RESEARCH PAPER

SIMULTANEOUS ESTIMATION OF DAPAGLIFLOZIN (DGF) AND TENELIGLIPTIN (TGT) USING MIXED HYDROTROPIC SOLUBILIZING AGENTS

Ashwini R. Dhavade[1]*, Dr. Dhyanendra Singh Bghel[1]
Mansarovar Global University, Sehore(M.P.), 466111, India.
Corresponding email: dhavadeashvini@gmail.com

Abstract
The present study aimed to develop and validate a simple, rapid, accurate, precise, and cost-effective mixed hydrotropic UV spectrophotometric method for the simultaneous estimation of Dapagliflozin (DGF) and Teneligliptin (TGT) in bulk drug and pharmaceutical dosage forms. To enhance the aqueous solubility of both drugs, different mixed hydrotropic systems were investigated. Among them, a mixture of 2 M Sodium Gluconate and 2 M Ammonium Acetate (1:1, v/v) was selected as the optimum solvent system, producing approximately 25.17-fold and 16.64-fold enhancement in the solubility of DGF and TGT, respectively. The maximum absorption wavelengths were found to be 226.0 nm for DGF and 248.0 nm for TGT. The method exhibited good linearity over the concentration ranges of 1–5 µg/mL for DGF and 2–10 µg/mL for TGT, with correlation coefficients (R^2) of 0.9964 and 0.9998, respectively. The developed method was validated according to ICH Q2(R2) guidelines. Recovery studies at 80%, 100%, and 120% levels yielded mean recoveries ranging from 98.13–98.98% for DGF and 98.59–98.98% for TGT, confirming the accuracy of the method. Precision studies demonstrated satisfactory repeatability, intermediate precision, and reproducibility, with all %RSD values below 2%. The assay of the marketed tablet formulation showed drug contents of 98.5% for DGF and 99.4% for TGT, indicating excellent agreement with the labeled claim. The developed mixed hydrotropic UV spectrophotometric method is simple, economical, environmentally friendly, and free from the use of organic solvents. It is suitable for the routine quality control analysis of Dapagliflozin and Teneligliptin in combined pharmaceutical dosage forms.

Keywords: Dapagliflozin, Teneligliptin, Mixed Hydrotropy, UV Spectrophotometry, Method Validation, Simultaneous Estimation, Solubility Enhancement, Pharmaceutical Analysis, ICH Q2(R2).
How to cite this article: Dhavade AR, Bghel DS. Simultaneous estimation of dapagliflozin (DGF) and teneligliptin (TGT) using mixed hydrotropic solubilizing agents. Int J Drug Deliv Technol. 2026;16(75s): 1344-1349. DOI: 10.25258/ijddt.16.75s.138

Introduction

Diabetes mellitus is a chronic metabolic disorder characterized by persistent hyperglycemia resulting from impaired insulin secretion, insulin action, or both (1). The increasing global prevalence of type 2 diabetes mellitus (T2DM) has become a major public health concern due to its association with serious microvascular and macrovascular complications (2). Effective glycemic control through combination therapy has emerged as an important strategy for improving therapeutic outcomes while minimizing the risk of adverse effects (3).

Dapagliflozin (DGF), a selective sodium-glucose co-transporter-2 (SGLT2) inhibitor, reduces plasma glucose levels by inhibiting renal glucose reabsorption and promoting urinary glucose excretion (4). Teneligliptin (TGT), a dipeptidyl peptidase-4 (DPP-4) inhibitor, enhances endogenous incretin activity, thereby stimulating glucose-dependent insulin secretion and suppressing glucagon release. Owing to their complementary mechanisms of action, the fixed-dose combination of DGF and TGT has gained considerable acceptance in the management of T2DM (5).

Reliable analytical methods are essential for the quality control and routine analysis of pharmaceutical formulations containing this combination. Several analytical methods, including reverse-phase high-performance liquid chromatography (RP-HPLC) (6–9), high-performance thin-layer chromatography (HPTLC) (10), and UV-visible spectrophotometry (11,12), have been reported for the determination of DGF and TGT either individually or in combination. Although chromatographic techniques provide excellent sensitivity and selectivity, they generally require expensive instrumentation, high-purity organic solvents, extensive sample preparation, and longer analysis times, limiting their routine application in laboratories with restricted resources.

UV-visible spectrophotometry offers a simple, rapid, economical, and widely accessible alternative for routine pharmaceutical analysis (13). However, the poor aqueous solubility of many drug molecules, including DGF and TGT, presents a significant challenge in developing

direct UV spectrophotometric methods. Conventionally, organic solvents such as methanol or acetonitrile are employed to improve drug solubility; nevertheless, these solvents are associated with higher costs, environmental hazards, toxicity, and disposal concerns.

Hydrotropy is an effective and environmentally friendly solubilization technique that enhances the aqueous solubility of poorly water-soluble drugs through the addition of high concentrations of hydrotropic agents (14). Mixed hydrotropy, which involves the combination of two or more hydrotropic agents, often produces a synergistic solubilizing effect while reducing the concentration required for each individual hydrotrope(15). This approach improves drug solubility without the use of organic solvents and has attracted increasing attention in pharmaceutical analysis because of its simplicity, cost-effectiveness, and compatibility with green analytical chemistry principles.

In the present investigation, different mixed hydrotropic systems were evaluated to enhance the solubility of Dapagliflozin and Teneligliptin. A combination of 2 M sodium gluconate and 2 M ammonium acetate (1:1, v/v) was identified as the most suitable solvent system, providing significant solubility enhancement for both drugs while exhibiting no interference at their respective absorption maxima. Based on this optimized solvent system, a simple and reliable UV spectrophotometric method was developed for the simultaneous estimation of DGF and TGT.

The developed method was validated in accordance with the International Council for Harmonisation (ICH) Q2(R2) guidelines with respect to linearity, accuracy, precision, and assay. The proposed mixed hydrotropic UV spectrophotometric method provides a rapid, accurate, economical, and eco-friendly alternative to conventional analytical techniques and is well suited for routine quality control analysis of Dapagliflozin and Teneligliptin in combined pharmaceutical dosage forms.

Material and Methods

Material

Dapagliflozin (DGF) and Teneligliptin (TGT) reference standards were obtained as gift samples from a reputed pharmaceutical manufacturer. The marketed tablet formulation containing both drugs was procured from a local pharmacy. Sodium gluconate, ammonium acetate, urea, and sodium acetate used as hydrotropic agents were of analytical reagent (AR) grade. Distilled water was used throughout the study for the preparation of solutions. All chemicals and reagents employed in the investigation were of analytical grade and used without further purification.

Methods

Determination of solubility

The solubility of DGF and TGT was determined in various solvents at room temperature (25 ± 1°C). Accurately weighed 10 mg of each drug was transferred separately into 10 mL volumetric flasks containing different solvents. The flasks were placed on a mechanical shaker and agitated for 8 h to attain equilibrium. After completion of shaking, the solutions were filtered through Whatman filter paper No. 41 to remove any undissolved drug. The filtrates were suitably diluted with the respective solvent and visually examined for solubility. The solubility of DGF and TGT in different solvents was recorded and compared (16).

Selection of solvent system

Dapagliflozin (DGF) and Teneligliptin (TGT) were scanned in various hydrotropic agents in the UV spectral range of 200–400 nm to identify a suitable solvent system for spectrophotometric analysis. Among the hydrotropic systems investigated, a mixture of 2 M Sodium Gluconate and 2 M Ammonium Acetate (1:1, v/v) was found to be the most suitable. This hydrotropic blend provided excellent solubility for both DGF and TGT while maintaining their stability throughout the analytical procedure.

Both drugs exhibited well-defined and distinct spectral characteristics in this medium, facilitating accurate and reproducible spectrophotometric measurements. The selected hydrotropic solution did not exhibit any interference at the respective λmax values of DGF and TGT, ensuring the specificity of the method. Furthermore, the hydrotropic system significantly enhanced the aqueous solubility of the drugs, producing more than a 25-fold increase in the solubility of Dapagliflozin and a 16.64-fold increase in the solubility of Teneligliptin. These findings demonstrate that the selected hydrotropic solvent system is highly suitable for the simultaneous UV spectrophotometric estimation of DGF and TGT.

Linearity range and calibration graph

Preparation of Standard Stock Solution (Stock-A)

Standard stock solutions were prepared by dissolving separately 10mg of each drug in 8mL mixed hydrotropic solution containing 2 M Sodium Gluconate : 2 M Ammonium Acetate (1:1) andtheflaskwassonicatedforabout 10mintosolubilizethedrugandthevolumewasmadeupt o 10mlwithmixed hydrotropic agent to get a concentration of 1000 µg/ml (Stock-A) for both drugs.

Preparation *of* Sub Stock Solution (Stock-B)

Aliquots of 1 ml withdrawn with help of pipette from standard stock solution Aof DGF and TGT and transferred into 10ml volumetric flask separately and diluted up to 10ml with Water that gave concentration of 100 µg/ml (Stock-B).

Preparation of Working Standard Solution

Aliquots of 0.1ml, 0.2ml, 0.3ml, 0.4ml and 0.5ml withdrawn with help of pipette from standard stock solution (Stock-B) separately in 10 ml volumetric flask and volume was made up to 10 ml with distilledwater. This gave the solutions of 1µg/ml, 2µg/ml, 3µg/ml, 4µg/ml and 5µg/ml respectively for DGF.

0.2 ml, 0.4 ml, 0.6 ml, 0.8 ml and 1.0 ml from sub stock solution (Stock-B) were taken separately in 10 ml volumetric flask and volume was made up to 10 ml with distilled water. This gave the solutions of 2µg/ml, 4µg/ml, 6µg/ml, 8µg/ml and 10µg/ml respectively for TGT.

Selection of wavelength for linearity

Solutions of 10µg/ml of DGF and 10µg/ml TGT were prepared separately. Both the solutions were scanned in the spectrum mode from 200 nm to 400 nm. The maximum absorbance of DGF and TGT was observed at 226.0 nm and 248.0 nm, respectively. DGF and TGT showed linearity in the concentration range of 1-5µg/ml and 2-10µg/ml at their respective maxima. Calibration curve was plotted, absorbance versus concentration.

Method (Simultaneous equation method)

Study of overlay spectra

Working standard solution from the standard stock solution prepared in concentration 5µg/ml of DGF and 10µg/ml of TGT were scanned in the spectrum mode over the range of 200-400 nm against RO Water as blank and the overlain spectra of the two were recorded. DGF showed an absorbance peak at 226.0 nm, whereas TGT at 248.0 nm. The overlain spectra also showed isoabsorptive points at 232.0 nm. Due to difference in absorbance maxima and having no interference with each other so both drug can be simultaneously estimated by simultaneous equation method.

Simultaneous equation method is based on the absorption of drugs (X and Y) at the wavelength maximum of the other. Two wavelengths selected for the method are 226.0 nm and 248.0 nm that are λ_{max} of DGF and TGT respectively. The absorbances were measured at the selected wavelengths and absorptivities ($A^{1\%,\ 1cm}$) for both the drugs at both wavelengths were determined as mean of five independent determinations. Concentrations in the sample were obtained by using following equations.

$$\boldsymbol{C\ DGF} = \frac{\boldsymbol{A1ay2 - A2ay2}}{\boldsymbol{ax1ay2 - ax2ay1}} \ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots \boldsymbol{Eq.(1)}$$

$$\boldsymbol{C\ TGT} = \frac{\boldsymbol{A1ax2 - A2ax2}}{\boldsymbol{ax1ay2 - ax2ay1}} \ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots \boldsymbol{Eq.(2)}$$

Where, A_1 and A_2 are absorbances of mixture at 226.0 nm and 248.0 nm respectively, ax_1 and ax_2 are absorptivities of DGF at λ_1 (226.0 i.e. λ_{max} of DGF) and λ_2 (248.0 i.e. λ_{max} of TGT) respectively and ay_1 and ay_2 are absorptivities of TGT at λ_1 and λ_2 respectively. C_{TGT} and C_{DGF} are concentrations of DGF and TGT respectively. Figurerepresenttheoverlain spectraofboththedrugsin 1:2ratioandthecriteriafor obtaining maximum precision [i.e. absorbance ratio $(A_2/A_1)/ax_2/ax_1$ and ay_2/ay_1]bythismethodwere calculatedandfoundtobeoutsidetherangeof0.1-2.0 which is satisfied for both the DGF and TGT.

Validation of simultaneous equation method (17)

Linearity

Linearity of both drugs was established by response ratios of drugs. Response ratio of drug calculated by dividing the absorbance with respective concentration. Then a graph was plotted between concentration and response ratio.

Accuracy

The accuracy of the proposed methods was assessed by recovery studies at three different levels i.e. 80%, 100%, 120%. The recovery studies were carried out by adding known amount of standard solution of DGF and TGTto preanalysed tablet solutions. The resulting solutions were then re-analysed by proposed methods. Wholeanalysisprocedurewasrepeatedtofindoutther ecoveryoftheaddeddrugsample.Thisrecoveryanalys iswasrepeated at 3 replicate of 5 concentrations levels.

Precision

Precision of the methods was studied at three level as at repeatability, intermediate precision (Day to Day and analyst to analyst) and reproducibility. Repeatability was performed by analyzing same concentration of drugs for five times. Day to Day was performed by analyzing 5 different concentration of the drug for three days in a week. The results are shown in tables.

Analysis of tablet sample

TwentymarketedtabletsofDGF and TGTwereweighedandgroundtoafinepowder; amount equal to 10mg of DGF was taken in 10 ml volumetric flask. The TGT present in this amount of tablet powder was 20mg. Then 8mlof2 M Sodium Gluconate : 2 M Ammonium Acetate (1:1) solution wasaddedandtheflaskwassonicatedforabout 10 mintosolubilizethedrugpresentintabletpowderandthe volumewasmadeuptothemarkwith hydrotropic solution.Aftersonication filtrationwas donethroughWhatmanfilter paper No. 41. Filtratewascollected and further diluted with Water to get the final concentrations of both drugs in the working range. The absorbances of final dilutions were observed at selected wavelengths and the concentrations were obtained from simultaneous equation method. The procedure was repeated for five times.

Results and Discussion

The present study was undertaken to develop and validate a mixed hydrotropic UV

spectrophotometric method for the simultaneous estimation of Dapagliflozin (DGF) and Teneligliptin (TGT). Initially, different mixed hydrotropic systems were evaluated to enhance the aqueous solubility of both drugs. As presented in Table 1, the mixed hydrotropic system comprising 2 M Sodium Gluconate and 2 M Ammonium Acetate (1:1) exhibited superior solubilization compared to 8 M Urea and 2 M Sodium Acetate (1:1). This system produced approximately 25.17-fold and 16.64-fold enhancement in the solubility of DGF and TGT, respectively, indicating its suitability as a solvent system for spectrophotometric analysis.

The UV absorption spectra of DGF and TGT were recorded in the selected hydrotropic medium. DGF exhibited a maximum absorbance λmaxat 226.0 nm, while TGT showed λmaxat 248.0 nm, as illustrated in Figure 1 and Figure 2, respectively. The overlay spectra (Figure 3) demonstrated that both drugs possessed distinct absorption maxima with minimal spectral interference, enabling their simultaneous estimation.

The developed method exhibited excellent linearity over the concentration ranges of 1–5 µg/mL for DGF and 2–10 µg/mL for TGT. The statistical parameters summarized in Table 2 revealed regression equations of Y = 0.0851X – 0.0123 for DGF and Y = 0.1007X + 0.0054 for TGT, with correlation coefficients (R^2) of 0.9964 and 0.9998, respectively. Furthermore, the response ratios remained nearly constant throughout the concentration range (Table 3), confirming compliance with the Beer–Lambert law.

The accuracy of the proposed method was assessed by recovery studies at 80%, 100%, and 120% levels. As shown in Table 4, the mean recoveries ranged from 98.13% to 98.98% for DGF and 98.59% to 98.98% for TGT. The corresponding %RSD values were all below 2%, demonstrating excellent accuracy and the absence of interference from formulation excipients.

The precision of the developed method was evaluated in terms of repeatability, intermediate precision (day-to-day and analyst-to-analyst), and reproducibility. The results summarized in Table 5 showed that the mean recoveries for both drugs ranged from 96.72% to 98.65%, while all %RSD values were below 2%, indicating that the method is highly precise, reproducible, and robust under normal laboratory conditions.

The applicability of the validated method was confirmed by the analysis of a marketed tablet formulation containing DGF and TGT. As presented in Table 6, the assay results were 98.5% for DGF and 99.4% for TGT, with low standard deviation and %RSD values, confirming the accuracy and precision of the proposed method for routine quality control analysis.

The developed mixed hydrotropic UV spectrophotometric method is simple, economical, environmentally friendly, and reliable. The use of a mixed hydrotropic solvent system effectively eliminated the need for organic solvents while significantly enhancing the aqueous solubility of both drugs. The method successfully satisfied the validation criteria recommended by ICH Q2(R2) with respect to linearity, accuracy, precision, and assay, making it suitable for routine simultaneous estimation of Dapagliflozin and Teneligliptin in pharmaceutical dosage forms.

Table 1: Results of solubility enhancement by UV VIS. Spectroscopy

S. No.	Mixed Hydrotropic System	Pure Drug in Water (10µg/mL)		With Hydrotropic Agents (10µg/mL)		Solubility Enhancement (Fold)	
		DGF	TGT	DGF	TGT	DGF	TGT
1	8 M Urea : 2 M Sodium Acetate (1:1)	0.035	0.061	0.785	0.985	22.43	16.15
2	2 M Sodium Gluconate : 2 M Ammonium Acetate (1:1)	0.035	0.061	0.881	1.015	25.17	16.64

Table 2: Statistical Parameter for Linearity of Dapagliflozin (DGF) and Teneligliptin (TGT)

Statistical Parameter	Dapagliflozin (DGF)	Teneligliptin (TGT)
Linearity range (µg/mL)	1–5 µg/ml	2–10 µg/ml
λ_{max}	226.0nm	248.0 nm
Regression Equation	Y=0.0851X-0.0123	Y=0.1007X+0.0054
Mean absorbance range	0.9964	0.9998
Standard deviation (SD) range	0.0008–0.0013	0.001–0.002
%RSD range	0.201–1.227	0.083–0.396

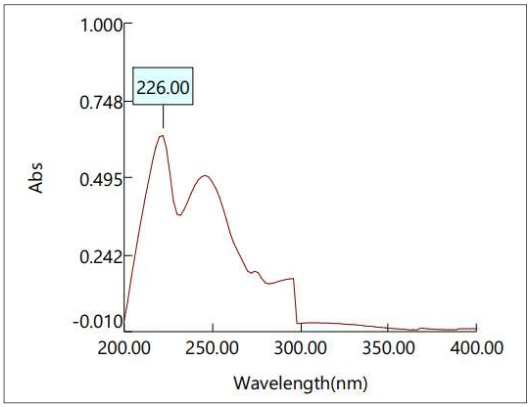

Figure 1: Determination of λ_{max} of DGF

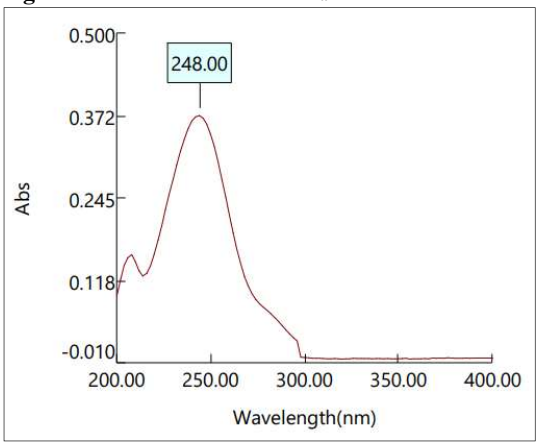

Figure 2: Determination of λ_{max} ofTGT

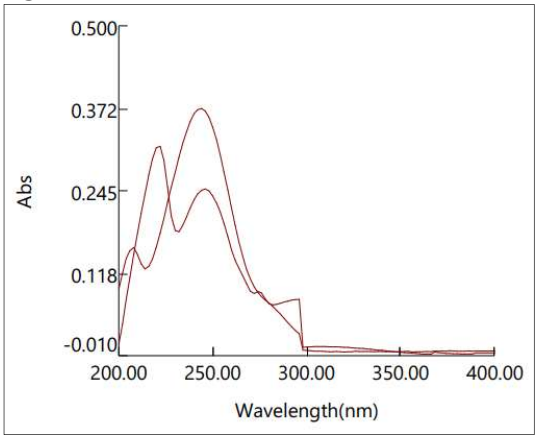

Figure 3: Overlay Spectra of DGF and TGT

Table 3: Response Ratio of Linearity of Dapagliflozin (DGF) and Teneligliptin (TGT)

S. No.	DGF			TGT		
	Conc. (µg/ml)	ABS	Response Ratio	Conc. (µg/ml)	ABS	Response Ratio
1	1	0.06	0.068	2	0.2	0.106
		82			12	
2	2	0.1464	0.073	4	0.415	0.104
3	3	0.2352	0.078	6	0.602	0.100
4	4	0.3366	0.084	8	0.813	0.102
5	5	0.4172	0.083	10	1.012	0.101

Table 4: Statistical Summary of Recovery Study of Dapagliflozin (DGF) and Teneligliptin (TGT)

Recovery Level (%)	DGF (% Recovery) Mean ± SD	%RSD	TGT (% Recovery) Mean ± SD	%RSD
80	98.25 ± 0.90	0.916	98.98 ± 0.48	0.488
100	98.13 ± 0.50	0.505	98.59 ± 0.43	0.439
120	98.98 ± 0.48	0.488	98.73 ± 1.20	1.216

Table 5: Statistical Summary of Precision Studies of Dapagliflozin (DGF) and Teneligliptin (TGT)

Precision Parameter	DGF (% Recovery, Mean ± SD)	%RSD	TGT (% Recovery, Mean ± SD)	%RSD
Repeatability	97.83 ± 0.05	1.670	97.70 ± 0.09	1.610
Intermediate Precision (Day-to-Day)	96.72 ± 0.05	1.625	97.77 ± 0.10	1.990
Intermediate Precision (Analyst-to-Analyst)	97.68 ± 0.06	1.710	98.65 ± 0.06	1.116
Reproducibility	96.96 ± 0.05	1.715	97.65 ± 0.08	1.348

Table 6: Analysis of tablet formulation of DGF and TGT

Drug	Label claim (mg)	Amount found (mg)	Label claim (%)	S.D.	% RSD
DGF	10	9.85	98.5	0.126	0.652
TGT	20	19.88	99.4	0.225	0.895

Conclusion

A simple, rapid, accurate, and eco-friendly mixed hydrotropic UV spectrophotometric method was successfully developed and validated for the simultaneous estimation of Dapagliflozin (DGF) and Teneligliptin (TGT) in tablet dosage forms. The selected hydrotropic system comprising 2 M Sodium Gluconate and 2 M Ammonium Acetate(1:1) significantly enhanced the aqueous solubility of both drugs, eliminating the need for organic solvents. The method demonstrated excellent linearity, accuracy, precision, and reproducibility in accordance with ICH Q2(R2) guidelines. The assay results confirmed its suitability for the routine quality control analysis of DGF and TGT in pharmaceutical formulations.

References

1. American Diabetes Association. Diagnosis and classification of diabetes mellitus. Diabetes Care. 2013;36(Suppl 1).
2. Dal Canto E, Ceriello A, Rydén L, Ferrini M, Hansen TB, Schnell O, et al. Diabetes as a cardiovascular risk factor: an overview of global trends of macro- and microvascular complications. Eur J PrevCardiol. 2019;26(Suppl 2):25-32.
3. Weinberg Sibony R, Segev O, Dor S, Raz I. Drug therapies for diabetes. Int J Mol Sci. 2023;24(24):17147.
4. Whaley JM, Tirmenstein M, Reilly TP, Poucher SM, Saye J, Parikh S, et al. Targeting the kidney and glucose excretion with dapagliflozin: preclinical and clinical evidence for SGLT2 inhibition as a new option for treatment of type 2 diabetes mellitus. Diabetes MetabSyndrObes. 2012;5:135-148.
5. Kishimoto M. Teneligliptin: a DPP-4 inhibitor for the treatment of type 2 diabetes. Diabetes MetabSyndrObes. 2013;6:187-195.
6. Patel K, Kachhiya T, Patel H, Tandel D, Parmar R, Gandhi T. Analytical Quality-by-Design-oriented high-performance liquid chromatographic method for quantification of metformin hydrochloride, teneligliptin hydrobromide hydrate and dapagliflozin in tablet dosage form. Sep Sci Plus. 2026;9(4).
7. Hıteksha D, Chotaliya U. Stability-indicating RP-HPLC method development and validation for simultaneous estimation of dapagliflozin propanediol monohydrate and teneligliptin hydrobromide hydrate in synthetic mixture. J Turk Chem Soc Sect A Chem. 2023;10(4):1025-1034.
8. Ponnusamy K, Manickam C. Development of a stability-indicating RP-HPLC method for the simultaneous estimation of metformin, teneligliptin and dapagliflozin in bulk and combined dosage form. J Chem Health Risks. 2026;16(2):1138.
9. Nargund SL, Nargund SL. Development and validation of RP-HPLC method for estimation of dapagliflozin propanediol monohydrate and teneligliptin hydrobromide hydrate in pharmaceutical dosage forms. Pharm Res. 2023;14(23):1113-1128.
10. Acharya H, Kotadiya R. Analytical technique advances for recently approved fixed-dose combination of dapagliflozin and teneligliptin hydrobromide hydrate. Sep Sci Plus. 2025;8(1).
11. Patel A, Jadeja P, Mashru R. Analytical method development and validation for simultaneous estimation of dapagliflozin and teneligliptin hydrobromide hydrate from synthetic mixture by three different UV spectrophotometric methods. World J Pharm Res. 2022;11(7):770-783.
12. Patel B, Prajapati KK, Koli T, Babariya D, Dave V, Patel B. Simultaneous estimation of dapagliflozin and teneligliptin hydrobromide hydrate in synthetic mixture by first-order derivative spectrophotometry. Prog Chem Biochem Res. 2025;8(3):270-277.
13. Passos ML, Saraiva ML. Detection in UV-visible spectrophotometry: detectors, detection systems, and detection strategies. Measurement. 2019;135:896-904.
14. Jain P, Goel A, Sharma S, Parmar M. Solubility enhancement techniques with special emphasis on hydrotropy. Int J Pharma Prof Res. 2010;1(1):34-45.
15. Abdullah Ali H, Kamal Omer H. Solubility enhancement of a poorly water-soluble drug using hydrotropy and mixed hydrotropy-based solid dispersion techniques. Adv Pharmacol Pharm Sci. 2022;2022:7161660.
16. Madan JR, Pawar KT, Dua K. Solubility enhancement studies on lurasidone hydrochloride using mixed hydrotropy. Int J Pharm Investig. 2015;5(2):114-120.
17. International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use. ICH harmonised guideline Q2(R2): Validation of analytical procedures. Geneva: ICH; 2023.