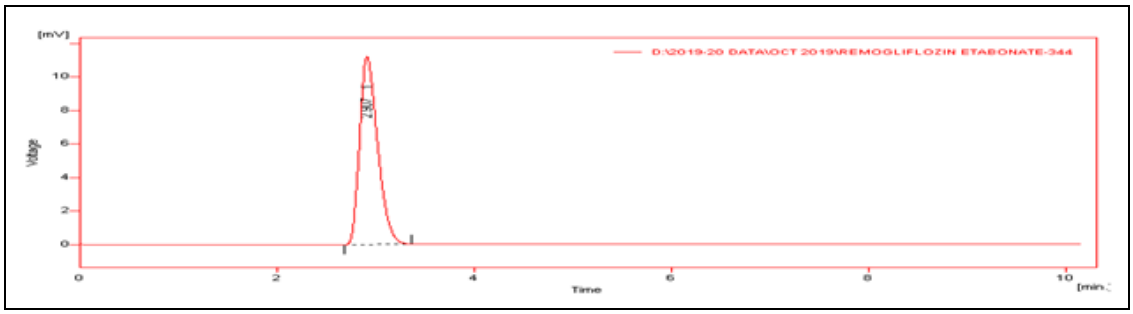

FIG. 12: PEAK ELUTED FOR ROBUSTNESS AT 0.9ml/min OF FLOW RATE

TABLE 12: RESULTS FOR ROBUSTNESS AT 1.1ml/min OF FLOW RATE

Concentration (µg/ml)	Retention Time (min)	Peak Area (mV)	% Assay	Mean	SD	%RSD
50	2.9	146.598	99.53	101.46	1.06	1.04
50	2.9	150.724	102.34			
50	2.9	151.954	102.42			
50	2.9	149.512	101.51			
50	2.9	148.963	101.14			
50	2.9	149.972	101.82			

Solution Stability: Solution stability was performed for 0 hr, 24 h and 48 h. 100% concentration (50µg/ml) of sample solution was injected for six times at 0 h, 24 h and 48 h. Peak areas obtained were noted and further calculation was done for % Assay, SD and %RSD was shown in **Table 13** and **Fig. 13, 14** and **15.**

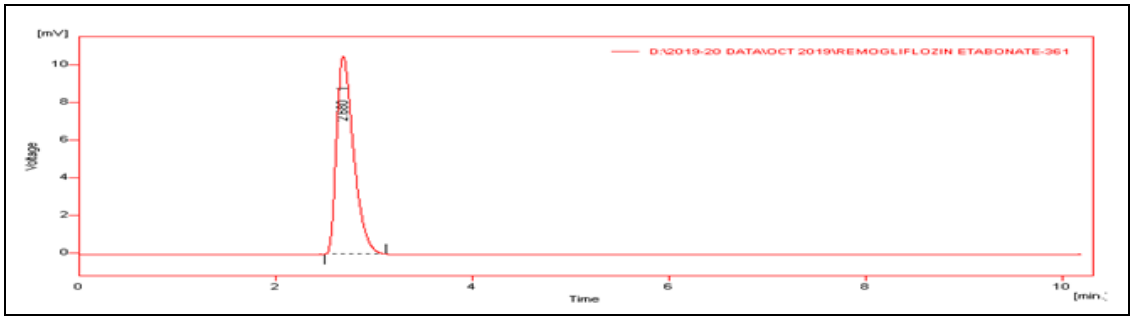

FIG. 13: PEAK ELUTED AT 0 h

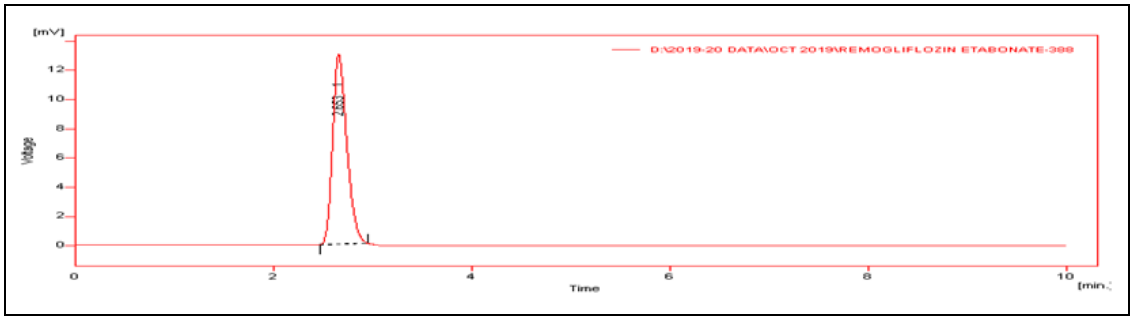

FIG. 14: PEAK ELUTED AT 24 h

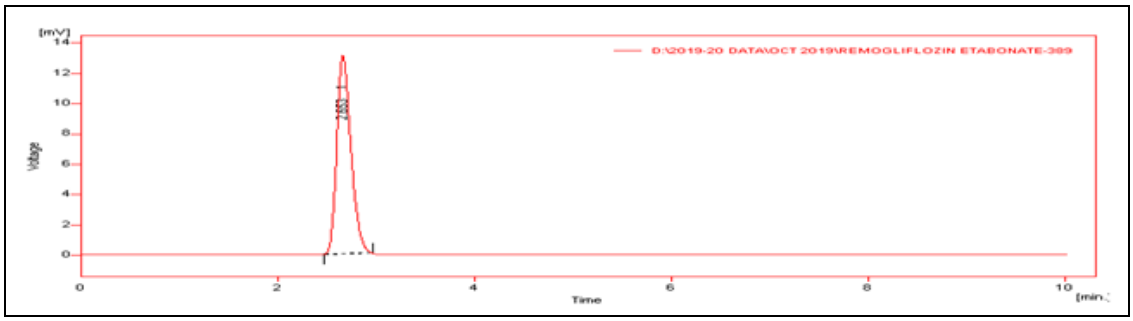

FIG. 15: PEAK ELUTED AT 48 h

TABLE 13: RESULTS FOR SOLUTION STABILITY AT 0 h, 24 h & 48 h FOR REMOGLIFLOZIN ETABONATE

	0 Hour			24 Hours		48 Hours	
Concentration (µg/ml)	Retention Time (min)	Peak Area (mV)	%Assay	Peak Area (mV)	%Assay	Peak Area (mV)	%Assay
50	2.6	147.134	99.90	147.152	99.91	149.474	101.42
50	2.6	147.247	99.97	146.242	99.29	146.242	99.22
50	2.6	146.634	99.56	148.190	100.61	148.770	100.92
50	2.6	148.776	101.01	148.770	101.01	147.152	99.82
50	2.6	145.369	98.70	149.474	101.49	145.534	98.72
50	2.6	148.449	100.79	145.534	98.81	148.190	100.52
		Mean	99.98	Mean	100.18	Mean	100.10
		S. D	0.841	S. D	1.03	S. D	1.03
		%RSD	0.841	%RSD	1.03	%RSD	1.03

Forced Degradation Studies: It was performed for Acid Degradation (0.1N HCl), Alkali Degradation (0.1N NaOH), Oxidative Degradation (3% H_2O_2), Thermolytic Degradation (60°C Heating) & Photolytic Degradation (sunlight).

Solutions Preparation:

0.1N HCl Preparation: 0.812 ml of HCl is taken into a 100ml volumetric flask, and volume it made up to the mark using distilled water.

0.1N NaOH Preparation: 0.4 gm of Sodium Hydroxide pellets are taken into a 100ml volumetric flask, and volume is made up to the mark using distilled water.

3% H_2O_2 Preparation: 3ml of H_2O_2 is pipetted out into a 100ml volumetric flask, and volume is made up to the mark using distilled water.

Procedure:

Acid Degradation Studies: From the stock solution (100µg/ml), pipette out 5ml and add into a 10ml volumetric flask, to it add 1ml of the prepared 0.1N HCl and then make up the volume up to the mark using Acetonitrile then kept for 60 mins and inject the prepared sample for six times and check the peak area at optimized conditions shown in **Fig. 16** and **Table 14**.

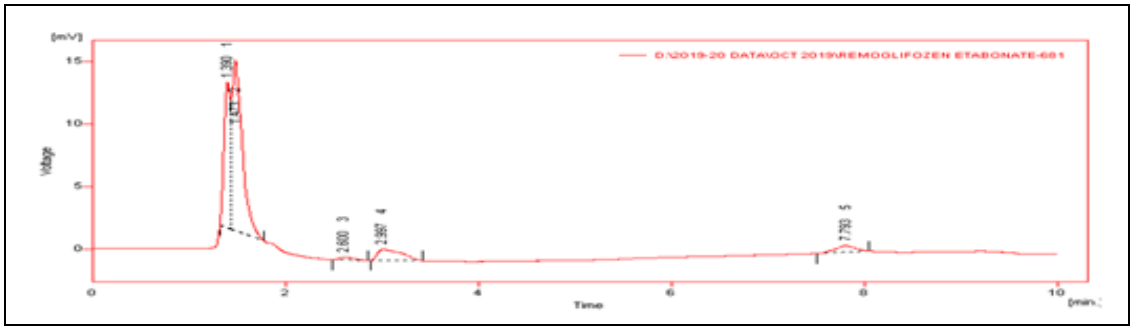

FIG. 16: PEAK ELUTED FOR ACID DEGRADATION

Alkali Degradation Studies: From the stock solution (100µg/ml) pipette out 5ml and add into a 10ml volumetric flask, to it add 1ml of the prepared 0.1N NaOH and then make up the volume up to the mark using Acetonitrile then kept for 60 min and inject the prepared sample for six times and check the peak area at optimized conditions shown in **Fig. 17** and **Table 14**.

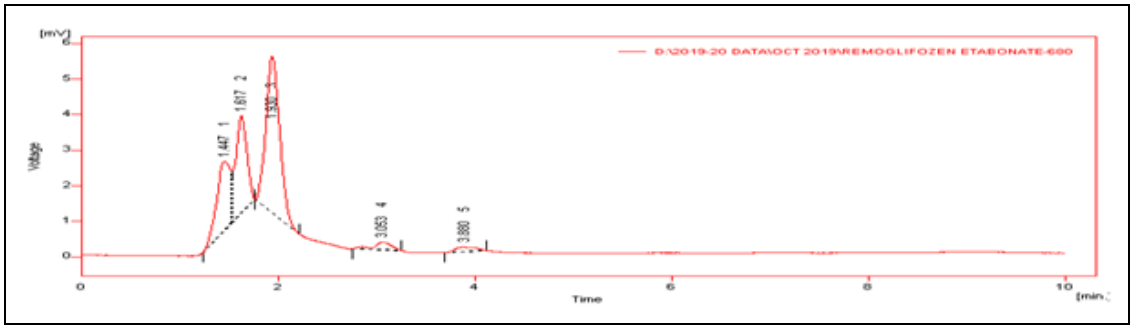

FIG. 17: PEAK ELUTED FOR ALKALI DEGRADATION

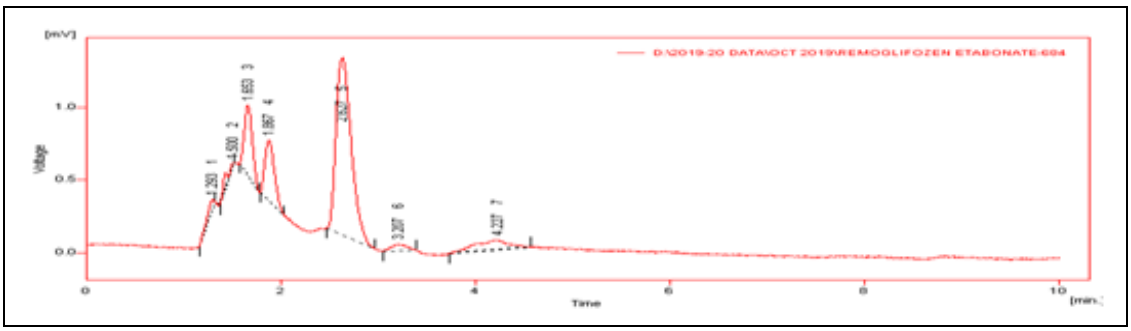

FIG 18: PEAK ELUTED FOR OXIDATIVE DEGRADATION

Oxidative Degradation Studies: From the stock solution (100µg/ml) pipette out 5ml and add into a 10ml volumetric flask, to it add 1ml of the prepared 3% H_2O_2 and then make up the volume up to the mark using Acetonitrile then kept for 60 min and inject the prepared sample for six times and check the peak area at optimized conditions shown in **Fig. 18** and **Table 14**.

Thermal Degradation Studies: From the stock solution (100µg/ml) pipette out 5ml and into a 10ml volumetric flask and then make up the volume up to the mark using Acetonitrile and kept the solution in Hot air oven at 60°C for 60 min and inject the sample for six times and check the peak area at optimized conditions shown in **Fig. 19** and **Table 14**.

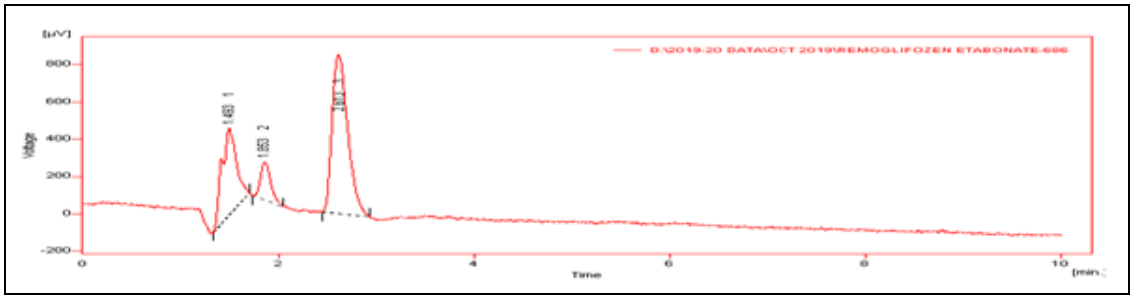

FIG. 19: PEAK ELUTED FOR THERMAL DEGRADATION

Photolytic Degradation Studies: From the stock solution (100µg/ml) pipette out 5ml and add into a 10ml volumetric flask and then make up the volume up to the mark using Acetonitrile and kept the solution in UV chamber for 60 min and then inject the sample for six times and check the peak area at optimized conditions shown in **Fig. 20** and **Table 14**.

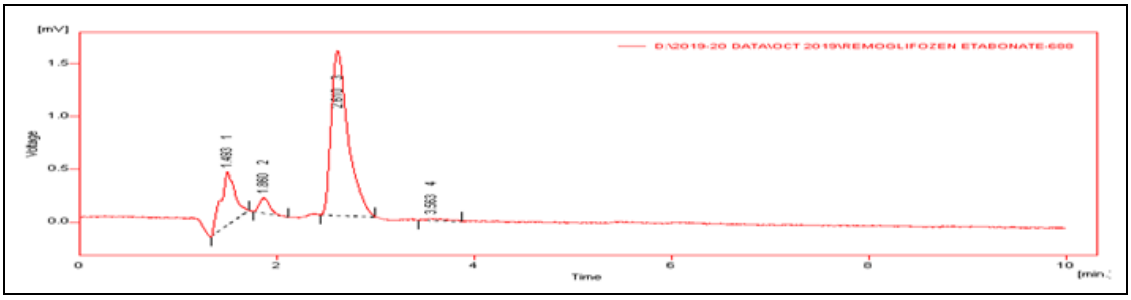

FIG. 20: PEAK ELUTED FOR PHOTOLYTIC DEGRADATION

TABLE 14: RESULTS FOR FORCED DEGRADATION STUDIES OF REMOGLIFLOZIN ETABONATE

Degradation parameter (n=3)	Concentration (µg/ml)	Peak Area (mV)	Average	%Degraded	%Recovered
Acid	50	51.02	51.38	65.06	34.94
	50	52.08			
	50	51.04			
Alkali	50	41.02	41.38	71.86	28.14
	50	42.04			
	50	41.08			
Peroxide	50	69.24	68.90	53.14	46.86
	50	68.16			
	50	69.32			
Thermal	50	145.01	145.52	1.03	98.97
	50	146.23			
	50	145.32			
Photolytic	50	146.34	146.52	0.35	99.65
	50	147.01			
	50	146.21			

From the above values, we can explain clearly that maximum degradation occurred in Alkali, Acid, and Peroxide. There was no degradation that occurred in Photolytic and Thermal.

CONCLUSION: From the obtained result, it was concluded that a simple, rapid, sensitive, linear, accurate, rugged, robust, and precise method was developed for the estimation of Remogliflozin

Etabonate by HPLC. Various validation parameters like Specificity, Linearity, Precision, LOD, LOQ, Accuracy, Solution Stability, and Forced Degradation Studies were carried out. The linearity was obtained in the concentration range of 25µg/ml - 150µg/ml with correlation factor (r^2) 0.999. The %RSD for all the parameters was found to within limits *i.e.,* less than 2%, and % recovery was also found to within limits *i.e.*, 98% - 102%. Hence, it was concluded that the projected method can be used for the determination of Remogliflozin Etabonate by Stability indicating and RP-HPLC method.

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