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QbD Guided Central Composite Design Optimized RP-HPLC Method for Teneligliptin Assay in Dosage Forms

Srinivasa Rao Yarguntla, Vasudha Dadi*, Bhagavan Rajesh Babu Koppisetty, Sridevi Ranjitha Karanam, Anusha Gandi, and Mounica Peela

[1]Department of Pharmaceutical analysis, Vignan Institute of Pharmaceutical Technology (Autonomous), Visakhapatnam-530046, Andhra Pradesh, India

*Corresponding author: vasudha4mpharm@gmail.com

Abstract

In this study, we present a robust and reliable RP-HPLC method designed to accurately assess the content of teneligliptin in marketed formulations. The process of method development included refining chromatographic conditions to effectively quantify Teneligliptin within formulations. The column used for optimal separation had a C18 composition and dimensions of (250 mm, 4.6 mm, 5 µm). The mobile phase consists of acetonitrile and 1-Octane sulfonic acid sodium salt buffer in a ratio of 62.5:37.5 v/v. at 0.90 mL/min. Detection occurred at 244 nm, with teneligliptin showing a retention time of 5.056 minutes. Validation investigations affirmed the method's appropriateness for quantification, showcasing exceptional linearity, precision, accuracy, and specificity. In summary, this RP-HPLC methodology presents a valuable resource for the routine assessment of teneligliptin formulations, guaranteeing the maintenance of product quality and integrity.

Keywords: Teneligliptin; RP-HPLC; Stability indicating; Forced degradation.

Introduction

Diabetes mellitus is a chronic metabolic disorder known for causing sustained elevated plasma sugar levels and manifests as a serious health issue. It mainly manifests in two types: Type 1 diabetes mellitus is an autoimmune condition resulting in the destruction of the pancreas' insulin-producing beta cells. In contrast, Type 2 diabetes mellitus (T2DM) is described by reduced insulin sensitivity and a decreased in insulin production. Proper diabetes management is essential to avoid immediate issues like hyperglycemia and to reduce the risk of long-term complications like cardiovascular issues, neuropathy, renal impairment, and ocular disorders are common.

Teneligliptin (TGT) is an oral medication used to lower blood sugar, classified as a dipeptidyl peptidase-IV (DPP-IV) inhibitor. It is primarily recommended for the management of T2DM. TGT functions by blocking the DPP-IV enzyme, which normally breaks down incretins. Incretins are hormones that promote the pancreatic insulin secretion. By inhibiting DPP-IV, TGT elevates the amounts of active incretins, enhancing insulin secretion and reducing glucagon levels in a manner that is dependent on glucose levels. This mechanism helps to lower blood glucose. TGT is recommended for use when nutrition and physical activity alone do not sufficiently control blood sugar levels. It can be used alone or along with other hypoglycemic drugs like metformin or thiazolidinediones. The standard dose of TGT is 20 mg given once daily, which can be taken with or without food. Based on the patient's clinical response and drug tolerability, the dosage may be enhanced to 40 mg once daily (1,2,3). Chemically, TGT (Fig. 1) with a molecular composition of $C_{22}H_{30}N_6OS$ and a molar weight of 426.6 (4)

A study of the published literature shows that multiple RP-HPLC methods have been described for the estimation of Teneligliptin, either as a single drug or in combinations with other antidiabetic drugs such as metformin (5). However, these

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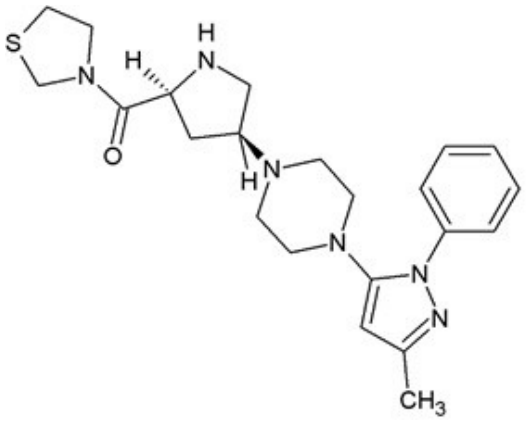

Fig. 1: Structure of teneligliptin

approaches had significant limitations, including extended analysis times ranging from 20 to 55 min (6,7) and inadequate robustness when exposed to deliberate changes in chromatographic conditions (8). In contrast, the method reported by Nagarajan et al. (9) utilized triethylamine and perchloric acid as mobile phase additives, but has a clear limitations. The current work offers marked advantages through the use of 1-Octane sulphonic acid sodium salt buffer, which provides a safer and less corrosive alternative. Unlike perchloric acid, which can damage stainless steel components, and triethylamine, which is volatile and prone to causing baseline drift and reproducibility issues, octane sulfonate is milder and more stable. Its ion-pairing effect also enhances analyte retention and improves peak symmetry for the moderately basic TGT, resulting in sharper, more consistent chromatograms. These improvements make the present method more robust, safer for routine quality control, and broadly applicable compared with previously reported triethylamine–perchloric acid systems. Furthermore, none of the earlier studies applied a statistically optimized design of experiments (DoE) to systematically define and control critical method parameters. Addressing these gaps, the present study introduces a QbD assisted, Central Composite Design optimized RP-HPLC method, which delivers shorter run time, higher sensitivity, and improved robustness, making it highly suitable for the assay of pharmaceutical dosage forms.

Materials and Methods

Reagents

TGT was acquired as complimentary material from Synpure Labs Pvt Ltd, India. The TENEPLA (20mg) medication from Cipla (India) was sourced from a nearby pharmacy. Chemical reagents ortho phosphoric acid solution (OPA), hydrochloric acid (HCl), 1- Octane sulphonic acid sodium salt (OSA), hydrogen peroxide (H_2O_2), sodium dihydrogen phosphate and sodium hydroxide (NaOH) are of analytical grade obtained from Fisher Scientific. Solvents such as methanol, acetonitrile (ACN) and water meet HPLC grade standards and were purchased from Merck (India).

Statistical assessment

Microsoft Excel 2007 was employed for statistical assessment. Design Expert software was applied to conduct ANOVA, construct three-dimensional response surface plots, and facilitate response surface optimization.

Instrumentation

The chromatographic analysis was executed on an HPLC (Shimadzu, LC-20AD model, Japan) integrated with a dual pump and detector photodiode array (PDA). The data interpretation was done by means of LC Solution platform. Spectroscopic evaluations were executed with a UV–Vis spectrophotometer (Lab India, India). Analytical measurements were undertaken using a balance from Mettler Toledo (ML303T model).

Chromatographic parameters

Isolation was conducted utilizing an Enable C_{18} separation column (25 cm, 4.6 mm, 5 µm). The separation was performed isocratically, with a solvent system composed of ACN and OSA buffer mixed in proportion of 62.5:37.5 v/v. and separation were carried at 0.90 mL/min at laboratory temperature. The

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eluents were monitored at 244 nm. The system was operated under room temperature conditions.

Solvent System preparation

The buffer solution was prepared by dissolving 2.1627 grams of OSA in 1000 ml of water and regulating the pH to 3.5 with dilute OPA solution. The solution was then purified through a 0.45 µm filter and degassed. The ACN and the buffer solution were then mixed in a 62.5: 37.5 ratio to be used as the mobile phase.

Standard solution preparation

A 25 mg portion of standard TGT was introduced into a 25 mL container. About 20 mL of ACN was added, and the mixture was ultrasonicated for 15 min to achieve full solubilization. The final volume was set to the mark with ACN, yielding the primary stock solution. From this solution, sequential dilutions were prepared with the solvent system to obtain 30 µg/mL of TGT. The resulting preparations were filtered through a filter size 0.45.

Preparation of sample solution

Utilizing the present developed chromatographic conditions, the assay of commercial tablets for the content of TGT was established, and it was found to be more accurate and reliable. For analysis of TENEPLA (TGT 20 mg), Ten tablets were triturated in a mortar to obtain a fine powder corresponding to 25 mg of TGT (Table 1). The resulting material was delivered into a 25 mL standard flask, with subsequent addition of approximately 20 mL of ACN. The solution was then ultrasonicated for 12 minutes to achieve full solubilization. The obtained mixture was subsequently diluted with the solvent system to get 30 µg/mL of TGT. It was then passed through a filter size 0.45.

Analytical method development through Quality by Design concepts

Analytical target profile (ATP)

ATP guided the method development (10,11,12,13,14), ensuring API quantification by HPLC without matrix or degradant interference. The objectives were to optimize chromatographic performance by refining plate number (N), and peak asymmetry (*Tf)* and to apply the method for accurate estimation of TGT in formulations. The method target was to achieve a minimum of 3000 theoretical plates, with the tailing factor maintained within the range of 1.0 to 1.5.

Table 1: Analysis of TGT in formulation

Drug product	Labelled quantity (mg)	Exp. quantity (mg)	Recovery ± RSD
TENEPLA	20	19.95	99.75±0.12

Risk assessment

In HPLC, the efficiency of separation is governed by variables like composition of the solvent system, column characteristics, operating temperature, detector settings, sample preparation techniques, and injection volume. Each stage of analysis was systematically examined, with risks evaluated in terms of severity, probability, and detectability, ensuring reliability through established chromatographic principles and practical proficiency.

Conducting an experiment's design

Central Composite Design (CCD) was adopted in this study following the initial risk assessment, as it offered advantages over other experimental designs such as Box–Behnken or full factorial approaches. CCD is well-suited for quadratic modeling, enabling the estimation of curvature effects in the response surface with high reliability. Initial experimental trials were carried out to assess method behavior and determine influential variables, employing ACN and water as solvents under different mobile phase ratios and flow rates. A QbD framework integrating risk analysis and an Ishikawa diagram was applied to recognize critical parameters. CCD, considering two independent factors (flow rate and ACN proportion) and two response attributes,

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produced 13 randomized experimental conditions, including five center points, to reduce bias (Table 2). Critical Quality Attributes (RT, N, and Tf) were analyzed. Statistical evaluation was done using software Design Expert.

Evaluation of study outcomes and improvement of the method

Experimental data were statistically interpreted in a structured manner using Design Expert software. A design space was established, and responses were assessed through statistical tools such as ANOVA, three dimensional contour mapping, and predictive modeling equations.

Method Validation

In accordance with ICH guidelines and related works (15,16,17) system suitability assessments and validation parameters were performed following established standard procedures.

Results and Discussion

Analytical Method development using QbD strategy

The strategy aims to incorporate quality into workflows from the beginning. The goals and key features of a product are established at the outset of a program, and it is then determined how procedures can impact a product's qualities through risk and data analysis. QbD thus offers a strong foundation for the development and execution of procedures that fulfill the predetermined requirements and attain a constant quality level. The primary objective of QbD was to achieve rapid separation of all peaks with excellent peak shapes. while maintaining compliance with guidelines (18,19). Precision and accuracy with %RSD less than 2 verified the reliability of the method. Different mobile phases, including methanol, ACN and their blends, were assessed to fulfill system performance criteria. Increased organic content enhanced TGT retention, with the ACN:OSA buffer ratio (62.5:37.5 v/v) providing good performance across all criteria. Lowering the organic fraction resulted in broader peaks and reduced plate number. The solvent system was also employed as a diluent to avoid solvent related intervention. Preliminary investigations highlighted ACN volume as a critical determinant of retention time.

Table 2: CCD experimental runs

Run	Ft1	Ft2	Rp1	Rp2
	A:ACN (mL)	B:Flow rate (mL/min)	TGT (T_f)	TGT (N)
1	62.5	0.9	1.2342	5749
2	62.5	0.75	1.3324	4577
3	62.5	0.9	1.2336	5708
4	45	0.8	1.1202	2646
5	80	0.8	0.9163	1265
6	62.5	0.9	1.2357	5728
7	62.5	1.0	1.2212	5815
8	62.5	0.9	1.2347	5787
9	80	0.9	0.8493	1754
10	45	1	1.0562	3842
11	62.5	0.9	1.2342	5796
12	80	1	0.8218	1943
13	37.75	0.9	0.8334	955

Ft1: Factor 1; Ft2: Factor2; Rp1: Response 1; Rp2: Response 2

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Table 3: ANOVA results

Response	Std. dev.	Mean	R^2	%C.V	Adjusted R^2	Predicted R^2	Adequate Precision	p value Lack of fit	p value Sequential
Rp1	0.0009	1.10	1.0000	0.076	1.0000	0.9999	908.98	0.3013	<0.0001
Rp2	63.03	3966.28	0.9995	1.61	0.9990	0.9967	115.31	0.0742	<0.0001

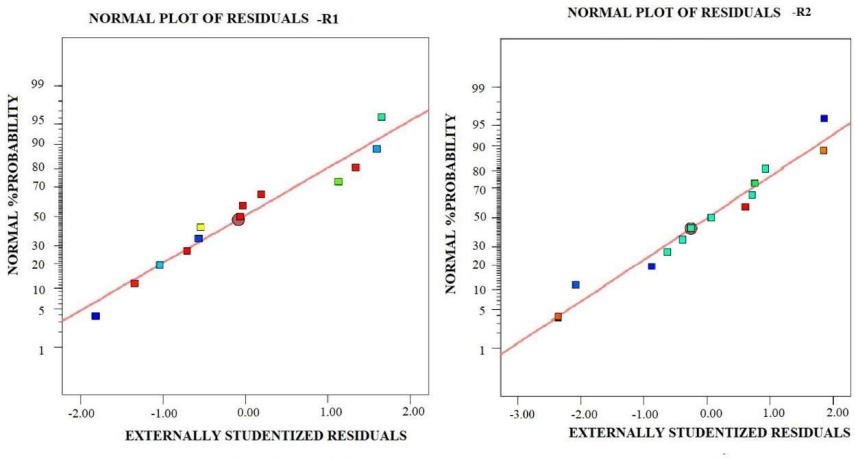

Fig. 2: Residual Normal Plots from Rp1 and Rp2

After conducting Ishikawa analysis and initial experiments, the volume of ACN and flow rate were identified as the two pivotal factors with the most pronounced impact on system suitability parameters. These factors were subsequently chosen for further scrutiny. CCD is designed to experiment with multiple variables and examine their interaction through response surface analysis. It includes points at the midpoints of each edge and replicates in the center of a multidimensional cube. The CCD approach was used to refine conditions of chromatographic by considering the effect of variables like ACN and flow rate on key aspects such as the *Tf* of TGT (Rp1), *N* of TGT (Rp2).

Model validation was performed using ANOVA in Design Expert software (Table 3). Quadratic models for the tailing factor of TGT (Rp1) and plate count (Rp2) were selected based on statistically significant sequential p-values (<0.05) and acceptable lack-of-fit statistics. Normal residual plots (Fig. 2) and Cook's distance confirmed the reliability of the model. Adequate Precision values above 4, together with greater adjusted R^2 and minimal %CV, indicated a strong fit between the experimental results and the model. Close agreement between predicted and adjusted R^2 values further supported the model's applicability for defining the design space and deriving predictive equations for response estimation. *Tf* of TGT (Rp1) = 1.25578 + 0.0141624 * A + -0.057115 * B + -0.0115737 * AB + -0.408315 * A^2 + 0.030872 * B^2 , *N* of TGT (Rp2) = 5,652.3 + 569.374 * A + 727.274 * B + -196.563 * AB + -4,477.01 * A^2 + -407.141 * B^2. The chromatogram is presented in (Fig. 3). Perturbation plots illustrate how a variable's response deviates from its nominal value, with curvature indicating the magnitude of the factor's impact. Figure 4(A) demonstrates the impact of both the flow rate and the ACN on the *Tf* of TGT. Figure 4(B) illustrates the effect of the flow rate and the ACN on the *N* of TGT.

QbD Guided Central Composite Design

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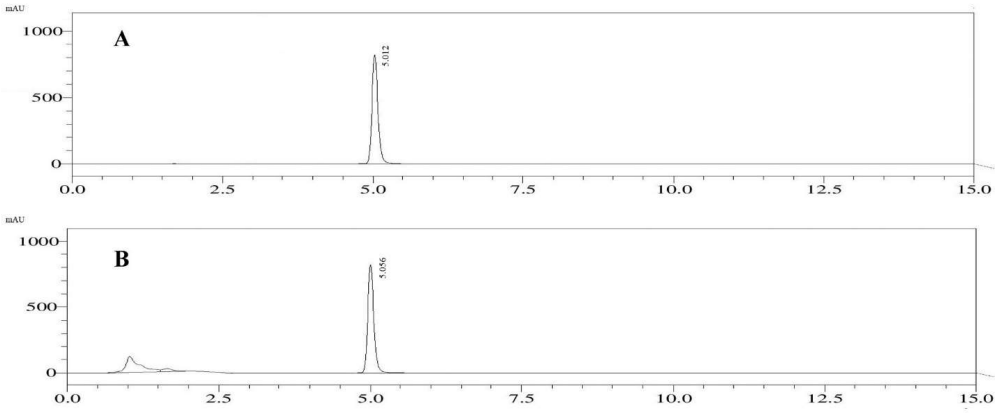

Fig. 3: Chromatogram from the standard solution of TGT(A) and Sample(B)

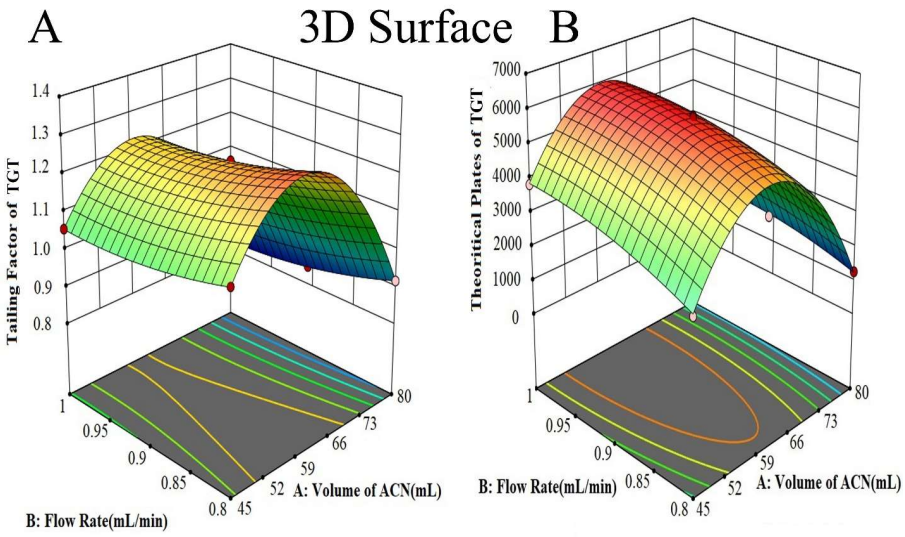

Fig. 4: 3-D plots of flow rate and ACN on T_f of TGT(A), N of TGT(B)

Design Space

The main objective of method development is to define a reliable design space that ensures consistent performance. For this study, the target for Response-1 was to achieve a N of at least 5000 for TGT. For Response-2, the ideal tailing factor (Tf) was set between 1.0 and 1.3. Figure 5 maps out the design space generated from the CCD trails. The results clearly indicate that the desired responses can be achieved when the concentration of organic phase solution- B is between 50% to 69.5 45%. Similarly, using a flow rate under 0.8 to 1.0 mL/min leads to good performance, signaling that the method is effective under those conditions.

Model Prediction and Validation

Based on the CCD and response surface approach, the model-predicted optimal chromatographic conditions were identified prior to experimental confirmation.

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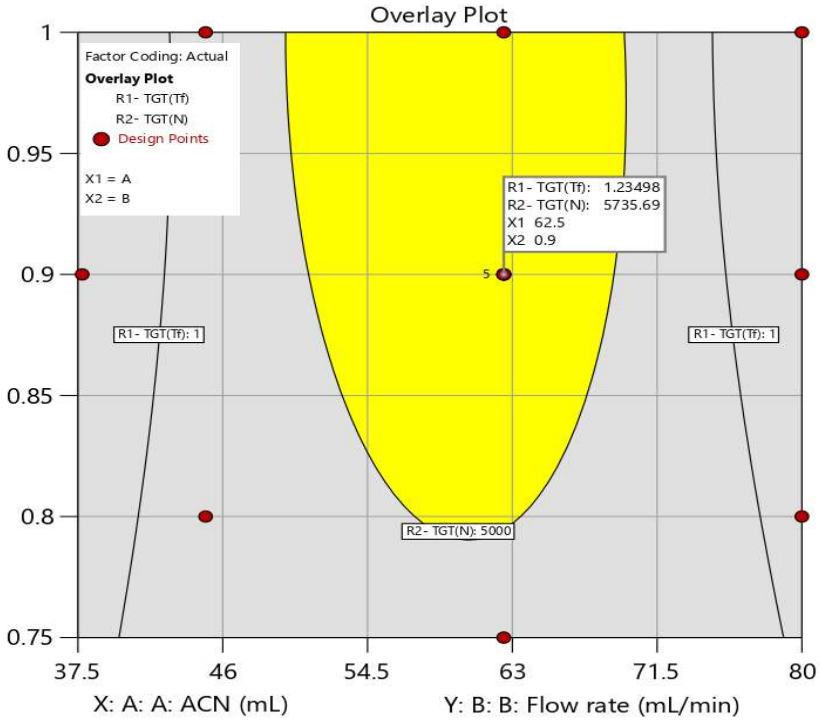

Fig. 5: Design Space of the method

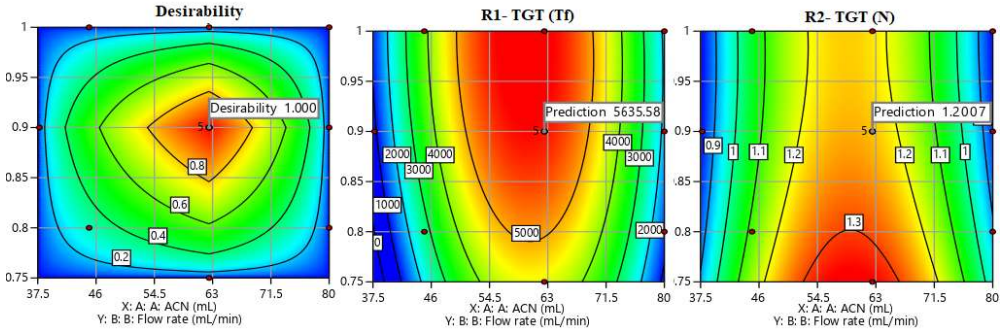

Fig. 6: 2-D plots for responses and desirability

The desirability function analysis suggested the following conditions as optimal for achieving maximum peak performance: ACN concentration 62.5% (v/v) and flow rate 0.95 mL/min**.** These predicted values of TGT tailing factor is 1.2007 and theoretical plates 5635 obtained from the fitted quadratic models and desirability of 1 from 2D plots (Fig. 6). Subsequent experimental validation under the predicted conditions demonstrated close agreement with the model, confirming that the optimization process was truly model-driven rather than empirical (Table 4).

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Table 4: Predicted mean relative to Actual value

Response	Actual	Predicted Mean	Error
Rp1	1.2305	1.2007	1.42 %
Rp2	5713	5635.58	1.35%

3.2 System Suitability Study

Following the establishment of optimized chromatographic conditions, system performance criteria were assessed and confirmed to be within permissible limits, ensuring method reliability (20,21,22). The technique was validated in compliance with ICH Q2 (R1) guidelines. UV spectral evaluation revealed significant absorbance of TGT at 244 nm, which was therefore selected for detection.

Method Validation

UV spectral analysis showed prominent absorbance of TGT at 244 nm, which was designated as the detection wavelength (23,24). The method was validated as per ICH Q2 (R1) standards. The optimized RP-HPLC method, characterized by more than 3000 theoretical plates and a tailing number below 1.5, indicates the system's efficiency. The % RSD values for all parameters, such as, peak area, N, and T_f, were all below 2%, indicating the system's suitability (Table 5).

Linearity

The calibration plot for TGT within the 6.25–50 µg/mL range yielded a regression equation of 348257x – 2527.5 and a correlation coefficient of 0.998, indicating good linearity and suitability for precise quantification in pharmaceutical formulations.

Precision

Precision was evaluated through repeatability and intermediate studies at 15, 30, and 45 µg/mL (n=3), where %RSD values remained under 2%, demonstrating the method's reliability.

Table 5: Results of validation studies

Validation	TGT
Range	6.25-50 (µg/mL)
Coefficient determination	0.998
Regression equation	Y= 348257x - 2527.5
Repeatability(%RSD)	0.85 – 1.33
Intermediate precision (%RSD)	0.97 – 1.25
Accuracy	
50%	99.40%
100%	99.68%
150%	99.75%
Robustness (%RSD)	
Wavelength	1.23
Flow change	1.07
Mobile phase	1.17

Accuracy

Accuracy was verified through recovery studies using the standard addition method at 50%, 100%, and 150% levels (n=3), yielding TGT recovery values between 99.40% and 99.75%, thereby confirming the method's validity.

Robustness

Method robustness was examined by introducing deliberate variations in flow (0.9–1.1 mL/min), ACN content (61.5–63.5 mL), detection wavelength (243–246 nm) and sonication duration (10–30 min). All system suitability parameters complied with acceptance limits, with consistent recoveries and %RSD values less than 2%, validating the robustness and stability of the method.

Assay of pharmaceutical formulation

The established method was utilized for the analysis of TGT tablet formulations, where the mean recovery and %RSD values showed strong agreement with the labeled content (Table 5), verifying its applicability for accurate quantification of TGT in marketed products (25,26).

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Conclusion

In this study, a robust and stability indicating RP-HPLC method for the quantification of TGT in formulation was developed and validated. The technique exhibited outstanding results regarding its consistency, accuracy, precision, specificity, and resilience. The separation was accomplished utilizing a C18 column and a mobile phase consisting of an optimized ratio of solvents, which provided a clear resolution of TGT from its degradation products and excipients. The method displayed ample sensitivity in detecting and measuring TGT at minimal concentrations, rendering it appropriate for regular quality control assessments, which is critical for ensuring the safety and efficacy of formulation throughout its shelf life.

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Conflict of Interest

The authors report that there are no competing interests to declare.

References

1. Li, X., Huang, X., Bai, C., Qin, D., Cao, S., Mei, Q., Ye, Y. and Wu, J. (2018). Efficacy and safety of teneligliptin in patients with type 2 diabetes mellitus: a systematic review and meta-analysis of randomized controlled trials. Frontiers in Pharmacology, 9, p.449.

2. Pelluri, R., Kongara, S., Nagasubramanian, V.R., Mahadevan, S. and Chimakurthy, J. (2023). Systematic review and meta-analysis of teneligliptin for treatment of type 2 diabetes. Journal of Endocrinological Investigation, 46(5), pp.855-867.

3. Ghosh, S., Tiwaskar, M., Chawla, R., Jaggi, S., Asirvatham, A. and Panikar, V. (2020). Teneligliptin real-world effectiveness assessment in patients with type 2 diabetes mellitus in India: a retrospective analysis (TREAT-INDIA 2). Diabetes Therapy, 11(10), pp.2257-2268.

4. National Center for Biotechnology Information (2025). PubChem Compound Summary for CID 11949652, Teneligliptin. Retrieved August 22, 2025 from https://pubchem.ncbi.nlm.nih.gov/compound/Teneligliptin.

5. Bichala, P. K., Kumar, K. J., Suthakaran, R. and Shankar, C. H. (2020). Development and Validation of an Analytical Method for the Estimation of Metformin and Teneligliptin in its Bulk and Tablet Dosage Form by using RP-HPLC. Asian Journal of Pharmaceutical Analysis, 10(1), 11-14.

6. Kumar, T. G., Vidyadhara, S., Narkhede, N. A., Silpa, Y. S. and Lakshmi, M. R. (2016). Method development, validation, and stability studies of teneligliptin by RP-HPLC and identification of degradation products by UPLC tandem mass spectroscopy. Journal of Analytical Science and Technology, 7(1), 27.

7. Biswas, B., Kumar, M., Sharma, J. B., Saini, V. and Bhatt, S. (2020). Method development and validation for estimation of teneligliptin in tablet dosage form by RP-HPLC. Research Journal of Pharmacy and Technology, 13(4), 1774-1778.

8. Patel, B. D., Dharsandiya, N. J. and Chaudhary, A. (2021). Development and validation of RP-HPLC method for estimation of teneligliptin and its impurity in tablet. International Journal of Pharmaceutical Sciences Review and Research, 69(2), 127-133.

9. Nagarajan, K., Goel, R., Bhardwaj, A. andGrover, P. (2024). Development and validation of fast and sensitive RP-HPLC stability indicating method for quantification of teneligliptin in bulk drug. Journal of Chromatographic Science, 62(5), 483-491.

10. Koppisetty, B.R.B., Kollabathula, V.R., Challa, G.N. and Yarraguntla, S.R., (2024). Quality by Design-Assisted RP-HPLC Method for Determination of Ritonavir and Darunavir in Pharmaceutical Formulation Using Central Composite Design. Separation Science Plus, 7(10), p.e202300210.

Vol. 20 (Supplementary Issue 2A), June 2026, ISSN 0973-8916 (Print)., 2230-7303 (Online)
10.5530/ctbp.2026.2s.4

11. Dadi, V., Medapati, S., Baratam, J.K., Tatapudi, H.K., Challa, G.N., Yarguntla, S.R. and Koppisetty, B.R.B. (2024). Quality by design assisted rp-hplc method for estimation of teriflunomide and its process impurities in drug substance. Journal of Faculty of Pharmacy of Ankara University, 48(3), pp.18-18.

12. Koppisetty, B.R.B., Prasad, Y.R., Amgoth, K.M.P., Yarraguntla, S.R., Dadı, V. and Tatapudı, H.K. (2023). Utility of quality by design approach in rp-hplc method development for quantification of lamivudine and effavirenz in combination formulation. Journal of Faculty of Pharmacy of Ankara University, 47(2), pp.625-636.

13. Vasudha, D., Naidu, C.G., Koppisetty, B.R.B., Yarraguntla, S.R. and Gullapudi, T.R. (2024). A quality by design assisted RP-HPLC method utilizing central composite design for the assay of eliglustat and its organic impurities in drug. Analytical Chemistry Letters, 14(5), pp.755-769.

14. Challa, G.N., Kunda, D.R., Mustaq, S.J.H., Marni, N., Ketha, S., Gorle, U., Jakkula, S. and Koppisetty, B.R.B. (2025). QbD assisted RP-HPLC method for determination of Pyridoxine and Doxylamine in pharmaceutical formulation using central composite design. Journal of Applied Pharmaceutical Science, 15(4), pp.072-083.

15. ICH, H. T. G. (1994, October). Text on Validation of Analytical Procedures. In International Conference on Harmonization, Geneva (pp. 1-5).

16. Kumari, P.V.K., Yarraguntla, S.R., Sharmila, M. and Gulibindala, E. (2021). Application of Box-Behnken Design for Formulation Parameters of Eslicarbazepine Tablets. Indian Journal of Pharmaceutical Sciences, 83(3).

17. Vidyadhara, S., Rao, Y.S., Ramu, A., Sasidhar, R.L. and Ramya, A.J. (2013). Method development and validation for the simultaneous estimation of cinitapride and pantoprazole in solid dosage forms by RP-HPLC. Oriental Journal of Chemistry, 29(3), p.1213.

18. Srinivasarao, Y., Kumar, T.H., Chiranjivi, P. and Rao, K.V. (2021). Simultaneous Estimation of Solifenacin Succinate and Tamsulosin Hydrochloride in Combined Dosage Form by Using First Order Derivative Spectrophotometric Method. Indian Journal of Pharmaceutical Sciences, 83(2).

19. Panda, M., Dadi, V., Yarraguntla, S.R. and Rao, V.P.K. (2023). RP-HPLC method for determination of azelnidipine and telmisartan in pharmaceutical dosage form. Research Journal of Pharmacy and Technology, 16(2), pp.509-513.

20. Swathi, S., Kumar, H.T. and Rao, P.K. (2015). Validated RP-HPLC method for simultaneous determination of rosuvastatin calcium and ezetimibe in pharmaceutical dosage form. Int. J. Pharm. And Pharm. sci, 7(4), pp.209-213.

21. Lakshmi, G.T., Rao, Y.S., Rao, K., Prasada, V. and Kumar, T.H. (2015). RP-HPLC method for estimation of atomoxetine hydrochloride in bulk and pharmaceutical dosage form. Research Journal of Pharmaceutical Biological and Chemical Sciences, 6(2), pp.1208-1214.

22. Koppisetty, B.R.B., Tatapudi, H.K., Dadi, V., Gayathri, P.R., Komali, P., Challa, G.N., Kollabathula, V.R. and Yarraguntla, S.R. (2023). QbD based RP-HPLC method for simultaneous determination of a emtricitabine, tenofovir diproxil fumarate and efavirenz in tablet dosage form-an application to stability indicating assay. Analytical Chemistry Letters, 13(3), pp.267-288.

23. Koppisetty, B.R.B., Yejella, R.P., Pawar, A.K.M., Yarraguntla, S.R., Kollabathula, V.R., Dadi, V. and Naidu, C.G. (2023). Development of a validated RP-HPLC assay method for quantitative separation of Teriflunomide and its process-related impurities in bulk drugs. Journal of Applied Pharmaceutical Science, 13(1), pp.028-033.

24. Panchumarthy, R., Bathula, S., Koppisetty, B. R. B. and Dadi, V. (2025). A Stability Indicating RP-HPLC Method for Determination of Foslevodopa and Foscarbidopa in Bulk and Formulation. Separation Science Plus, 8(5), e70063.

Vol. 20 (Supplementary Issue 2A), June 2026, ISSN 0973-8916 (Print)., 2230-7303 (Online)
10.5530/ctbp.2026.2s.4

25. Kumar, T.H., Asha, C.H. and Sankar, D.G. (2019). Estimation of amlodipine besylate and irbesartan in pharmaceutical formulation by RP-HPLC with forced degradation studies. Int. J. Appl. Pharm, 11(3), pp.159-167.

26. Bhanu, M.S., Dadi, V., Rao, Y.S. and Rao, V.P.K., 2023. RP-HPLC method for quantification of bilastine and monteleukast sodium in pharmaceutical dosage form. Research Journal of Pharmacy and Technology, 16(3), pp.1079-1084.