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Research Article

UV-AUC Spectrophotometric Method for Quantitative Estimation of Teneligliptin

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Abstract

Objective: The main objective of this work is to establish a simple, rapid, accurate and economical spectrophotometric method has been developed for estimation of teneligliptin in bulk and pharmaceutical formulation.

Material and Method: The λ max of teneligliptin in methanol: water (50:50) was found to be 245 nm. The area under curve (AUC) spectrum was recorded between 232.80 nm to 258.60 nm. The accuracy of the method was checked by recovery experiment performed at three different levels i.e, 80%, 100% and 120%. The precision of the method was studied as an intra-day, inter-day variation and repeatability. Ruggedness of the proposed method was studied with the help of two analysts.

Results: The drug followed linearity in the concentration range 10-35 µg/ml with correlation coefficient value (r^2) 0.999. The proposed method was applied to pharmaceutical formulation and % amount of drug estimated 97.2 % was found in good agreement with the label claim. The % recovery was found to be in the range 97.78% - 98.12%. The low value of % R.S.D. was indicative of the accuracy and reproducibility of the method. The % R.S.D. value of precision method less than 2 indicated that the method was precise.

Conclusion: The above method was a rapid and cost effective quality control tool for routine analysis of teneligliptin bulk and in pharmaceutical dosage form. This UV spectrophotometric technique is quite simple, accurate, precise, reproducible and sensitive. The validation procedure confirms that this is an appropriate method for their quantification in the plant material and formulation. It is also used in routine quality control of the raw materials as well as formulations.

Keywords: Teneligliptin; UV-Spectrophotometric; Quantitative Determination; Validation, AUC

Introduction

Teneligliptin is chemically {(2s,4s)-4-[4-(3-Methyl-1-phenyl-1-H pyrazole-5-yl) piperazin-1-yl] pyrrolidin-2-yl} (1,3-thiazolidin-3-yl) methanone (Figures 1,2,3), having molecular formula:C17H27NO4, with a molecular mass of 309.40 g/mol. Teneligliptin is a Type-2 diabetismellitus drug that belongs to dipeptidyl peptidase-4 inhibitors or "gliptins". It appears to have potent, sustained effects on glycemic control, thereby reducing the complications oh hypoglycaemia and postprandial hyperglycemia. Glucagon like peptidase (GLP-1) a peptidase secreted from the GIT in response to food ingestion increase insulin secretion and suppresses glucagon secretion from the pancreas, there by playing an important role in controlling postprandial blood glucose level.

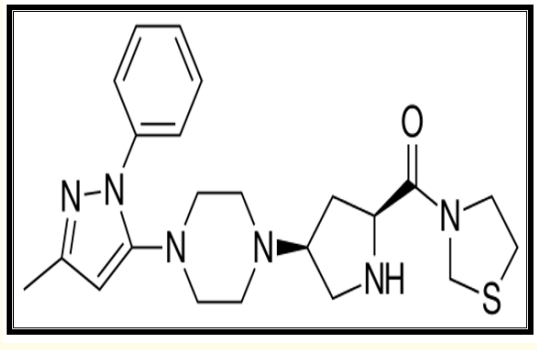

Figure 1: Chemical structures of Teneligliptin.

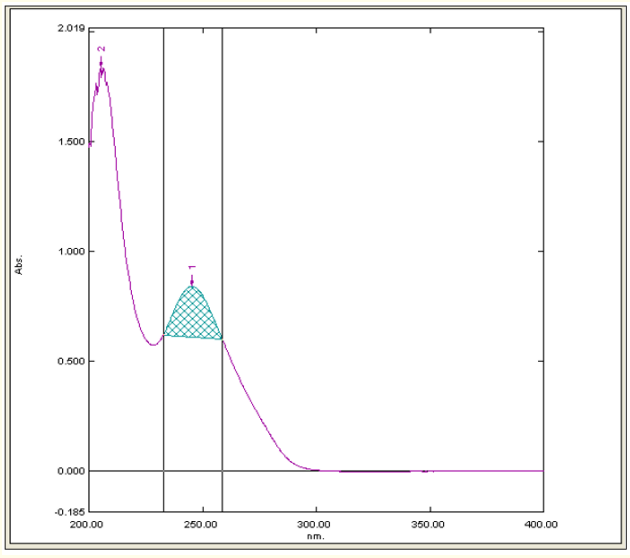

Figure 2: UV-AUC spectra of Teneligliptin.

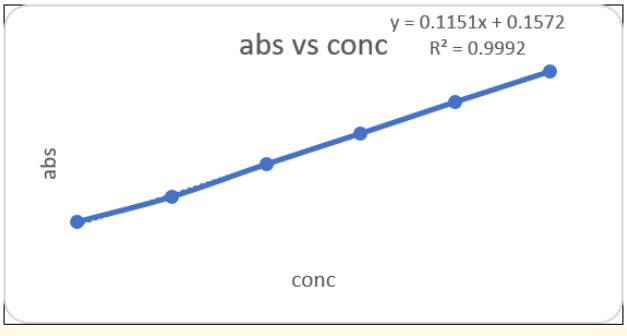

Figure 3: Linearity curve of Teneligliptin.

Analysis part is an important from formulation development of any drug molecule. A suitable and validated method should be vacant for the drug delivery system for analysis of bulk drug and formulation. Various methods are reported for the analysis of individual drug as HPLC and LCMS/MS but no spectrophotometric method is reported estimation of drug in pharmaceutical dosage form. Accordingly, the objective of this study is to develop and validate the spectrophotometric method for the estimation of teneligliptin in bulk and pharmaceutical formulation as per ICH guidelines.

Material and Method

Teneligliptin was supplied as a gift sample by Ipca laboratory, Mumbai. Tablets of 20 mg strength were purchased from the local pharmacy in Mumbai under commercial available brand name Teneza (Glenmark pharmaceutical Ltd.), tablets were used as pharmaceutical formulation for further analysis.

Instrument

A double beam UV-VIS spectrophotometer (UV-2450, Shimadzu, Japan) connected to a computer loaded with spectra manager software UV Probe 2.21 with 10 mm quartz cells was used. The spectra were obtained with the instrumental parameters as follows: Wavelength range: 400–200nm; scan speed: Medium; sampling interval: 1.0 nm. All weights were taken on an electronic balance (Model Shimadzu AUX 120).

Preparation of stock standard solution and selection of wavelengths

Accurately weighed 10mg was transferred to 100 ml volumetric flask, dissolved in 100 ml methanol: water (50:50) to obtain a concentration of 100 µg/mL. From it, an appropriate concentration of 10 µg/mL was prepared and scanned in the UV-visible range 400–200 nm; teneligliptin showed a maximum absorbance at 245 nm.

Validation of the method

Study of linearity

From the stock standard solution, an appropriate amount of aliquots portion in the range of 1-3.5 mL were transferred into a series of 10 mL volumetric flasks and diluted up to mark using the methanol: water (50:50) solvent to obtain a concentration in the range of 10-35 µg/mL. The solutions were scanned on a spectrophotometer in the range of 400–200 nm. The calibration plot was constructed as concentration vs. absorbance.

Accuracy

To the preanalyzed sample solutions, a known amount of standard stock solution was added at different levels i.e. 80%, 100% and 120 %. The solutions were reanalyzed by proposed method.

Precision

Precision of the method was studied as intra-day and inter-day variations. Intra-day precision was determined by analyzing the 10, 20 and 30µg/ml of teneligliptin solutions for three times in the same day. Inter-day precision was determined by analyzing the 10, 20 and 30 µg/ml of teneligliptin solutions daily for three days over the period of week.

Sensitivity

The sensitivity of measurements of teneligliptin the use of the proposed methods was estimated in terms of the limit of quantification (LOQ) and the limit of detection (LOD). The LOQ and LOD

were calculated using equation LOD=3.3 × N/B and LOQ=10 × N/B, where N' is the standard deviation of the AUC of the drugs (n=3), taken as a measure of noise, and 'B' is the slope of the corresponding calibration curve.

Repeatability

Repeatability was determined by analyzing 20 µg/ml concentration of teneligliptin solution for six times.

Ruggedness

Ruggedness of the proposed method was determined for 15 µg/ml concentration of teneligliptin by analysis of aliquots from homogenous slot by two analysts using same operational and environmental conditions.

Application of proposed method for pharmaceutical formulation:

Twenty tablets were accurately weighed, average weight determined and ground into fine powdered. A quantity of powder equivalent to 10mg was transferred into a 100 mL volumetric flask, the volume was adjusted to the mark using the solvent. An appropriate volume 2 mL was transferred into a 10 mL volumetric flask and the volume was adjusted to the mark to obtain the desired concentration of 20 µg/mL.

Determination of teneligliptin in bulk

A quantity of powder equivalent to 10mg was transferred into a 100 mL volumetric flask, the volume was adjusted to the mark using the methanol solvent. An appropriate volume 2 mL was transferred into a 10 mL volumetric flask and the volume was adjusted to the mark to obtain the desired concentration of 20 µg/mL.

Results and Discussion

Method validation

The proposed method was validated as per ICH guidelines. The solutions of the drugs were prepared as per the earlier adopted procedure given in the experiment.

Linearity studies

The linear regression data for the calibration curves showed good linear relationship over the concentration range 10–35µg/ml for teneligliptin. Linear regression equation was found to be Y = 0.115 X + 0.157 (r^2 = 0.999). The result is expressed in table 1 and 2.

Parameters	Method
Linearity range (µg/ml)	10-35
Selected range (nm) for AUC	232.80-258.60
Slope	0.115
Intercept	0.157
Correlation coefficient	0.999
Limit of detection (µg)	6.1779
Limit of quantification (µg)	18.7209

Table 1: Optical characteristics and linearity data of Teneligliptin.

Sr. no.	Concentration (µg/ml)	Absorbance Mean ± S.D	%R.S.D
1	10	0.2785 ± 0.003536	1.269492
2	15	0.3765 ± 0.002121	0.563432
3	20	0.5025 ± 0.002121	0.422153
4	25	0.611 ± 0.001414	0.229208
5	30	0.733 ± 0.001414	0.192935
6	35	0.847 ± 0.003536	0.417172

Table 2: linearity study of Teneligliptin.

Accuracy

The % recovery of teneligliptin was found at three concentration level 80, 100 and 120%. Result shown in table 3.

% Value	Amount of drug added(µg/ml) (n=3)	Amount found (µg/ml) (n=3)	% Recovery	% RSD
80	27	26.401	97.7814	1.32557
100	30	29.385	97.9500	1.15261
120	33	32.38	98.1212	0.97087

Table 3: Accuracy.

Average of three estimations

Precision

The precision of the developed method was determined in terms of % relative standard deviation (% RSD). The % R.S.D. values were found to be less than 2. Result shown in table 4.

Concentration	Intra-day precision (n=3)	Inter-day precision (n=3)
	Amount found %RSD	Amount found %RSD
10	9.725 1.3257	9.724 1.3634
20	19.502 1.1526	19.492 0.8952
30	29.274 0.9708	29.264 0.4773

Table 4: Precision.

Average of three estimations

Sensitivity

The sensitivity of the method was performed in terms of Limit of Detection (LOD) and Limit of Quantification (LOQ). The LOQ and LOD for teneligliptin were found to be 0.281 µg and 0.365µg, respectively.

Repeatability

Repeatability was determined by analyzing 20 µg/mL concentrations of teneligliptin solution for six times and the % amount determined with % RSD<2 for both the methods. The results are expressed in table 5.

Component	Amount taken (µg/ml) (n=6)	Amount found (%)(n=6)	%RSD
Teneligliptin	20	97.515 ± 0.0051	1.03273

Table 5: Repeatability.

Average of Six estimations

Ruggedness

The method was performed by changing the condition of the method for the same concentration. The %RSD was found less than 2. The results were given in table 6.

Component	Amount taken (µg/ml)	Amount found (%)
	(n=3)	Analysis 1 ± SD Analysis 2 ± SD
Teneligliptin	15	97.4933 ± 0.0025 97.4733 ± 0.0020

Table 6: Ruggedness.

Average of three estimations

Determination of teneligliptin in Bulk

The % amounts reveal from in-house tablet, that there is no interruption from excipients present in it. The % amount for all the method was determined results shown in table 7.

Concentration (µg/ml) (n=6)	Amount found (µg/ml) (n=6)	Amount found (%)	% RSD
20	19.498	97.49	0.6278

Table 7: Determination of Teneligliptin in Bulk.

Average of six estimations

Application of proposed method for pharmaceutical formulation

The spectrum was recorded at 245 nm. The concentrations of the drug were calculated from linear regression equation. The % amount was found between 97.49% to 100.00% in table 8 and table 9 [1-8].

Concentration (µg/ml) (n=6)	Amount found (µg/ml) (n=6)	Amount found (%)	% RSD
20	19.445	97.225	1.9791

Table 8: Analysis of pharmaceutical formulation. Brand name- Teneza 20mg (Glenmark.).

Average of six estimations

Concentration	Area
10	1.728
15	1.818
20	2.223
25	2.247
30	3.148
35	3.487

Table 9: Analysis the area under curve.

Conclusion

This UV spectrophotometric technique is quite simple, accurate, precise, reproducible and Sensitive. The validation procedure confirms that this is an appropriate method for their quantification in the Bulk and formulation. It is also used in routine quality control of the raw materials as well as formulations containing this entire compound.

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