IJPSR (2019), Volume 10, Issue 4 **(Research Article)**

INTERNATIONAL JOURNAL OF PHARMACEUTICAL SCIENCES AND RESEARCH

Received on 28 July 2018; received in revised form, 03 October 2018; accepted, 19 November 2018; published 01 April 2019

SIMULTANEOUS ESTIMATION AND ANALYTICAL METHOD DEVELOPMENT, VALIDATION FOR THE TENELIGLIPTIN AND METFORMIN BY RP-UFLC

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Keywords:

RP-UFLC, Teneligliptin, Metformin, ICH guidelines

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ABSTRACT: The study aims to develop an analytical method for the simultaneous estimation of Teneligliptin and Metformin using RP-UFLC. A simple, sensitive and accurate method was developed for Teneligliptin and Metformin using the chromatographic conditions of C18 Phenomenex Kinetex (250 mm × 4.6 mm *i.e.*, 5 µm particle size) column in gradient elution mode with the mobile phase consisting of methanol, acetonitrile and potassium dihydrogen orthophosphate adjusted to pH 4.6 using orthophosphoric acid (40:20:40) with a flow rate of 1.0 mL/min, injection volume 10 µl and the eluent was detected at 250 nm using PDA and UV detector. The retention time of Teneligliptin and Metformin were found to be 5.2 min and 2.5 min respectively. The above method was validated concerning system suitability, linearity, precision, limit of detection (LOD) and limit of quantification (LOQ), accuracy (recovery) and robustness according to ICH guidelines. The linearity of the above methods was found to be 2-10 µg/mL for Teneligliptin and 25-125 µg/mL for Metformin. Hence, these methods can be used for routine analysis in quality control laboratories.

INTRODUCTION: Analytical chemistry is the science [1, 2] of obtaining, processing and communicating information about the composition and structure of matter. It deals with the separation of materials into their components and identifying each one and how much there is of each one. Pharmaceutical analytical chemistry [3] is defined as the branch of practical chemistry which deals with the resolution, separation, identification, determination, and purification of a given sample of a medicine or a pharmaceutical, the detection and estimation of impurities that may be present therein is also included.

QUICK RESPONSE CODE

DOI: 10.13040/IJPSR.0975-8232.10(4).1811-19

The article can be accessed online on www.ijpsr.com

DOI link: http://dx.doi.org/10.13040/IJPSR.0975-8232.10(4).1811-19

The use of analytical sciences in the discovery, development, and manufacture of pharmaceuticals is wide-ranging. From the analysis of minute amounts of complex biological materials to the quality control of the final dosage form, the use of analytical technology covers an immense range of techniques and disciplines.

Gliptins are ordinarily known as DPP-IV inhibitors have turned out to be a new class of potential medication applicant and are being sought as a lasting eraser after sort 2 diabetes. Consequently, gliptins have been a focal point of innovative work. Teneligliptin hydrobromide is a dipeptidyl peptidase 4 inhibitors is an uncommonly persuading in chopping down blood glucose levels. Teneligliptin hydrobromide hydrate is a very strong, focused, and durable DPP-4 inhibitor (1, 2, 3, and 4). Glucagon-like peptidase (GLP-1) a peptidase discharged from the GIT because of sustenance consumption upgrades insulin emission

and stifles glucagon emission from the pancreas, consequently assuming a critical part in controlling postprandial blood glucose level. The peptide is quickly inactivated by debasement by DPP-4 inhibitor; a chemical generally conveyed in the body. DPP-4 inhibitor debasement, expanding the centralization of dynamic GLP-1 in the blood, which fortifies glucose subordinate insulin discharge and in the meantime, smothers glucagon emission, subsequently displaying glucose bringing down impact. It is successfully used to treat type 2 diabetes mellitus.

The most typically detailed unfavorable responses incorporate hypoglycemia, clogging, and feeling of the developed stomach area, stomach distress, sickness, stomach torment, meteorism, stomatitis, skin irritation, rash, pruritus, dermatitis, and disquietude. Composing study reveals RP-UFLC techniques have been represented the assessment of Teneligliptin hydrobromide pure and tablet dosage forms [4, 5, 6, 7].

Teneligliptin:

Class: Anti-diabetic drugs known as dipeptidyl peptidase-4 inhibitors gliptins.

Chemical (IUPAC) Name: [(2S, 4S) -4 -[4-(5-methyl -2 –phenylpyrazol -3 -yl) piperazin-1-yl] pyrrolidin-2-yl]-(1, 3-thiazolidin-3-yl) methanone.

Physical State: White to off-white powder

Chemical Formula: $C_{22}H_{30}N_6OS$

Chemical Structure:

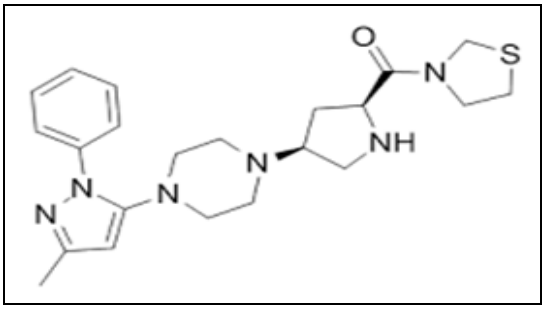

FIG. 1: CHEMICAL STRUCTURE OF TENELIGLIPTIN

Molecular Mass: 426.6 g/mol

Melting Point: 211ºC

pKa: 8.7

Solubility: Soluble in water, DMSO and methanol

Brand Name: Tenepride 20 mg

Applications: Used in the treatment of type 2 diabetes mellitus.

Metformin hydrochloride is 1, 1-Dimethyl-biguanide hydrochloride [1] and is used in the treatment of diabetes mellitus. It is completely different from the hypoglycemic sulfonamides [2] both in its structure and its mode of action. It possibly interferes with mitochondrial respiratory chains and promotes peripheral glucose utilization by enhancing anaerobic glycolysis, or it enhances the binding of insulin to its receptors and potentiates its action. Another explanation is that it suppresses hepatic gluconeogenesis and inhibits intestinal absorption of glucose. It causes little or no hypoglycemia in non-diabetic patients.

Metformin:

Class: Metformin is a biguanides anti-hyperglycemic agent.

Chemical (IUPAC) Name: 1-carbamimidamido-N, N-dimethylmethanimidamide.

Physical State: white crystalline powder.

Chemical Formula: $C_4H_{11}N_5$

Chemical Structure:

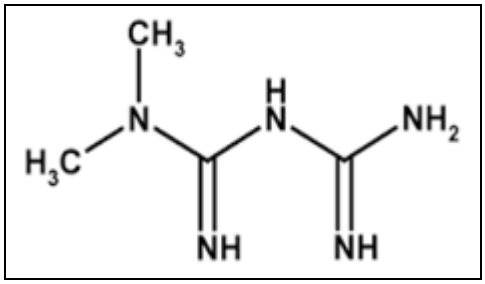

FIG. 2: CHEMICAL STRUCTURE OF METFORMIN

Molecular Mass: 129.16 g/mol

Melting Point: 223-226 ºC

pKa: 12.4

Solubility: Freely soluble in water, methanol.

Brand name: Exermet 500 mg

Application: First-line medication for the treatment of type 2 diabetes

There is no Pharmacopoeia method for simultaneous analysis of Trelagliptin and Metformin. A literature review revealed that chromatographic methods for determination of

Trelagliptin and Metformin alone or in a combination of others are available. Literature search also revealed LC methods for simultaneous determination of Trelagliptin and Metformin in bulk forms with different mobile phase composition and using wavelength programming technique [9]. The objective of the present study is to develop a simple, accurate, precise and selective reverse phase UFLC method for simultaneous determination of Trelagliptin and Metformin from bulk forms available in the market [8, 9, 10, 11, 12].

Preparation of Mobile Phase: To a 1000 ml volumetric flask, add 1.36 g of potassium dihydrogen orthophosphate was taken and diluted with Millipore water and made up to the mark, and the pH was adjusted to 4.6 using orthophosphoric acid. The solution was then filtered through a 0.45µ membrane filter.

Preparation of Diluent: The diluent is a mixture of 50 parts of methanol and 50 parts of acetonitrile mixed thoroughly.

Preparation of Standard Stock Solution for Teneligliptin: 100 mg of Teneligliptin was taken into 100 ml volumetric flask. To this add 50 ml of diluent and sonicate to dissolve and the volume was made up to the mark with diluent (1000 µg/mL). Pipette 1 ml of the above solution into 10 ml volumetric flask and make up the volume using diluent (100 µg/mL).

Preparation of Solutions for Linearity: The solutions for linearity were prepared from the stock solution by diluting with diluent. The concentration ranging from 2, 4, 6, 8, 10 µg/mL were prepared for Teneligliptin. Pipette 0.2, 0.4, 0.6, 0.8, 1.0 ml in 10 ml volumetric flasks and make up the volume using diluent to get the above concentrations.

Preparation of Standard Stock Solution for Metformin: 100 mg of Metformin was taken into 100 ml volumetric flask. To this add 50 ml of diluent and sonicate to dissolve and the volume was made up to the mark with diluent (1000 µg/mL).

Preparation of Solutions for Linearity: The solutions for linearity were prepared from the stock solution by diluting with diluent. The concentration ranging from 25, 50, 75, 100, 125 µg/mL were prepared for Metformin. Pipette 0.25, 0.50, 0.75, 1.0, and 1.25 in 10 ml volumetric flasks and make up the volume using diluent to get the above concentrations.

Chromatographic Conditions:

TABLE 1: CHROMATOGRAPHIC CONDITIONS FOR TENELIGLIPTIN AND METFORMIN

S. no.	Chromatographic Conditions	
1	Column	Phenomenex Kinetex C18 (250 × 4.6 mm)
2	Flow Rate	1.0 mL/min
3	Wavelength	250 nm
4	Detector	UV detector
5	Injection volume	10 µl
6	Mobile phase	Methanol, acetonitrile, and potassium dihydrogen orthophosphate (40:20:40)
7	pH	4.6
8	Run time	10 min

Method Validation:

Linearity and Range: The linearity of an analytical method is its ability to elicit test results that are directly, or by a well-defined mathematical transformation, proportional to the concentration of an analyte in samples within a given range.

Procedure: 2-10 µg/mL for Teneligliptin and 25-125 µg/ml for Metformin was prepared. The regression line obtained was linear. From the data obtained, co-relation coefficient, slope, and Y-intercept were calculated. Ideally co-relation coefficient should be not less than 0.99 and statistical Y- should be not more than 2.0.

Accuracy: Accuracy is performed in three different levels for Teneligliptin and Metformin using standard addition method at 50%, 100%, and 150%. A known quantity of sample was spiked to the standards. Samples are analyzed in triplicate for each level. From the results, % recovery was calculated. % Recovery at each spike level shall be not less than 98.0 % and not more than 102.0%, % RSD for the duplicate observations shall be not more than 2.0. Overall % RSD for the % Recovery shall be not more than 2.0.

$$\% \text{ Recovery} = \frac{\text{Amount of drug recovered}}{\text{Amount of drug added}} \times 100$$

Procedure:

Accuracy at 50%: A known amount of standard drug solution of Teneligliptin and Metformin (25µg/mL) from the stock solution was added to

the sample solution of a determined concentration (50 µg/mL) the solutions were taken in a 10 ml volumetric flask and the volume was made up with diluent and filtered through 0.2 µ syringe filter. The solutions were injected, analyzed and the recovery was calculated.

Accuracy at 100%: A known amount of standard drug solution of Teneligliptin and Metformin (50µg/mL) from the stock solution was added to the sample solution of a determined concentration (50µg/mL). The solutions were taken in a 10 mL volumetric flask, and the volume was made up with diluent and filtered through a 0.2 µ syringe filter. The solutions were injected, analyzed and the recovery was calculated.

Accuracy at 150%: A known amount of standard drug solution of Teneligliptin and Metformin (75 µg/mL) from the stock solution was added to the sample solution of a determined concentration (50 µg/mL) the solutions were taken in a 10 ml volumetric flask and the volume was made up with diluent and filtered through 0.2 µ syringe filter. The solutions were injected, analyzed and the recovery was calculated.

Precision:

System Precision: The system precision is checked by injecting 6 sample injections and checking the reproducibility in the retention time and area. The % RSD calculated must be less than 2%.

Method Precision:

Intraday Precision: The intraday precision is checked by using standard Teneligliptin and Metformin samples to ensure that the analytical system is precise. The retention time and area of three determinations was measured, and RSD was calculated. % RSD of the assay value for three determinations shall not be more than 2.0%.

Interday Precision: The interday precision is checked by using the same standard Teneligliptin and Metformin samples analyzed for intraday precision on an alternate day to ensure that the analytical system is precise.

The retention time and area of three determinations was measured, and RSD was calculated. % RSD of the assay value for three determinations shall not be more than 2.0%.

Limit of Detection (LOD) and Limit of Quantification (LOQ): LOD and LOQ were calculated using the mathematical equations:

$$LOD = 3.3\ \sigma/S$$

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

$$LOQ = 10\ \sigma/S$$

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

Robustness: The robustness of an analytical method is a measure of its capacity to remain unaffected by small but deliberate variations in method parameters and provides an indication of its reliability during normal usage.

Procedure: Robustness was done by changing the flow rate (± 0.1 ml), and mobile phase ratio (± 2) and pH (± 0.1). All the system suitability parameters must meet as per the method. The flow rate of the mobile phase was increased to 1.1mL/min and decreased to 0.9 mL/min from 1.0mL/min. The final variation was done by changing the mobile phase (methanol: acetonitrile: potassium dihydrogen orthophosphate) ratio to 38: 18: 44 and 42: 22: 36 from 40: 20: 40. The pH was changed to 4.5 and 4.7 from 4.6.

System Suitability: Five replicate injections of standard solutions were injected, and the chromatograms were recorded. The system is suitable for analysis if

- The theoretical plates in five replicate injections should be not less than in 2000.
- USP tailing factor for Teneligliptin and Metformin peaks should be not more than 2.0.
- The % relative standard deviation for five replicate injections should not be more than 2%.

Procedure: The standard solution (10 µg/mL) was prepared and injected into the UFLC system six times. The tailing factor and theoretical plate count were recorded.

Assay of Marketed Formulation:

Sample Preparation: In case of marketed formulations, twenty tablets were taken, weighed, finely powdered and an accurate amount equivalent

to 100 mg of drug powder was transferred into a 100 ml volumetric flask. The stock solution was further diluted with diluents, and it was filtered through a 0.45µ nylon filter to obtain a concentration of 100 µg/mL of Teneligliptin and Metformin, and then the resultant solution is analyzed.

Method Validation:

System Suitability: System suitability tests are used to verify the reproducibility of the chromatographic system. To ascertain its effectiveness, system suitability tests were carried out on freshly prepared stock solutions.

TABLE 2: SYSTEM SUITABILITY RESULTS FOR TENELIGLIPTIN AND METFORMIN

S. no.	System suitability parameters	Observed value		Acceptance criteria
		Teneligliptin	Metformin	
1	% RSD for six replicate injections of analyte peak in standard solution	0.029	0.042	<2
2	Tailing factor for analyte peak in the standard solution	1.036	1.064	<2
3	USP plate count for analyte peak in the standard solution	3303	3080	>2000

Data Interpretation: It was observed from the data tabulated above that the method complies with system suitability parameters. Hence, it was concluded that the system suitability parameter met the requirement of method validation.

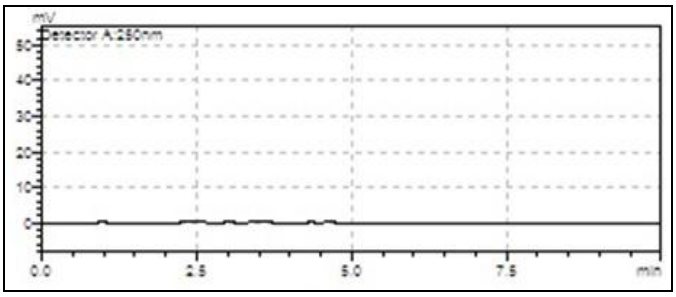

FIG. 3: CHROMATOGRAM OF BLANK

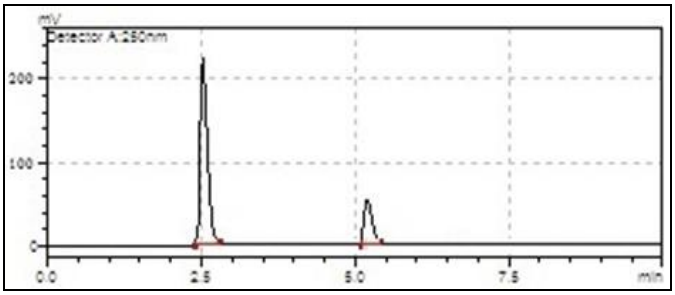

FIG. 4: CHROMATOGRAM OF STANDARD

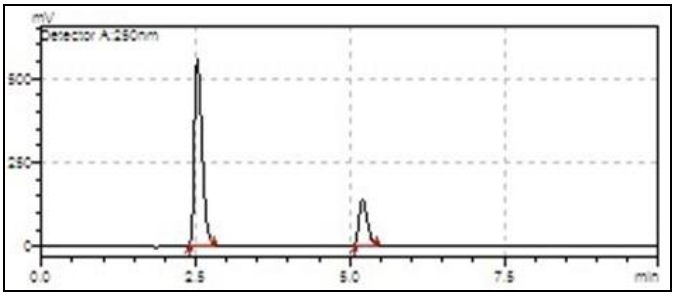

FIG. 5: CHROMATOGRAM OF SAMPLE

Linearity and Range:

Teneligliptin: The linearity of an analytical method is its ability to elicit test results that are directly, or by a well-defined mathematical transformation, proportional to the concentration of an analyte in samples within a given range of 2-10µg/mL.

Data Interpretation: The method for Teneligliptin was found to be linear in the concentration range of 2 µg/mL to 10 µg/mL and the correlation coefficient obtained is 0.997.

Metformin: The linearity of an analytical method is its ability to elicit test results that are directly, or by a well-defined mathematical transformation, proportional to the concentration of an analyte in samples within a given range of 25-125 µg/mL.

TABLE 3: RESULTS FOR LINEARITY OF TENELIGLIPTIN

S. no.	Concentration	Peak area of Teneligliptin
1	2	29581
2	4	41208
3	6	57922
4	8	78323
5	10	96266
Slope		14142
Intercept		21.8
Co-efficient of correlation		0.9997
Acceptance criteria		The coefficient of Correlation shall be not less than 0.999

Data Interpretation: The method for Metformin was found to be linear in the concentration range of 25 µg/mL to 125 µg/mL and Correlation coefficient obtained is 0.999.

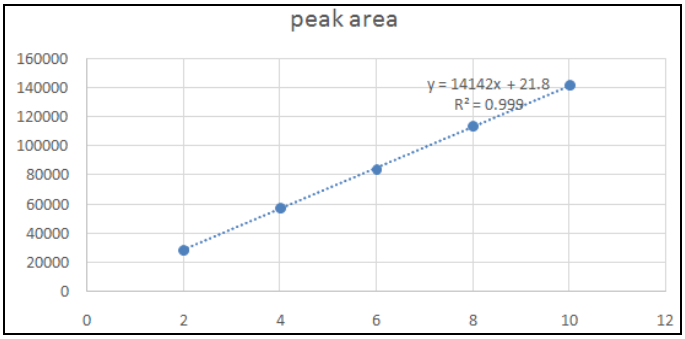

FIG. 6: CALIBRATION CURVE FOR TENELIGLIPTIN

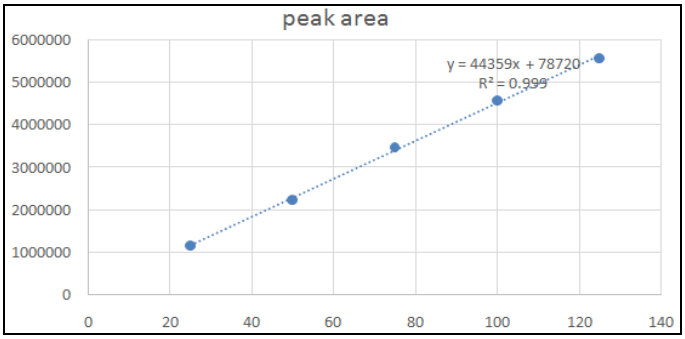

FIG. 7: CALIBRATION CURVE FOR METFORMIN

TABLE 4: RESULTS FOR LINEARITY OF METFORMIN

S. no.	Concentration	Peak area of Metformin
1	25	1174353
2	50	2254654
3	75	3469456
4	100	4566437
5	125	5563342
Slope		44359
Intercept		78720
Co-efficient of correlation		0.999
Acceptance criteria		The coefficient of Correlation shall be not less than 0.999

Precision: The precision of an analytical method is the degree of agreement among individual test results when the method is applied repeatedly to multiple sampling of a homogeneous sample.

System Precision: The system precision was carried out to ensure that the analytical system was working correctly. The system precision is performed by 6 sample injections and checking the reproducibility in the peak area.

TABLE 5: SYSTEM PRECISION FOR TENELIGLIPTIN

S. no.	Concentration µg/mL	Intraday precision peak area	Interday precision peak area	Acceptance criteria
1	4	57250	57258	The % RSD for peak area of Teneligliptin from six replicate injections of standard solution should be not more than 2.0.
2		57321	57325	
3		57249	57253	
4		57369	57377	
5		57356	57369	
6		57258	57263	
Average		57300.5	57307.5	
SD		55.13891548	57.13055225	
%RSD		0.096227634	0.099691231	

TABLE 6: SYSTEM PRECISION FOR METFORMIN

S. no.	Concentration µg/mL	Intraday precision peak area	Interday precision peak area	Acceptance criteria
1	50	2254654	2254762	The % RSD for peak area of Metformin from six replicate injections of standard solution should be not more than 2.0.
2		2255710	2256142	
3		2255669	2256237	
4		2254930	2255242	
5		2255543	2255674	
6		2255657	2255957	
Average		2255360.5	2255669	
SD		452.3302997	571.7167131	
%RSD		0.020055787	0.025345772	

Data Interpretation: It is observed from the data tabulated above, that the area responses are consistent as evidenced by the values of relative standard deviation. Hence, it can be concluded that the system precision parameter meets the requirement of method validation.

Method Precision:

Intraday Precision: The precision express reliability of the method, where it defines the extent for the individual test results can agree to repeated test result on the same operating conditions at a

short period. Repeatability of the method is accepted.

Interday Precision: Repeatability method procedure was repeated on the next day. The method passed the test, as both retention time (<1%) and response peak areas (<2%), % RSD obtained were in the limits.

Data Interpretation: From the above results, it was concluded that the method is precise.

TABLE 7: METHOD PRECISION FOR TENELIGLIPTIN

Concentration	Intraday Precision				Interday Precision			
	Retention time		Peak area		Retention time		Peak area	
	Mean	% RSD	Mean	%RSD	Mean	% RSD	Mean	%RSD
2	5.234	0.6081	28315	0.3508	5.298	0.8269	28320	0.3403
	5.267		28456		5.212		28460	
	5.298		28264		5.267		28275	
	5.264		28345		5.267		28351.6	
	0.03201		99.45350		0.04355		96.47971	
4	5.278	0.7935	57250	0.0799	5.203	0.7474	57260	0.084
	5.272		57340		5.272		57354	
	5.203		57280		5.27		57289	
	5.252		57290		5.254		57301	
	0.04167		45.82575		0.03927		48.13522	
6	5.243	0.8294	83652	0.0501	5.214	0.7186	83710	0.0487
	5.298		83578		5.244		83631	
	5.212		83649		5.289		83653	
	5.251		83626.3333		5.253		83664.667	
	0.04355		41.88476		0.03774		40.77172	

TABLE 8: METHOD PRECISION FOR METFORMIN

Concentration	Intraday Precision				Interday Precision			
	Retention time		Peak area		Retention time		Peak area	
	Mean	% RSD	Mean	% RSD	Mean	% RSD	Mean	% RSD
25	2.531	0.26262	1174353	0.00464	2.535	0.24052	1174357	0.0048
	2.543		1174452		2.547		1174459	
	2.532		1174442		2.539		1174451	
	2.535		1174415.7		2.5403		1174422	
	0.00666		54.5008		0.00611		56.72154	
50	2.563	0.43067	2254654	0.00474	2.565	0.50967	2254657	0.0046
	2.545		2254789		2.546		2254791	
	2.565		2254578		2.571		2254582	
	2.55767		2254673.7		2.5606		2254677	
	0.01102		106.8659		0.01305		105.879	
75	2.573	0.31325	3469456	0.00088	2.575	0.31301	3469459	0.0009
	2.589		3469462		2.591		3469468	
	2.579		3469512		2.581		3469519	
	2.58033		3469476.7		2.5823		3469482	
	0.00808		30.7463		0.00808		32.3574	

Data Interpretation: From the above results, it was concluded that the method is precise.

Limit of Detection and Limit of Quantitation: Limit of detection is the lowest amount of analyte in a sample that can be detected, but not necessarily quantitated, under the stated experimental conditions. Limit of quantitation is the lowest amount of analyte in an example that can be quantitated with acceptable accuracy and precision, under the stated experimental conditions.

Limit of detection (LOD) and Limit of quantitation (LOQ) was calculated based on residual standard deviation of response and slope.

TABLE 9: RESULTS OF LOD AND LOQ OF TENELIGLIPTIN AND METFORMIN

Parameter	Teneligliptin	Metformin
LOD (µg/mL) 3.3*sd/slope	0.0232	0.0040
LOQ (µg/mL) 10*sd/slope	0.0703	0.0122

Accuracy: The accuracy of an analytical method is the closeness of test results obtained by that method to the true value (Standard value).

% Recovery = Amount of drug recovered / Amount of drug added × 100

Robustness: The robustness of an analytical procedure is a measure of its capacity to remain unaffected by small, but deliberate variations in method parameters and provides an indication of its reliability during normal usage [13-26].

TABLE 10: RECOVERY RESULTS FOR TENELIGLIPTIN AND METFORMIN

% of recovery	Formulation concentration	Spiked concentration	Total concentration	Conc. obtained	% recovery
50	50	25	75	74.80	99.80
				74.92	99.89
				75.01	100.01
				Mean	99.96
100	50	50	100	100.03	100.03
				99.98	99.98
				100.1	100.1
				Mean	100.03
150	50	75	125	124.92	99.93
				125.04	100.03
				124.96	99.96
				Mean	99.97

TABLE 11: RESULTS FOR ROBUSTNESS OF TENELIGLIPTIN

Condition		Tailing factor	Theoretical plates	% RSD
Optimized condition		1.064	3080	0.042
Mobile phase ratio	42:22:36	0.992	3102	0.039
(40:20:40)	38:18:44	1.081	3221	0.054
Flow rate(ml/min)	0.9	1.066	3109	0.029
(1.0 mL/min)	1.1	1.087	3198	0.054
pH of phosphate buffer	4.5	1.042	3157	0.044
(4.6)	4.7	1.120	3192	0.068
Wavelength	249	1.056	3139	0.031
(nm) 250	251	1.0671	3153	0.049

TABLE 12: RESULTS FOR ROBUSTNESS OF METFORMIN

Condition		Tailing factor	Theoretical plates	% RSD
Optimized condition		1.064	3080	0.042
Mobile phase ratio	42:22:36	0.992	3102	0.039
(40:20:40)	38:18:44	1.081	3221	0.054
Flow rate(ml/min)	0.9	1.066	3109	0.029
(1.0 mL/min)	1.1	1.087	3198	0.054
pH of phosphate buffer	4.5	1.042	3157	0.044
(4.6)	4.7	1.120	3192	0.068
Wavelength	249	1.056	3139	0.031
(nm) 250	251	1.0671	3153	0.049

CONCLUSION: A novel, simple, rapid and cost-effective RP-UFLC method was successfully developed for simultaneous estimation of Teneligliptin and Metformin present in the formulation. The proposed method was optimized and validated for the various experimental parameters. Influence of pH of the mobile phase, mobile phase ratio and flow rate on the analysis of Teneligliptin and Metformin was evaluated. All the analytes were well resolved and separated in less than 10 min. The developed method can be conveniently used by quality control outfits to determine the contents of Teneligliptin and Metformin simultaneously in routine and stability samples. This method could be used for the analysis of the drugs in pharmaceutical preparations and routine laboratory analysis. Overall, the proposed method provides high throughput for determination of Teneligliptin and Metformin with excellent accuracy, precision, selectivity, and reproducibility.

ACKNOWLEDGEMENT: The authors express their sincere thanks to the Principal, JSS College of

Pharmacy, and Mysuru for providing the necessary facilities to carry out the research work.

CONFLICT OF INTEREST: No

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How to cite this article:
Maruthi R, Chandan RS and Raikar P: Simultaneous estimation and analytical method development, validation for the Teneligliptin and Metformin by RP-UFLC. Int J Pharm Sci & Res 2019; 10(4): 1811-19. doi: 10.13040/IJPSR.0975-8232.10(4).1811-19.