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ROBUST SIMPLE ANALYTICAL TECHNIQUE FOR DEVELOPMENT AND VALIDATION OF STABILITY INDICATING ASSAY METHOD FOR ESTIMATION OF TENELIGLIPTIN IN PHARMACEUTICAL DOSAGE FORM

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Keywords:

Teneliglitpin hydrobromide, HPLC, Degradation Study, Method Validation, Methanol, Acetonitrile

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ABSTRACT: As per the ICH guidelines and regulatory authorities' worldwide, it has become mandatory to establish a stability-indicating assay method (SIAM) for the drug substance (DS) and drug product (DP) to generate the stability data. It was undertaken to develop a precise, accurate, reliable, rapid, simple and specific method for estimating Teneligliptin free of interference from its probable degradation products. The present investigation has exploited the high-performance liquid chromatography (HPLC) technique. The retention time of Teneligliptin under optimized chromatographic conditions was found to be 5.71 ±0.02 min with a sharp, symmetrical peak (asymmetry of 0.66 ± 0.02). In the system suitability, the drug was found to adequately retain at 5.71 ±0.02 min with a sharp, symmetrical peak and high theoretical plate value of 4808, indicating high column efficiency. The solutions were observed to undergo hydrolysis in 0.1 N HCl and 0.1 N NaOH at room temperature and reflux. Teneligliptin was also found to be susceptible to rapid oxidation. Photolytic stress study indicates that drug in solid-state upon exposure to sunlight for 12 days up to 48%. Thermal stress conditions do not degrade the drug upon exposure to 100 ˚C for 15 days. This indicates that Teneligliptin is quite stable in thermal stress conditions. The standard and sample solutions of the drug have reasonably good stability over a period of about 24 h. The results of the assay of the Tenglyn tablet obtained by the proposed HPLC method are quite concurrent and reproducible. The recovery rate of the drug was 100% which indicates accuracy and reproducibility.

INTRODUCTION: The active pharmaceutical ingredients (API) in the formulation, processing and storage may expose to a variety of environmental conditions like heat, humidity, light, *etc*. and may undergo degradation.

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This would contaminate the product with its degradation products, thus adversely affecting the therapeutic efficacy and safety of drug products (DP).

Therefore, the stability studies of API and its formulation are an utmost important aspect of formulation development to minimize its degradation and establish appropriate storage conditions [1]. The ICH guidelines explicitly require forced decomposition studies under various conditions like extreme pH, light, oxidation, dry

heat, *etc*., and separation of drug from degradation products. Many such SIAM is reported for single-ingredient drug products; however, most of them fall short of meeting the current regulatory requirements [2].

Teneligliptin Hydrobromide ($C_{22}H_{30}N_6OS$) is {(2S, 4S)-4-[4-(3-Methyl-1-phenyl-1H-pyrazol-5-yl)-1piperazinyl] 2-pyrrolidinyl} (1, 3-thiazolidin-3-yl) methanone. Teneligliptin is an active drug for the treatment of type 2 diabetes mellitus. It belongs to the class known as dipeptidyl peptidase-4 inhibitors or gliptins. Teneligliptin has a unique J-shaped or anchor locked domain structure because of which it has a potent inhibition of DPP 4 enzyme [3-5]. Teneligliptin significantly controls glycemic parameters with safety.

MATERIALS AND METHODS: Teneligliptin hydrobromide was obtained as a gift sample from Glenmark Pvt. Ltd. (Nashik, India), Methanol, and Acetonitrile were procured from Loba Chem, Mumbai, All other chemicals and reagents used were of analytical grade.

Methods:

Chromatographic Conditions: Different solvents and buffers of different pH were tried by permutation and combination to obtain adequate drug retention.

Finally, a mixture of 10 mM ammonium acetate buffer (adjusted to pH 4.0 with glacial acetic acid), and methanol in the ratio of 52:48 v/v was found to yield a satisfactory retention time of Teneligliptin at 5.7 min, with sharp, symmetrical peak and well resolved from all the degradation products [6].

The column used was Kromasil 100-5CI8 Column [(150 x 4.6) mm i.d., 5 µm] with mobile phase 10 mM ammonium acetate buffer (adjusted to pH 4.0 with glacial acetic acid) and methanol in the ratio of 52:48: v/v.

Force Degradation study of Teneligliptin (API) [7-10]:

Acid Hydrolysis: Teneligliptin (50.0 mg) was dissolved in an adequate amount of methanol in 50 ml volumetric flask, the remaining volume was made up to the mark with aqueous HC1 so as to give 0.1 N HC1 (concentration 1.0 mg/m1). From this, 25 ml solution was refluxed in a round bottom flask on an electric water bath for 4 h and 25 ml solution was kept at room temperature for 8 h.

Base Hydrolysis: Teneligliptin (50.0 mg) was dissolved in an adequate amount of methanol in 50 ml volumetric flask, the remaining volume was make up to the mark with aqueous NaOH so as to give 0.1 N NaOH (concentration1.0 mg/ml). From this, 25 ml solution was kept in a round bottom flask on an electric water bath at 50°C for 5 h and 25 ml solution was kept at room temperature for 5 h. In the case of acid and base hydrolysis, samples were neutralized appropriately prior to dilution.

Neutral hydrolysis: Teneligliptin (50.0 mg) was dissolved in adequate amount of methanol in 50 ml volumetric flask and diluted appropriately with water (conc. 1.0 mg/m1). From this, 25 ml solution was refluxed in a round bottom flask on an electric water bath for 8 h, and 25 ml solution was kept at room temperature for 8 h.

Oxidative Degradation: Teneligliptin (50.0 mg) was dissolved in adequate amount of methanol in 50 ml volumetric flask, the remaining volume was made up to the mark with H_2O_2 solution to form 3% H_2O_2 (concentration 1.0 mg/ml), and it was kept at room temperature in a dark place for 24 h. The entire above-stress sample was diluted appropriately with mobile phase to give 50µg/m1 concentration.

Thermal degradation: A sufficient quantity of Teneligliptin (about 100mg) was uniformly spread in a covered petri-dish and kept in an oven at 70°C for different time intervals. Ten mg sample was withdrawn periodically on 1, 3, 7 and 15day.

Photo Degradation: A sufficient quantity of Teneligliptin (about 100mg) was uniformly spread in a covered petri -dish and kept in sunlight. Ten mg sample was withdrawn periodically. In the case of thermal and photodegradation, samples were dissolved and diluted appropriately with methanol (concentration 1mg/ml).

Further dilution was made with the mobile phase (concentration 50µg/ml). A mixed stress sample of Teneligliptin was made by mixing 25ml of each acidic, alkaline, oxidative, and photo stressed sample having a 100µg/ml concentration of Teneligliptin. Finally, the prepared stressed

samples and a mixed sample of Teneligliptin were analyzed in HPLC under optimized chromatographic conditions, and chromatograms were recorded.

Validation of Proposed Method [11-14]:

System Suitability test Parameters: For system suitability test parameters, six replicate injections of working standard solution of Teneligliptin (50 µg/ml) were injected and analyzed under optimized chromatographic conditions.

Linearity: One ml of a standard solution of Teneligliptin was transferred in a 10.0 ml volumetric flask, and the volume was made up to the mark with the mobile phase to give 100 µg/ml concentration of Teneligliptin. Eight aliquot portions of this solution (0.2, 0.5, 1, 2, 4, 6, 8, and10 m1) were further diluted separately to 10.0 ml with mobile phase to give a concentration of 2-40 µg/ml. All the solutions were analyzed using the standard chromatographic condition, and the responses were measured as peak areas. The calibration curve was obtained by plotting peak area vs. concentration.

Precision: The standard working solution of Teneligliptin (50 µg/ml concentration) was used for the comparison with sample solutions by the area normalization method. An accurately weighed six quantities of tablet powder equivalent to 10 mg of Teneligliptin was transferred to different 10 ml volumetric flasks and dissolved in an adequate quantity of methanol using ultrasonication for 20 minutes. The solutions were filtered through Millipore Nylon filter (0.45µ). The volume of each flask was adjusted to 10.0 ml with methanol. The solutions were further diluted appropriately with mobile phase to obtain a 50 µg/ml concentration of Teneligliptin. The solutions were analyzed using the optimized chromatographic conditions.

Accuracy: To ascertain the accuracy of the proposed methods, a recovery study was carried out by standard addition method at 80%, 100%, and 120% of the test concentration. Accurately weighed quantity of pre-analyzed tablet powder equivalent to about 5 mg of Teneligliptin (10% of label claim) was transferred individually to nine different 25.0 ml volumetric flasks. To each flask, standard Teneligliptin (in solution form) was added at 30%, 50%, and 70% levels in triplicate so as obtain a concentration range of 80-120% of the label claim. The contents were dissolved in adequate amount of methanol using ultrasonication for 20 minutes. All these solutions were filtered through a Millipore Nylon filter (0.45µ), and the volume was made up to the mark with methanol. Each filtrate was diluted to 10.0 ml with the mobile phase. Five ml of this solution was further diluted to 10.0 ml with the mobile phase. The solutions were filtered and analyzed using the optimized chromatographic conditions.

Robustness: The robustness method was studied by varying the chromatographic condition by making a small, deliberate change in the detection wavelength by ±2 nm and change in flow rate by 0.1ml/min, and the result was recorded.

Ruggedness: The study of ruggedness conditions was ascertained based on three different conditions as follows:

Inter-day Study: The study was performed by replicating the same sample of tablet formulation on three different days by the proposed method.

Intra-day Study: The study was performed by replicating the same sample of tablet formulation on the same day at three different intervals by the proposed method.

Different Analysts [15-18]: The study was performed by replicating the same sample of tablet formulation by three different analysts by the proposed method. The forced degradation study was performed on Teneligliptin (API) and tablet formulation to determine whether any observed degradation occurred because of drug properties or was due to drug-excipients interactions.

Teneligliptin's working standard solution was freshly prepared (50µg/ml concentration) and used for comparison of results by peak area normalization method. Accurately weighed quantity of tablet powdered equivalent to about 10 mg Teneligliptin were transferred to six different 10.0 ml volumetric flasks. The samples were then exposed to stress conditions similarly to API's case. The solutions were then analyzed similarly to the underestimation of Teneligliptin in tablets.

RESULTS AND DISCUSSION:

Forced Degradation (Stress) Study of Teneligliptin: The solutions were observed to undergo hydrolysis in 0.1 N HCl and 0.1 N NaOH at room temperature and reflux. The requisite degradation (about 20 %) was observed after the drug solution was refluxed in an electric water bath for about 4 h under acidic hydrolytic stress conditions. In the case of basic hydrolysis, the degradation is rapid as the drug was found to degrade up to 35 % after exposure to 0.1 N NaOH at room temperature in 24 h. Degradation product formed under both the conditions are same as it was eluted at a same retention time of 3.703 min. This indicates that the degradation product formed in acidic and basic hydrolysis is the same. Neutral hydrolysis, even after reflux, does not show any drug degradation. Teneligliptin was also susceptible to rapid oxidation as exposure of drug to 3% H2O2 at room temperature for 5 h. lead to 40% degradation with the formation of two degradation product eluated at 2.928 4.870 min. Photolytic stress study indicates that drug in solid-state upon exposure to sunlight for 12 days (approx. 1.0×10^5 Lux h.) had been degraded to 48% with four degradation products evaluated at 2.604, 3.219, 5.016, and 11.360 min. Thermal stress conditions do not degrade the drug upon exposure to 100 ˚C for 15 days. This indicates that Teneligliptin is quite stable in thermal stress conditions.

TABLE 1: SUMMARY OF FORCED DEGRADATION STUDIED

Sample and condition of exposure	Retention time of degradation product (min.)	% Estimation
Neutral (Refluxed for 8 h)	No degradation	99.89
0.1 N NaOH (At room temp. 24 h)	3.70	63.39
0.1 N HCl (Refluxed for 4 h)	2.97, 3.69	80.12
Sunlight (12 days)	2.604, 3.219, 5.016, 11.306	52.70
Thermal (At 100°C for 15 days)	No degradation	97.92
3% H_2O_2 (At room temp for 5 h)	2.928, 4.970	69.31

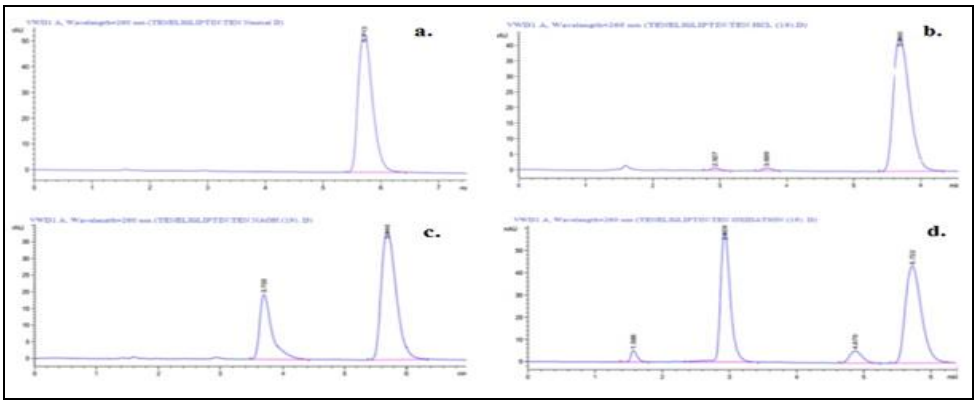

FIG. 1: A) HPLC CHROMATOGRAM OF STRESS SAMPLE OF TENELIGLIPTIN B) NEUTRAL (REFLUX 8 H) AND 0.1 N HCL (REFLUX 4 H). C) HPLC CHROMATOGRAM OF STRESS SAMPLE OF TENELIGLIPTIN C) 0.1 N NAOH (AT ROOM TEMP 24 H) AND D) 3% H_2O_2 (AT ROOM TEMP FOR 5 H)

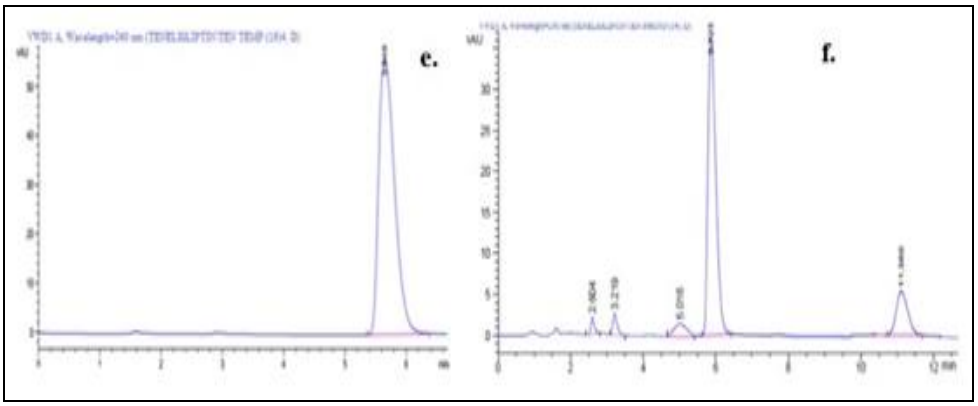

FIG. 2: E) HPLC CHROMATOGRAM OF STRESS SAMPLE OF TENELIGLIPTIN F) THERMAL (AT 100°C FOR 15 DAYS) AND SUNLIGHT (12 DAYS)

Development of Validated Stability Indicating RP-HPLC Method for Estimation of Teneligliptin:

System Suitability Test Parameters: For system suitability test parameters, six replicate injections of working standard solution of Teneligliptin (50 µg/ml) were injected and analyzed under optimized chromatographic conditions.

TABLE 2: SYSTEM SUITABILITY TEST OF PARAMETERS OF TENELIGLIPTIN

S. no.	Retention Time (min.)	Capacity Factor (k')	Symmetry	Area	No. of Plates
1	5.70	2.81	0.67	1050.50	4811
2	5.71	2.79	0.68	1054.11	4822
3	5.75	2.82	0.66	1048.12	4780
4	5.69	2.80	0.67	1055.90	4813
5	5.72	2.77	0.61	1056.81	4815
6	5.70	2.89	0.68	1050.82	4810
Mean	5.71	2.81	0.66	1052.46	4808.52
±SD	0.021	0.04	0.02	3.10	14.59
%RSD	0.35	1.42	3.93	0.295	0.303

HPLC Method Development: The chromatographic separation of Teneligliptin and its degradation products was done on Kromacil 100-5 C18 column (150 × 4.6mm, i.d. 5um). Several mobile phase compositions were tried to resolve the peaks of Teneligliptin and their degradation products. Out of these combinations, the mobile phase containing 10 mM Ammonium acetate buffer (pH 4 adjusted with glacial acetic acid) and methanol (52:48 v/v) was found to be most satisfactory as it gave good resolution of drug and degradation products with reasonably aligned sharp peaks. Therefore, this mobile phase was selected throughout the analytical studies. A detection wavelength of 260 nm was optimized as Teneligliptin has substantially high absorbance. A flow rate of 1.0 ml/min at ambient (25 °C) temp was found to be optimum. The retention time of Teneligliptin under optimized chromatographic conditions was 5.71 ±0.02 min with a sharp symmetrical peak (asymmetry of 0.66 ± 0.02). The capacity factor was 2.81 ±0.04 with mean theoretical plates 4808. The degradation studies on Teneligliptin have established that the drug degrades under acidic, alkaline, oxidative stress, and under sunlight (in solid form). However, no degradation was observed under neutral hydrolysis and thermal stress conditions.

TABLE 3: SUMMARY OF RESULT OF ESTIMATION OF TENELIGLIPTIN IN TABLET

Statistical parameters	% estimation (n=6)
Mean	98.19
± SD	0.70
% RSD	0.71

Validation of Proposed HPLC Method: The proposed HPLC method was validated for system suitability, linearity, and range, precision, accuracy, robustness, ruggedness, and specificity.

System Suitability: System suitability is a pharmacopoeial requirement and is used to verify whether the resolution and reproducibility of the chromatographic system are adequate for analysis to be done. The tests were performed by collecting data from six replicate injections of standard solutions. The drug was adequately retained at 5.71 ±0.02 min with a sharp symmetrical peak and a high theoretical plate value of 4808, indicating high column efficiency.

Linearity of Method: A graph plotted as detector responses as a function of the concentration range for Teneligliptin 2-100 µg/ml.

This has indicated the method's capability to estimate the drug accurately over a wide range.

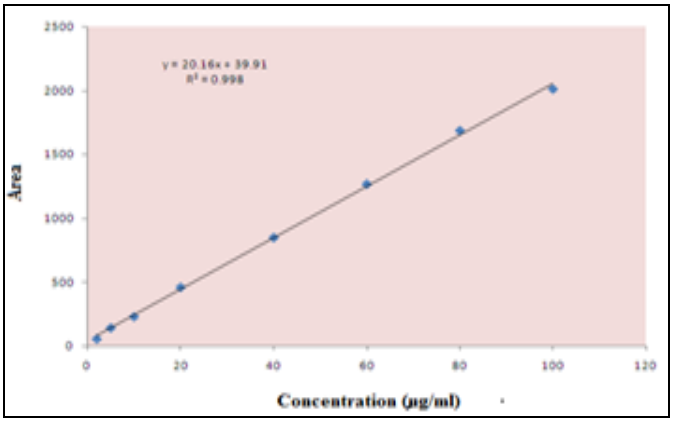

FIG. 3: STUDY OF LINEARITY OF TENELIGLIPTIN

TABLE 4: SUMMARY OF RESULTS OF LINEARITY STUDY

Concentration Range	2-100 µg/ml
Equation for straight line	Y = 20.16x – 39.91
Correlation Coefficient	0.998
Slope	20.16
Y - Intercept	39.91

Precision: Six replicate estimations of Teneligliptin in tablet by proposed HPLC method have yielded quite concurrent results which speak about repeatability of proposed HPLC methods.

Accuracy: Accuracy was ascertained by carrying out recovery studies on marketed formulations with a standard addition method over 80 to 120 % of the labeled Claim.

Recoveries of the drug were observed to be very close to 100% representing the method's accuracy and noninterference of excipients.

TABLE 5: RESULTS OF RECOVERY STUDY

% Label Claim	Wt. of Tablet Powder (mg)	Wt. of pure drug Added (mg)	Peak Area	Amt. of Drug Estimated (mg)	Amt. of Drug Recovered (mg)	% drug Recovered
	31.65	3.0	840	8.0	3.0	100.00
80%	31.5	3.0	838	7.92	2.98	99.33
	31.6	3.0	832	7.92	2.92	97.40
	31.60	5.0	1049	9.99	4.99	99.80
100%	31.4	5.0	1040	9.90	4.9	98.00
	31.65	5.0	1042	9.92	4.92	98.40
	31.60	7.0	1269	12.08	7.08	101.10
120%	31.5	7.0	1248	11.88	6.88	98.28
	31.6	7.0	1250	11.90	6.9	98.50
					Mean	99.97
					±SD	1.164
					% RSD	1.17

Robustness: The method's robustness was ascertained by a deliberate change in the chromatographic parameters like change in wavelength by ±2 nm and change in flow rate by 0.1 ml/min. There was no significant difference in results obtained by a change in detection wavelength by ±2 nm, change in flow rate by ± 0.1 ml/min. and change in buffer ±2%. This indicates that the method is robust with respect to changes in wavelength, flow rate, and buffer composition.

TABLE 6: ROBUSTNESS STUDY FOR TENELIGLIPTIN

S. no.	Change in Wavelength (±2 nm)	% Estimation	Change in Flow rate (± 0.1 ml/ min)	% Estimation	Change in buffer	% Estimation
1	1048	99.80%	1038	98.85%	1039	98.95%
2	1044	99.42%	1033	98.38%	1049	99.90%
3	1043	99.33%	1041	99.14%	1038	98.85%
	Mean	99.51	Mean	98.79	Mean	99.23
	±SD	0.24	±SD	0.31	±SD	0.47
	% RSD	0.24	% RSD	0.31	% RSD	0.47

Ruggedness: Ruggedness of the proposed method was ascertained by analyzing sample on same day at three different intervals, on different days and by three different analysts using similar operational and environmental conditions. The result of estimation of sample on intraday, inter day and by different analyst were very much reproducible with maximum % RSD of the order of 0.62 .This indicates the ruggedness of the method in the hands of a different expert analyst and at different time intervals.

TABLE 7: RUGGEDNESS STUDY FOR TENELIGLIPTIN

S. no.	% Drug Estimation		
	Intra day	Inter day	Different analyst
1	99.70	98.99	100.08
2	98.91	99.12	98.98
3	100.12	99.90	99.01
Mean	99.57	99.33	99.35
±SD	0.61	0.49	0.62
% R.S.D.	0.61	0.49	0.62

Specificity: These studies were carried out to ascertain how accurately and specifically, the analyte of interest is estimated in the presence of other components (*e.g.*, impurities, degradation products. and excipients) by exposing the tablet powder samples to different stress conditions such as acids, alkali, oxidation, heat and light and then analyzing them by the proposed method.

TABLE 8: RESULTS OF SPECIFICITY STUDY OF TENELIGLIPTIN

Sample and condition of exposure	% Labeled Claim
Neutral (Refluxed for 8 h)	100.33
0.1 N NaOH (At room temp 24 h)	64.90
0.1 N HCl (Refluxed for 4 h)	81.65
Sunlight (12 days)	50.73
Thermal (At 100℃ for 15 days)	96.90
3% H_2O_2 (At room temp for 5 h)	61.89

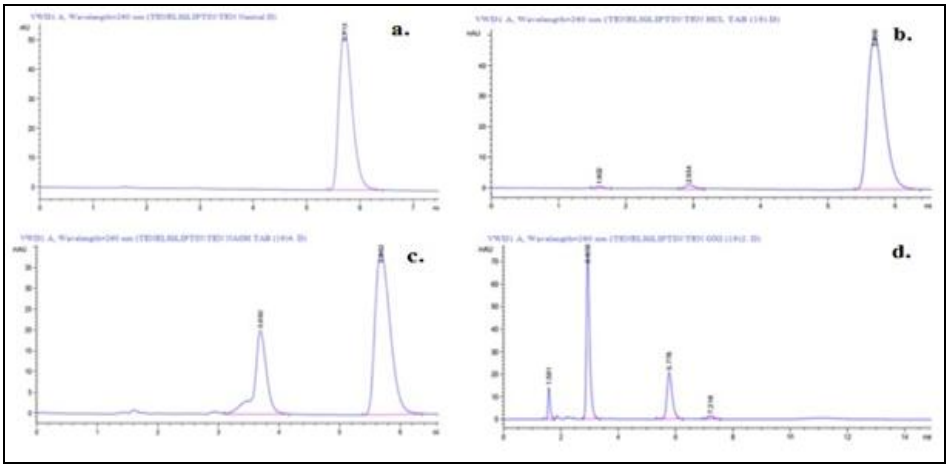

FIG. 4: A) HPLC CHROMATOGRAM OF STRESS SAMPLE OF TENELIGLIPTIN B) NEUTRAL (REFLUX 8 H) AND 0.1 N HCL (REFLUX 4 H) C) 0.1 N NAOH (AT ROOM TEMP 24 H) AND D) 3% H_2O_2 (AT ROOM TEMP FOR 5 H)

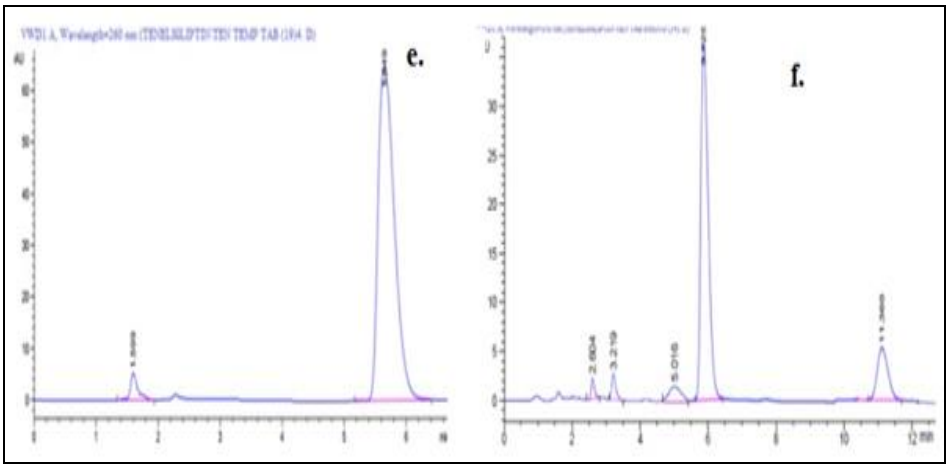

FIG. 5: HPLC CHROMATOGRAM OF STRESS SAMPLE OF TENELIGLIPTIN E) THERMAL (AT 100℃ FOR 15 DAYS) AND F) SUNLIGHT (12 DAYS)

CONCLUSION: In the present project, stability indicating the RP-HPLC method was developed and validated to estimate Teneligliptin in tablet formulation. The force degradation study carried out on drugs showed significant degradation products generated under the various exposure conditions. All the degradation products are well resolved from the parent drug under the optimized chromatographic conditions. Moreover, the method is, in a true sense, can be said to be a specific stability-indicating assay method for Teneligliptin due to its capability to estimate the drug content unequivocally free of interference from its degradation products. The validation of method indicates that the method is simple, precise, accurate, rugged and reasonably specific for the estimation of Teneligliptin in pharmaceutical formulations. The proposed RP-HPLC method can be adopted for estimation of Teneligliptin in routing quality control in the pharmaceutical industries.

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CONFLICTS OF INTEREST: The authors declare that there is no conflict of interest

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