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A Stability-Indicating RP-HPLC Approach for Assessing Glimepiride Content in Formulations

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Abstract

This investigation reports the advancement of a robust and reliable RP-HPLC technique for the accurate quantification of glimepiride in dose form with particular emphasis on stability assessment. The technique was designed to achieve effective chromatographic separation of glimepiride from its degradants, which are commonly formed during storage. Efficient separation was attained using a C18 column with dimensions of 25 cm ,4.6 mm, 5 µm) and a movable phase comprising of acetonitrile and monobasic sodium dihydrogen phosphate of strength 20 mM buffer at pH 5 in a 60:40 ratio, pumped at a 1.0 mL/min. Identification was done at 228 nm, yielding a elution time for glimepiride of 7.214 minutes. Forced degradation studies demonstrated that glimepiride was susceptible to neutral, acidic, alkaline, hydrolytic, thermal and oxidative condition, whereas it remained stable under photolytic conditions. Method validation, conducted in accordance with regulatory guidelines, confirmed the validity of the method for routine quantification. Furthermore, the forced degradation results verified the method's degradation monitoring capability, allowing reliable estimation of glimepiride content even in the influence of degradants. In conclusion, the developed RP-HPLC technique provides a reliable analytical tool for quality assessment and stability monitoring of glimepiride drug product, thereby supporting the assurance of product quality and therapeutic integrity.

Keywords: Glimepiride; RP-HPLC; validation; Forced degradation; Stability indicating

Introduction

Diabetes mellitus is a chronic metabolic disorder marked by sustained hyperglycemia and represents a significant health concern. The condition is broadly classified into two main forms. diabetes mellitus Type 1 (T1DM) is an autoimmune disorder causing the damage of insulin synthesis beta cells in the pancreas. In contrast, diabetes mellitus Type 2 (T2DM) arises from a combination of reduced insulin sensitivity and reduced insulin release. Effective control of diabetes is crucial to reduce risk of acute complications such as hyperglycemia and to reduce the risk of long-term consequences such as cardiac disease, neuropathy, retinopathy and nephropathy. Glimepiride (GLI) is an orally administered antidiabetic drug commonly prescribed for the control of plasma glucose levels in patients with T2DM (1,2). Belonging to the sulfonylurea class, GLI (Fig. 1) is a pale yellow crystalline powder with no pronounced odor and is formulated into tablets for oral use. Its therapeutic action is primarily mediated through the activation of insulin release secreted pancreatic β cells. It attains this by binding to targeted receptors situated on these cells, resulting in the blocking of potassium channels, which in turn causes reduction in membrane potential and the subsequent entry of calcium ions. This calcium entry induces insulin release, which helps lower plasma glucose levels.

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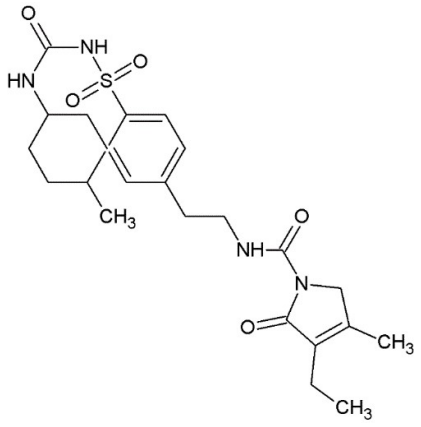

Fig. 1: Structure of GLI

Glimepiride is a potent and extended duration with blood sugar-lowering properties. It is more efficient and lasts longer than other sulfonylureas. This drug is biotransformed by CYP2C9 and exhibits agonist activity for the γ-isomer of peroxisome proliferator-activated receptor (PPAR- γ) (3,4,5).

A review of the reported research reveals that GLI has been quantified individually or combination with other drug substances using a different analytical approaches, including liquid chromatography (LC) (6,7,8) and tandem LC-MS (9,10,11). Dash et al. reported a quality by design (QbD)-based HPLC method for the estimation of GLI in a nanoemulsifying formulation (12), while Kovarikova et al. investigated its stability under hydrolytic stress conditions followed by HPLC analysis (13). According to the USP monograph, the assay for GLI is carried out using a 250 x 4.6 mm C18 column (5 µm), with a phosphate buffer (pH 2.1 - 2.7) and acetonitrile (ACN) in a 50:50 ratio, a flow rate of 1.2 mL/min, and a run time of approximately 30 minutes (14). This method, while compliant with system suitability criteria, requires relatively long analysis time and greater solvent consumption. By comparison, the present study developed an RP-HPLC method employing an Enable C18 G column (25 cm × 4.6 mm, 5 µm), with a mobile phase of monobasic sodium dihydrogen phosphate (NaH_2PO_4) 20 mM buffer of pH 5 and ACN in a 40:60 ration at 1.0 mL/min. This modification resulted in a shorter retention time of 7.48 minutes (Table 1), significantly reducing overall run time and solvent usage. In terms of sensitivity, the developed method achieved an LOD of 0.92 µg/mL and an LOQ of 2.71 µg/mL, which are adequate for quantitative determination of GLI in formulations, comparatively less sensitive than LC-MS techniques. Robustness was verified through intentional commute in flow rate, solvent system proportions, and detection wavelength, with %RSD values below 2%, desirable reliable performance under small method adjustments. Overall, the proposed method demonstrates advantages over the official USP assay in terms of speed, cost-effectiveness, and robustness, making it highly suitable for routine stability and assay analysis of GLI in pharmaceutical QC laboratories. Although the created RP-HPLC technique is robust, precise, and suitable for typical assay and stability studies, it is comparatively less sensitive than hybrid instruments such as LC–MS/MS. The isocratic approach also limits its ability to fully resolve complex impurity profiles, where gradient methods may provide superior separation. Future work will therefore focus on integrating LC–MS/MS for enhanced sensitivity and employing gradient-based approaches for comprehensive impurity characterization.

Materials and Methods

Reagents

Glimepiride (GLI) was provided as a donated sample by Synpure Labs Pvt. Ltd., India. The commercial formulation, GLIMY-2, manufactured by Dr. Reddy's Laboratories (India), was procured from a local pharmacy. Analytical grade monobasic NaH_2PO_4, sodium hydroxide (NaOH), hydrogen peroxide (H_2O_2) and hydrochloric acid (HCl) were used in the study. ACN and water were obtained from Merck, Bangalore, India.

Instrumentation

Chromatographic evaluation was done using a Shimadzu HPLC system (LC-20AD)

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equipped with a dual pump and a detector photodiode array. Sample injection was carried out using a Rheodyne injector, and data acquisition was managed through LC Solution software. UV–visible spectroscopic measurements were conducted on a Lab India spectrophotometer (India). All weighing procedures were performed using a Mettler Toledo analytical balance. The chemical structure was drawn using software ChemSketch (ACD Labs, Canada).

Chromatographic Conditions

Chromatographic analysis was done on an Enable C18 column (25 cm; 4.6 mm; 5 µm). The solvent system comprised ACN and monobasic NaH_2PO_4 20 mM buffer of pH 5 in a 60:40 ratio, pumped at a 1.0 mL/min and at 228 nm. All analyses were conducted under laboratory conditions of (25 ± 2 °C). The injector needle was washed with a mixture of ACN and water in 80:20 ratio between injections to prevent carry over.

Preparation of 20 mM monobasic sodium dihydrogen phosphate buffer (pH 5.0)

A 20 mM NaH_2PO_4 buffer (monobasic) was prepared by dissolving 2.40 g of anhydrous NaH_2PO_4 (MW 119.98) in 1 L of milli-Q water. The pH was brought to 5.0 ± 0.05 with 0.1 M NaOH/orthophosphoric acid, and the solution was processed by 0.45 µm nylon membrane filtration and degassed prior to application.

Preparation of standard solutions

An exactly weighed quantity of 25 mg of pure GLI was delivered to a 25 mL calibrated container. About 10 millimetre of ACN was incorporated, the solution was ultrasonicated for 15 mins to complete total solubilization. The volume was then adjusted with ACN to achieve the standard stock solution. From this solution, stepwise dilutions were prepared using the solvent system to yield a working standard of 30 µg/mL of GLI. Finally, the solution was passed using a nylon membrane filter.

Preparation of sample solution

A total of 100 Glimy-2 tablets (2 mg GLI) were measured and crushed in a mortar. A weighed fraction of the powdered sample, equal to 25 mg of GLI, was added a 25 mL container. Nearly 10 mL of ACN was dispensed into the container, and the solution was ultrasonicated for 12 min to obtain total solubilization. The mixture was then stepwise diluted with movable phase to yield a sample solution of 30 µg/mL. The mixture was processed through a nylon filter and tested with the HPLC system. Recovery studies were performed by spiking solution of 30 µg/mL with glimepiride standard (80%, 100%, and 120%) for confirming efficient extraction without loss

Method Validation

According to the guidelines issued by ICH and related studies (15-21), the system suitability testing and validation parameters were conducted. Method validation parameters were harmonized with ICH Q2(R1). The forced degradation and stress testing studies were aligned with ICH Q1A(R2) to confirm the stability indicating method.

Forced degradation

Degradation profile studies on the drug product (Glimy-2) were performed adhering with ICH provisions of Q1A(R2) to analyze the stability determining capability of the method (22,23,24,25,26). The formulation was subjected to acid, alkaline, peroxide, heat, and light stress conditions. For the experiments, one hundred tablets were measured and reduced to fine powder. A precisely weighed quantity corresponding to 50 mg of GLI was conveyed to a clean, dry 100 mL flask, to which 60 mL of diluent was incorporated. The mixture was ultrasonicated for 30 min to achieve total solubilization, and the final volume was adjusted with diluent. The filtered solution was subjected to degradation. The acidic hydrolysis was conducted by reflux heating in 0.01 N HCl near 65 °C for 12 h, alkaline hydrolysis by

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treating with 0.01 N NaOH at ambient temperature for 72 h, and neutral hydrolysis by heating in distilled water at 75 °C for 30 h. Oxidative stress was induced by treating the solution with 3% H_2O_2 at ambient temperature for 72 h. Heat stress was executed on solid form of the drug by placing them in a oven at 65 °C for a duration of 72 h. Effect of light was assessed by exposing both solid sample to UV light for 72 h. The stressed samples were neutralized prior to the analysis. The *mass balance* was calculated as the sum of the assay value of glimepiride and the percentage of all detected degradation products relative to the initial content. Purity angle values were consistently lower than the corresponding purity threshold values, indicating no co-eluting peaks and establishing method as stability indicating.

Results and Discussion

System Performance Study

After establishing the ideal chromatographic parameters, system suitability factors were assessed and compared against the prescribed acceptance criteria (27,28,29,30). All parameters remained inside the specified limits, confirming the adequacy of the method for analysis. Validation of method was subsequently performed as per ICH guidelines of ICH Q2(R1). UV spectral analysis revealed that GLI exhibited maximum absorbance at 228 nm. Figure 2 presents the chromatograms obtained for the standard solution and the tablet formulation sample. The optimized RP-HPLC method, characterized by more than 3000 theoretical plates and a tailing number below 1.5, indicates the system's efficiency. Additionally, the % RSD values for all parameters, including retention time, peak area, theoretical plates, and tailing number, were less than 1%, demonstrating the system's superior suitability (Table 1). The validation test outcomes are reported in (Table 2).

Linearity

Calibration curves for GLI were prepared over the range of 12.5–50 µg/mL. The regression model obtained was 15200x – 6590, with a coefficient of correlation (R^2) of 0.9992. Residual analysis indicated a random distribution of errors across the calibration range, with no evidence of heteroscedasticity. Hence, unweighted regression was considered appropriate. The linear model

Table 1: System suitability parameters

Peak	Peak time	Column efficiency	Peak Tailing	%RSD (n=6)
GLI	7.48	8754	1.167	0.89

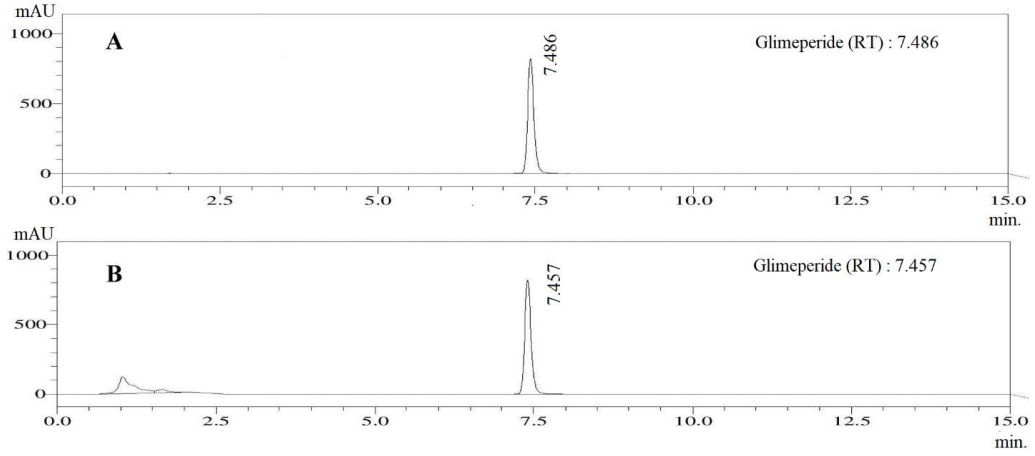

Fig. 2: Chromatogram from the standard solution of GLI(A) and Sample (B)

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analysis confirmed an good linear relationship within the studied range indicating the method's applicability for the assay of GLI in drug products.

Precision

Precision were assessed using three batches of triplicate determinations at different concentrations of GLI (12.5, 30, and 40 µg/mL) on various days. The %RSD was calculated for each set. In both the %RSD values were found to be less than 2%, indicating acceptable precision. The results are shown in (Table 3).

Table 2: Validation studies

Validation Parameters	GLI
Range	12.5-50 (µg/mL)
Coefficient determination	0.9992
Regression equation	15200x – 6590
Precision	
Repeatability(%RSD)	0.94 – 1.21
Intermediate precision (%RSD)	0.87 – 1.19
Accuracy Levels (n=3), (Mean Recovery±SD)	
80%	99.35± 0.08
100%	99.71 ± 0.10
120%	99.82 ± 0.04
Robustness (%RSD)	
Flow rate change	1.27
Mobile phase	1.34
Wavelength	1.36
LOD (µg/mL)	0.93
LOQ (µg/mL)	2.86

Accuracy

A recovery study was carried out by spiking sample solution of 30 µg/mL with a known amount of glimepiride standard at three concentration levels (80%, 100%, and 120%). For each level, analyses were executed in three replicates, and the percent recovery for GLI was calculated. The results showed recovery values ranging from 99.35% to 99.82%, all within the acceptable limits, confirming the accuracy and applicability of the method (Table 4).

Robustness

Method robustness was assessed by applying intentional small changes in analytical parameters to determine their influence on the result. The flowrate is altering between 0.90 and 1.1 mL/min, the proportion of ACN content (59 and 61 mL), and the detection at 227 and 229 nm were investigated. The results demonstrated that system performance parameters fell within the tolerance ranges despite these deliberate changes, confirming the robustness of the method.

LOD and LOQ

The LOD and LOQ were derived by means of standard deviation from the regression analysis of the calibration range for GLI. The method yielded an LOD of 0.93 µg/mL and an LOQ of 2.86 µg/mL.

Table 3: Results of precision

Concentration (µg/mL)	Condition	Replicate 1	Replicate 2	Replicate 3
LOQ (2.86), (n=3)	Precision	98.84	98.76	98.92
12.5 (n=3)	Repeatability	99.20	99.74	99.11
30 (n=3)	Repeatability	100.12	100.21	100.31
40 (n=3)	Repeatability	100.47	100.33	100.24
12.5 (n=3)	Inter. Precision	99.39	99.47	99.56
30 (n=3)	Inter. Precision	100.27	100.34	100.24
40 (n=3)	Inter. Precision	100.51	100.63	100.43

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Table 4: Accuracy data of GLI

%Conc. (at spec. Level)	Amount Added (µg/mL)	Amount Found (µg/mL)	Percent. Recovery	Mean Recovery % ± SD
80%	24	23.82	99.25	99.35± 0.08
	24	23.86	99.41	
	24	23.85	99.37	
100%	30	29.9	99.66	99.71 ± 0.10
	30	29.89	99.63	
	30	29.95	99.83	
120%	36	35.92	99.77	99.82 ± 0.04
	36	35.95	99.86	
	36	35.94	99.83	

Table 5: Analysis of LGZ in marketed product

Drug product	Label amount (mg)	Measured value (mg)	%Recovery*± SD
GLIMY-2	2.0	1.99	99.52±0.12

Solution Stability

To evaluate solution stability, both the sample formulation and standard were analyzed at intervals of 0, 12, 24, 36, and 48 h. No significant variation was observed in the chromatographic responses, and the results consistently remained within acceptable limits, with %RSD under 2%.

Assay of marketed product

The method was applied for the estimation of a pharma dosage form containing GLI as the active pharmaceutical ingredient. The mean percentage assay values indicated close agreement with the label claim (Table 5). Based on the obtained mean recovery and %RSD values. The developed technique is reliable, precise, and suitable for typical assay and stability studies in pharmaceutical quality control laboratories

Forced degradation study

The investigation subjected to degradation behavior of the formulation sample under various stress conditions was conducted using LC analysis. Results (Fig. 3) showed that in acid degradation tests, 8.28% of GLI underwent degradation. In alkaline degradation tests, 7.11% of GLI degraded. Neutral degradation tests revealed 6.16% degradation for GLI. In oxidative degradation tests, 7.43% of GLI degraded. In thermolytic degradation tests, 6.29% of GLI degraded. No notable deterioration was detected for GLI during photolytic degradation examinations. The *mass balance* was calculated as the sum of the assay value of glimepiride and the percentage of all detected degradation products relative to the initial content. Purity angle values were consistently lower than the corresponding purity threshold values, indicating no co-eluting peaks and establishing method as stability indicating. The resulting degradation experimental data is provided in (Table 6). The peak purity plots at various degradation conditions for GLI are shown in (Fig. 4). The drug is liable to degradation under acidic, basic, neutral, oxidative and thermolytic conditions but shows

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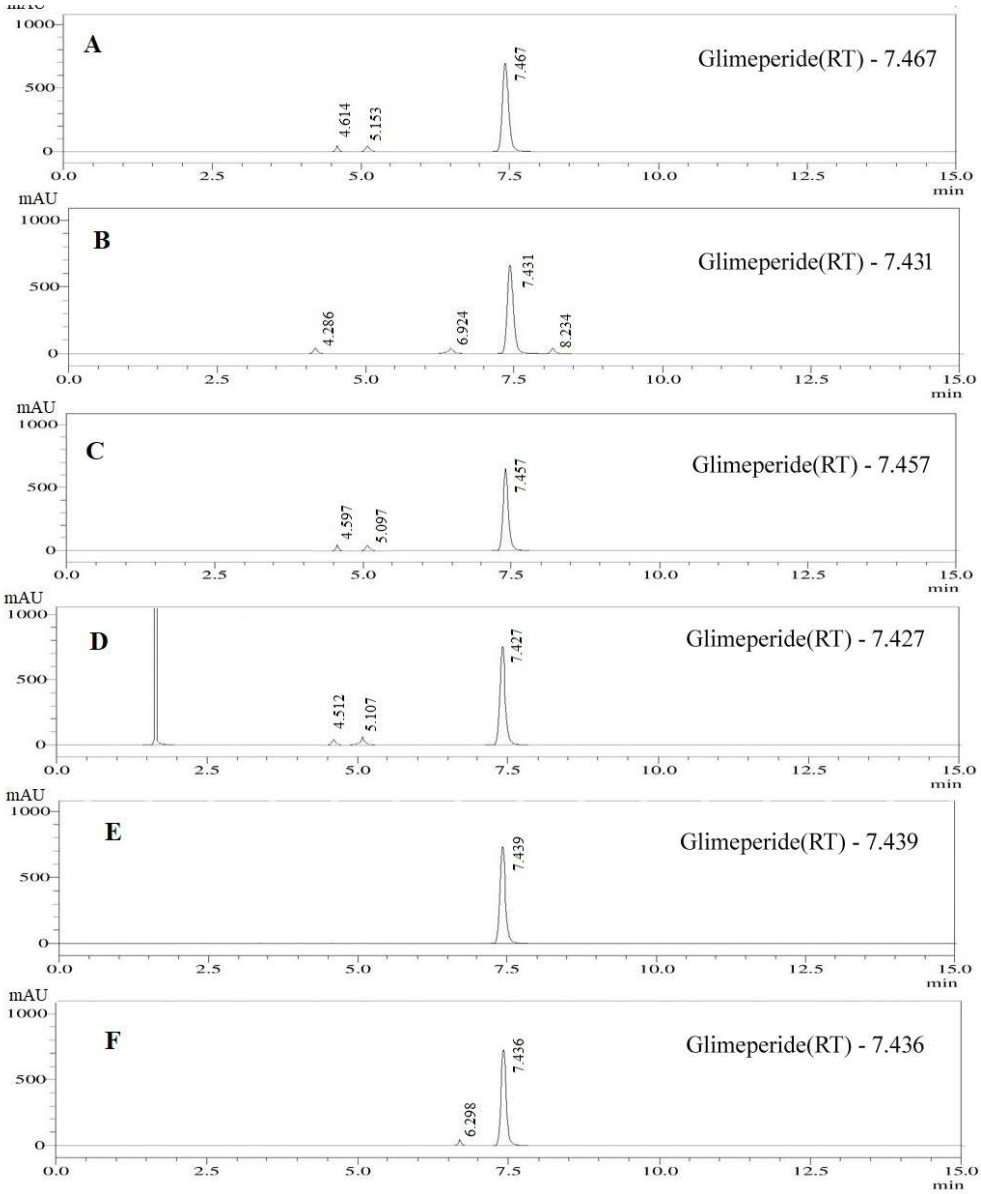

Fig. 3: The chromatograms for all degradation A) Acid induced B) Basic induced C) Neutral medium D) Oxidation medium E) Photolytic stress F) Thermal stress

stability when exposed to photolysis conditions. Through stress testing across different conditions, the method's ability to indicate stability was confirmed, enabling precise quantification of GLI content even in the presence of potential degradants. In summary, this method provides a valuable means for the regular analysis of glimepiride formulations, guaranteeing product quality and consistency.

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Table 6: Stability data				
Stress	Assay (%)	Mass Balance	Purity Angle	Purity Threshold
Acidic	91.72	99.36	0.136	0.363
Basic	92.89	98.87	0.148	0.339
Neutral	93.84	99.14	0.152	0.375
Oxidative	92.57	98.81	0.139	0.362
Photolysis	99.83	99.27	0.149	0.356
Thermal	93.71	98.53	0.154	0.377

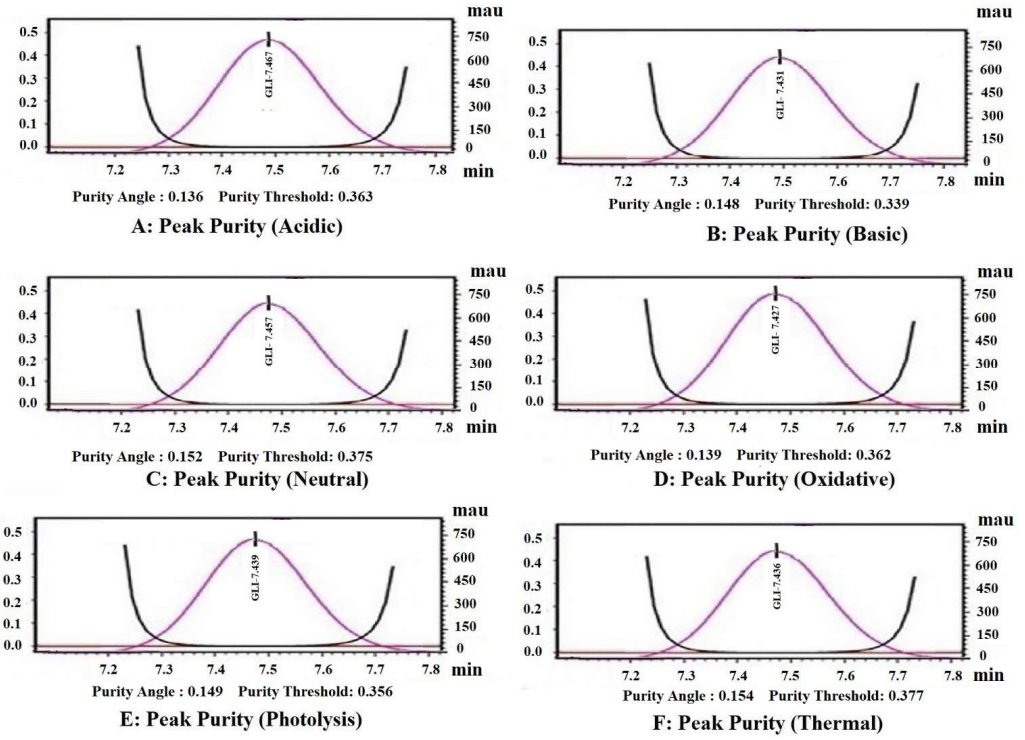

Fig. 4: Peak purity plots

Conclusion

In the present work, a robust and stability determining RP-HPLC technique was developed and validated for the assay of GLI in pharma formulations. The method demonstrated good performance in terms of validation parameters. Separation was fulfilled using a C18 column with an optimized mobile phase composition, ensuring effective resolution of GLI from its degradation products and formulation excipients. The method exhibited high sensitivity, enabling reliable detection and quantification of GLI at low levels, making it suitable for regular quality control evaluations. These studies confirmed its ability to distinctly separate GLI

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from its degradation products, thereby establishing its stability-indicating nature. This capability ensures the method's reliability for monitoring GLI stability under various stress conditions, which is essential for it's safety, efficacy and quality during the shelf life.

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Conflict of Interest

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

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