International Journal of Pharmacy and Biological Sciences-IJPBS™ (2021) 11 (4): 139-142
Online ISSN: 2230-7605, Print ISSN: 2321-3272
Research Article | Pharmaceutical Sciences | OA Journal | MCI Approved | Index Copernicus

Estimation of Teneligliptin in Oral Solid Dosage Form by Reverse Phase Chromatographic Technique Using HPLC

R. Narsimha Rao[1], P. Sandhya[2], N. Karnakar[3] and P. Amani[4]
[1,2,3,4]**Venkateshwara Institute of Pharmaceutical Sciences, Charlapally, Nalgonda, Telangana.**

Received: 02 Jul 2021/ Accepted: 9 Aug 2021 / Published online: 1 Oct 2021
***Corresponding Author Email:** rnrao007@yahoo.com

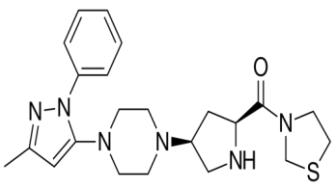
Abstract
A new method was established for estimation of Teneligliptin by RP-HPLC method. The chromatographic conditions were successfully developed for the separation of Teneligliptin by using Agilent column (4.6×150mm) 5µ, flow rate was 1.0 ml/min, mobile phase ratio was Phosphate buffer: meoH (25:75% v/v), detection wavelength was 270nm. The instrument used was WATERS HPLC Auto Sampler, Separation module 2695, photo diode array detector 996, Empower-software version-2. The retention times were found to be 2.182 mins. The % purity of Teneligliptin was found to be 98.56%. The system suitability parameters for Teneligliptin such as theoretical plates and tailing factor were found to be 4343.2, 1.6. The analytical method was validated according to ICH guidelines (ICH, Q2 (R1)). The linearity study of Teneligliptin was found in concentration range of 20µg-100µg, and correlation coefficient (r^2) was found to be 0.999, % recovery was found to be 98.96%, %RSD for repeatability was 0.3, % RSD for intermediate precision was 0.8. The precision study was precision, robustness, and repeatability. LOD value was0.439 and LOQ value was 1.466.

Keywords
Agilent column, Teneligliptin, RP-HPLC.

*****

INTRODUCTION
Teneligliptin (INN; trade name Tenelia) is a pharmaceutical drug for the treatment of type 2 diabetes mellitus. It belongs to the class of anti-diabetic drugs known as dipeptidyl peptidase-4 inhibitors or "gliptins.

Teneligliptin



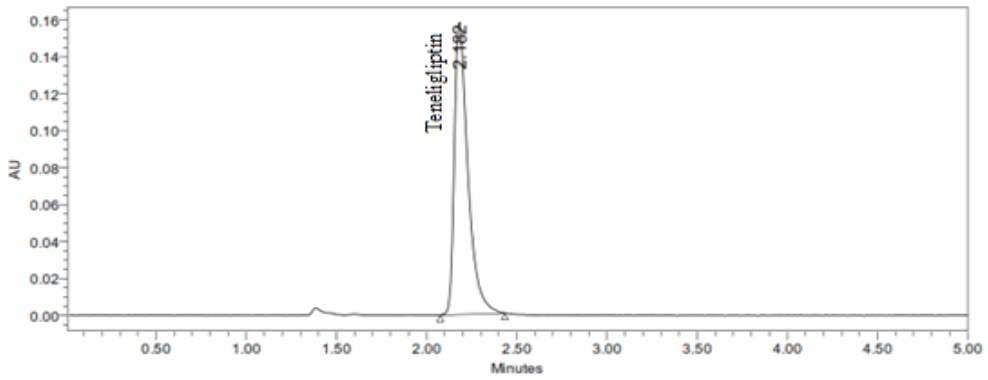
MATERIALS AND METHOD AND INSTRUMENTATION
HPLC- Alliance, model No. Waters 2695, Empower 2, U.V double beam spectrometer UV 3000+ U.V win software Lab India Digital weighing balance (sensitivity 5mg) pH meter sonicator Suction pump. Teneligliptin, API, Ortho phosphoric acid, KH_2PO_4, K_2HPO_4, Acetonitrile, Methanol, Water.

Trial -4 (Optimized method):

Chromatographic conditions

Column	:	Zodiac silRP C18 4.6×250mm 3.0µm
Mobile phase ratio (70: 30 % v/v)	:	Methnol: pH 3 buffer
Detection wavelength	:	271nm
Flow rate	:	1.0ml/min
Injection volume	:	10µl
Run time	:	10min

Fig.No.1. Chromatogram showing trial-4 injection



Preparation of the individual Teneligliptin standard preparation

10 mg of Teneligliptin working standard was accurately weighed and transferred into a 10 ml clean dry volumetric flask and add about 2 ml of diluent and sonicate to dissolve it completely and make volume up to the mark with the same solvent (Stock solution). Further pipette out 1.0 ml from the above stock solution into a 10 ml volumetric flask and was diluted up to the mark with diluent.

Preparation of the Teneligliptin standard and sample solution

Sample solution preparation:

10 mg of Teneligliptin tablet powder was accurately weighed and transferred into a 10 ml clean dry volumetric flask, add about 2ml of diluent and sonicate to dissolve it completely and making volume up to the mark with the same solvent (Stock solution). Further pipette 10ml of the above stock solution into a 100ml volumetric flask and was diluted up to the mark with diluent.

METHOD VALIDATION

- Linearity
- Accuracy
- Precision
- Intermediate Precision
- Limit of Detection
- Limit of Quantification
- Robustness
- System suitability testing

RESULTS AND DISCUSSIONS

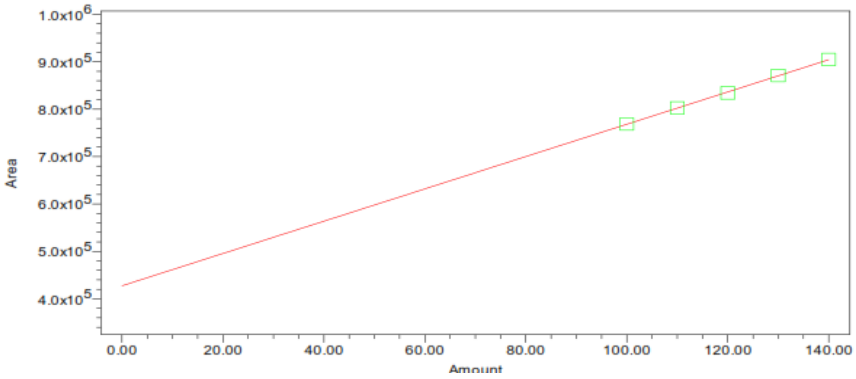
Linearity

Table No.1. Linearity Results for Teneligliptin

	Peak Name	RT	Area	Height
1	Teneligliptin	2.176	905957	171899
2	Teneligliptin	2.178	933632	178806
3	Teneligliptin	2.179	830130	160124
4	Teneligliptin	2.183	803642	152938
5	Teneligliptin	2.188	758820	146161

S.No	Linearity Level	Concentration	Area
1	I	20 ppm	**905957**
2	II	40 ppm	**933632**
3	III	60 ppm	**830130**
4	IV	80 ppm	**803642**
5	V	100 ppm	**758820**
Correlation Coefficient			0.991

Fig.No.2. Showing calibration graph for Teneligliptin



Accuracy

Table.No.2. Showing accuracy results for Teneligliptin

%Concentration (At specification level)	Average area	Amount added (mg)	Amount found (mg)	% Recovery	Mean recovery
50%	1143519	5	4.86	98.81%	
100%	2938342	10	9.88	99.08%	98.96%
150%	4452758	15	15.0	100.0%	

Precision

Table.No.3. Showing% RSD results for Teneligliptin

	Peak Name	RT	Area	Height
1	Teneligliptin	2.185	824170	158772
2	Teneligliptin	2.191	826053	157336
3	Teneligliptin	2.204	823442	156124
4	Teneligliptin	2.207	818967	155674
5	Teneligliptin	2.210	823476	156033
Mean			823221.9	
Std.Dev.			2604.2	
%RSD			0.3	

Intermediate precision/Ruggedness

Table.No.4. Showing results for intermediate precision of Teneligliptin

	Peak Name	RT	Area	Height
1	Teneligliptin	2.180	830760	160374
2	Teneligliptin	2.184	832532	160030
3	Teneligliptin	2.185	823385	159662
4	Teneligliptin	2.188	840724	161107
5	Teneligliptin	2.188	829385	160286
Mean			831357.4	
Std.Dev.			6263.2	
%RSD			0.8	

Robustness

Table.No.5. Showing system suitability results for Teneligliptin

S. No	Flow rate (ml/min)	System suitability results	
		USP Plate Count	USP Tailing
1	0.8	4517	1.7
2	**1.0**	**4343**	**1.6**
3	1.2	4209	1.6

Table.No.6. Showing system suitability results for Teneligliptin

S. No	Change in organic composition in the mobile phase	System suitability results	
		USP Plate Count	USP Tailing
1	5 % less	4623	1.6
2	***Actual**	**4543**	**1.6**
3	5 % more	4864	1.6

SUMMARY AND CONCLUSION

This method was successfully validated for all the parameters and could detect the the correct amounts of active drug substance in formulations that are available in the market. This developed method in the present study could be successfully employed for the simultaneous estimation of teneligliptin in API and Pharmaceutical dosage form.

BIBLIOGRAPHY

1. M. V. Basaveswara Rao et al, Development and Validation of New RP-HPLC Method for the Determination of Teneligliptin. Indian J Pharm Sci. 2012 Nov-Dec; 74(6): 588–591.
2. B.D Shah, S. Kumar, Y. C. Yadav, A.K. Seth, T. K. Ghelani, G. J. Deshmukh et al, Analytical Method Development and Method Validation Of Tiotropium Bromide And Formoterol Fumarate Metered Dose Inhaler (Mdi) By Using Rp-Hplc Method. Asian Journal of Biochemical and Pharmaceutical Research Issue 1 (Vol. 1) 2011
3. T.A. Phazna Dev A simple and reproducible method was developed for Teneligliptin by Reverse Phase High Performance Liquid Chromatography (RP-HPLC) Vol –I Pg. No-715.
4. Kalyan Hazra Development this research work was to formulate and evaluate the tablets of Teneligliptin. The tablets were prepared by direct compression method. The formulations Vol-I Pg. No-136.