

Reverse-Phase High-Performance Liquid Chromatography Method Development and Validation for Estimation of Glimepiride in Bulk and Tablet Dosage Form

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ABSTRACT

The present work demonstrates a simple, rapid, precise, specific, and sensitive reverse-phase high-performance liquid chromatography (RP-HPLC) method for analyzing glimepiride in pure and tablet forms. The present method was developed using a C18 column 150 × 4.6 mm, with 5 μm, and packing L1 maintained at a temperature of 30°C. The mobile phase was prepared by dissolving 0.5 gram of monobasic sodium phosphate in 500 mL of distilled water, pH of the solution adjusted to 2.1 to 2.7 with 10% phosphoric acid, and added 500 mL of acetonitrile. The mobile phase was pumped in the high-performance liquid chromatography (HPLC) system at a flow rate of 1 mL/min, and separation was carried out at 228 nm, using an ultraviolet (UV) detector. The chromatographic separation was achieved with peak retention time (RT) at about 9.30 minutes, and the method was found to be linear over a concentration range of 40 to 140 μg/mL. The specificity of the method represented no interference of the excipients during the analysis, and stability testing after 24 hours also showed that the method is suitable and specific.

The accuracy was between 99.93 to 99.96%, with limit of detection (LOD) and limit of quantitation (LOQ) being 0.354 μg/mL, 1.18 μg/mL, respectively. Satisfactory results were found for precision and robustness parameters during the development and validation stage for the analytical method. The proposed method was also adopted for the analysis of glimepiride tablets to improve the overall quality control.

Using this method, symmetric peak shape was obtained with reasonable retention time. The retention time of glimepiride for six repetitions is 9.3 ± 0.1 minutes; the run time is 21 minutes.

The proposed RP-HPLC method is a modification of the United States Pharmacopeia (USP) method, and it was found to be valid for glimepiride within concentration ranges 40 to 140 μg/mL, using C18 analytical columns, and isocratic elution with UV detection, and at 1 mL/min of flow rate.

Keywords: Assay, Glimepiride, International Conference on Harmonisation (ICH), Method validation, Reverse-phase high-performance liquid chromatography (RP-HPLC).

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INTRODUCTION

Glimepiride is an oral antidiabetic molecule used in the therapeutics of diabetes mellitus type-II.¹ The molecular formula of glimepiride is C₂₄H₃₄N₄O₅S with a molecular mass of about 490.617 g/mol, and it belongs to the sulfonylurea group.² It is used either alone, or in combination with metformin for diabetic therapy as the first-line drugs.³ As per the biopharmaceutical classification system (BCS), glimepiride is a class-II (low solubility and high permeability)

drug molecule for oral administration.⁴ It is insoluble in water, slightly soluble in dichloromethane, very slightly soluble in methanol, and soluble in dimethylformamide.²⁻⁴ In acidic and neutral aqueous media, glimepiride exhibits its solubility of < 0.004 mg/mL (at 37°C), which is very poor, whereas, at pH > 7, solubility is slightly increased up to 0.02 mg/mL.^{5,6} Glimepiride acts by stimulating the functioning pancreatic beta cells to release insulin and thereby, lowering the blood glucose level in the body. It binds to Adenosine triphosphate

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(ATP) sensitive potassium ion (K^+ ion) channel receptors on the pancreatic cell surface, which reduces potassium conduction, causing depolarization of the membrane. This membrane depolarization stimulates calcium ion reflux via voltage-sensitive calcium ion channels. This increase in intracellular calcium ion (Ca^{++} ion) concentration persuades the release of insulin from beta cells.⁷ Various analytical methods have been demonstrated for the estimation of glimepiride in bulk, and dosage forms using techniques, such as, RP-HPLC, UV spectroscopy, and reverse-phase ultra-fast liquid chromatographic (RP-UFLC).⁸⁻¹¹ The present study reports a simple HPLC method for analyzing glimepiride in bulk, and tablet formulation on column 150×4.6 mm with $5 \mu\text{m}$, and packing L1 maintained at temperature 30°C . The mobile phase comprised of 0.5 gram of monobasic sodium phosphate dissolved in 500 mL of water, adjusted to pH 2.1 to 2.7 with 10% phosphoric acid, and added 500mL of acetonitrile, pumped at 1 mL/min, and detection was done at 228 nm.¹² The parameters and procedures as mentioned in International Conference on Harmonisation (ICH) guidelines for validation of analytical procedures: text and methodology Q2 (R1), were followed for validation of the proposed method.¹³

MATERIALS AND METHODS

Instrument

Method validation was accomplished on a Shimadzu make (Kyoto, Japan) HPLC system equipped with an LC 2010 with degasser, autosampler, and UV detector. Shimadzu software program installed within the computer automatically combined the peak areas and presented them in tabular form.

Chemicals and Reagents

An analytically pure sample of glimepiride was received as a gift sample from IPCA Laboratories, Mumbai, India. All the chemicals used in the method were of analytical grade. A commercial sample of Amaryl (glimepiride tablets) was purchased from the local market.

All the reagents and chemicals used in the analysis were of either pharmaceutical grade or special analytical grade. During all processes, the ultra-pure mobile phase was prepared using a Milli-Q gradient A10 system.

Preparation of Mobile Phase

Accurately weigh 500 mg of monobasic sodium phosphate and transfer to 1,000 mL volumetric flask, and 500 mL distilled water is added to it. Adjust the pH of the solution between 2.1 to 2.7 with 10% phosphoric acid. Then, add 500 mL of acetonitrile to make up the volume. This solution was kept in a cool and dark place, and used as a mobile phase.

Preparation of Standard Stock Solution

The stock solution was prepared by precisely weighing 10 mg glimepiride, transfer it to a 10 mL volumetric flask, and diluting up to the volume with the mobile phase, to obtain a concentration of $1,000 \mu\text{g/mL}$ of glimepiride. This solution was protected from light and stored at 2 to 8°C .

Preparation of Standard Solution

To prepare a standard solution of glimepiride, 10 mL of the standard stock solution was measured and transferred to a 100 mL volumetric flask, and volume was made up to 100 mL with mobile phase to get a concentration of $100 \mu\text{g/mL}$ of glimepiride.

Standard Curve Preparation

Preparation of Dilutions for Standard Curve

The standard curve within a concentration range of 1 to $10 \mu\text{g/mL}$ for glimepiride was prepared using a standard solution of glimepiride by serial dilution method. Measure 1, 2, 4, 6, 8, and 10 mL of standard solution individually, and transfer to 100 mL of volumetric flasks. Volume was makeup to 100 mL with mobile phase to get a concentration of 1, 2, 4, 6, 8, and $10 \mu\text{g/mL}$, respectively. All the prepared solutions were subjected to HPLC analysis at 228 nm, using a 150×4.6 mm column with $5 \mu\text{m}$, and packing L1 maintained at temperature 30°C , mobile phase pumped at a flow rate of 1 mL/min. The analysis was performed, and areas were recorded against the respective concentrations. The outcomes of the analysis are indicated in Figure 1 and Table 1.

Analytical Method Validation

The analytical method was validated in accordance with ICH guidelines for validation of analytical procedures Q2 (R1), for the estimation of glimepiride by evaluating the below mention parameters. The precision and repeatability of the assay were stated as relative standard deviation (RSD).

Accuracy and Precision

The precision of the analytical method is defined as the level

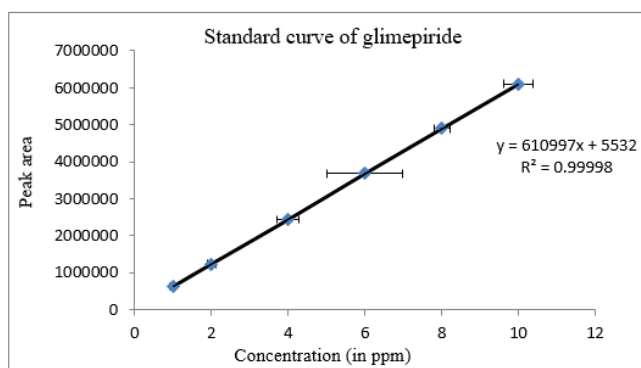


Figure 1: Calibration curve of glimepiride

Table 1: Calibration curve data of glimepiride

S. No.	Conc. in ppm	Area \pm SD
1	1	619,413 \pm 0.086
2	2	1,228,400 \pm 0.108
3	4	2,433,475 \pm 0.293
4	6	3,684,334 \pm 0.976
5	8	4,899,532 \pm 0.21
6	10	6,108,947 \pm 0.387

of agreement amongst individual test results, while the method is applied repetitively to numerous sampling of a homogenous sample. Method precision was determined by two parameters, *viz.*, repeatability, as well as, intermediate precision. Precision is represented by repeatability, when the analysis is performed under the same operating environment over a small period of time. Repeatability of the method was performed by analyzing six samples of the same concentration on the same day and under the same operating conditions. Repeatability is also called as intra-precision.

Intermediate precision (sometimes called within laboratory reproducibility) shows variation within laboratories, *i.e.*, different days, different analysts, different instruments, and more. Intermediate precision was calculated by analyzing samples of the same concentration on three different days (intermediate), and by different analysts analyzing under the same laboratory (between-analysts).

Accuracy of the method is a representative of the closeness of results to the true value. Solutions of 80, 100, and 120 $\mu\text{g}/\text{mL}$ are evaluated for accuracy, by using the proposed method to analyze the solutions equivalent to 80, 100, and 120% of standard drug concentration. Accuracy is calculated as the percentage of analysis recovery from the formulation matrix. For 80% of Standard (A) sol: Dilute 8 mL of standard solution to 10 mL with mobile phase

For 100% of Standard (A) sol: Use the prepared standard solution
For 120% of Standard (A) sol: Dissolve in the mobile phase an accurately weighed 12 mg of glimepiride, dilute the volume gradually, if necessary, with mobile phase to obtain a solution of 120 $\mu\text{g}/\text{mL}$ glimepiride concentration.

Linearity and Range

The linearity of an analytical method is the potential of the method to give test results to be proportional to the analytical concentration of a given sample. Linearity was determined by analyzing concentrations of 40, 60, 80, 100, 120, and 140% of glimepiride standard solution in the range of 40 to 140 $\mu\text{g}/\text{mL}$. Prior to injecting the solutions, the column was conditioned by flowing mobile phase through the system for at least 21 minutes. Six replicate injections (10 μL) of the standard solution were injected to confirm the repeatability of the detector response. The linearity curve was obtained by plotting the areas of the chromatograms against the corresponding concentrations of glimepiride.

For 40% of Standard (A) sol: Dilute 4 mL standard solution up to 10 mL, with mobile phase

For 60% of Standard (A) sol: Dilute 6 mL standard solution up to 10 mL, with mobile phase

For 80% of Standard (A) sol: Dilute 8 mL standard solution up to 10 mL, with mobile phase

For 100% of Standard (A) sol: Use working standard solution

For 120% of Standard (A) sol: Dissolve in the mobile phase an accurately weighed 12 mg of glimepiride, dilute the volume gradually, if necessary, with mobile phase to obtain a solution of 120 $\mu\text{g}/\text{mL}$ glimepiride concentration

For 140% of Standard (A) sol: Dissolve in the mobile phase an

accurately weighed 14 mg of glimepiride, dilute the volume gradually, if necessary, with mobile phase to obtain a solution of 140 $\mu\text{g}/\text{mL}$ glimepiride concentration

For Limit of Detection (LoD) and Limit of Quantitation (LoQ)

Quantitation LOQ were computed, as defined by the ICH guidelines, using the values of areas obtained with a concentration of 4, 6, 8, 10, 12, and 14 $\mu\text{g}/\text{mL}$ of glimepiride and plotting analytical curves of areas against the respectively, applying linear regression model. LOD and LOQ were calculated by multiplying 3.3, and 10 multiplied to the ratio of the standard deviation of the intercept and the slope.

Dilute 1 mL of each dilution of 40, 60, 80, 100, 120, and 140% of STD-A prepared as above, to 10 mL with the mobile phase.

Robustness

It is the dependability of the analysis with respect to intentional variations in method parameters. Robustness was established by analyzing the same analyte samples (100 $\mu\text{g}/\text{mL}$) under the variability of conditions in method parameters, *viz.*, the composition of mobile phase, and flow rate.

The stability of sample solutions was assessed in the mobile phase by placing the samples in an autosampler at room temperature and analyzing the same after 24 hours.

Mobile phase-I: Weight 0.5 gram of monobasic sodium phosphate and dissolve it in 500 mL of water, adjust to pH 2.1 to 2.7 with 10% phosphoric acid, and add 500 mL of acetonitrile.

Mobile phase-II: Weight 0.5 gram of monobasic sodium phosphate and dissolve it in 490 mL of water, adjust to a pH 2.1 to 2.7 with 10% phosphoric acid, and add 510 mL of acetonitrile.

Mobile phase-III: Weight 0.5 gram of monobasic sodium phosphate and dissolve it in 510 mL of water, adjust to a pH 2.1 to 2.7 with 10% phosphoric acid, and add 490 mL of acetonitrile.

System Suitability Test

System suitability check is primarily based on the concept that the system, electronics, and analytical operations, in addition to samples to be analyzed, set up an imperative system that can be assessed as a whole. The system suitability testing was performed to evaluate the resolution, repeatability (including retention time and relative standard deviation of the peaks), and tailing factor using six replicate injections of a glimepiride standard solution of 100 mcg/mL. The parameters noticed were peak retention time, peak area, theoretical plates, and tailing factor (including peak symmetry).

Analysis of Glimepiride Solution

For quantitation of glimepiride in the tablet formulations, the corresponding stock solutions were suitably diluted with the mobile phase to the required concentration (100 $\mu\text{g}/\text{mL}$), filtered, and injected. The recovery of the analyte was calculated against the reference substance.

Chromatographic Conditions

Column: C18 column (150 \times 4.6 mm ID); particle size, 5 μm ;

and pore size. To safeguard the analytical column, a security guard holder (4 × 3 mm ID) was used.

Temperature : Ambient controlled temperature (30°C)
 Mobile phase : Weight 0.5 gram of monobasic sodium phosphate and dissolve it in 500 mL of water, adjust to a pH 2.1 to 2.7 with 10% phosphoric acid and add 500mL of acetonitrile.
 Flow rate : 1 mL/min
 Wavelength : 228 nm
 Injection volume : 10 µL

Specificity

Specificity is described as the ability of the proposed method to detect precisely and specifically the analyte of interest in the presence of other excipients, which can be present in the drug formulation. The proposed method must accurately quantify the analyte/ drug of interest without the interference of impurities, degradation products, and excipients.

Solution for Specificity

For Placebo Solution

Dissolved an accurately weighed amount of placebo material (proportionate to the amount which will be present with glimepiride 10 mg) in mobile phase, and dilute stepwise and quantitatively, if necessary, with mobile phase to get a solution of known concentration of the solution (A).

Preparation of Test Solution

For the preparation of the test solution, 20 tablets were precisely weighed and grounded to a fine powder. Transfer the tablet powder equivalent to 10 mg of glimepiride to 100 mL volumetric flask, add 10 mL of distilled water to prepare a solution of approximately 0.1 mg/mL of glimepiride, shake the flask to completely dissolve the powder. Add about 70 mL of acetonitrile to the flask, and swirl. Sonicate the samples in a water bath not to exceed 20°C for Not less than (NLT) 5 minutes and Not more than (NMT) 10 minutes, with occasional shaking. Allow the solutions to come to room temperature, dilute with acetonitrile to volume, mix, and filter. The final solution (100 µg/mL) of the glimepiride was kept at 2 to 8°C away from light, filtered daily via a 0.45 mm membrane filter (Millipore), and injected, and the amount of the drug was determined by analysis against the reference substance.

Data Analysis

For the determination of glimepiride, separately inject equal volumes of the standard solution, sample solution, and test solution prepared, into the HPLC system, record the chromatograms, and measure the responses for the peaks.

Calculation:

$$\% \text{ of glimepiride} = (r_u/r_s) \times (C_s/C_u) \times 100$$

Where,

r_u = Peak area of the sample solution,

r_s = Peak area of standard solution,

C_s = Concentration of glimepiride in standard solution (in µg/mL), and

C_u = Concentration of glimepiride in the sample solution (in µg/mL).

RESULTS AND DISCUSSION

The optimized RP-HPLC method for the estimation of glimepiride was validated according to the parameters mentioned in Q2 (R1) of ICH guidelines for validation of the analytical method.

Preparation of Calibration Curve

The results of areas obtained with 1, 2, 4, 6, 8, and 10 µg/mL were plotted against the respective concentration to obtain a standard curve of glimepiride. A straight line was obtained in the graph with the value of the correlation coefficient (R^2) as 1. The results of the calibration curve are shown in Figure 1 and Table 1.

Validation of Analytical Method for Estimation of Glimepiride

Precision and Accuracy

Precision studies were performed for repeatability and inter and intra-mediate precision.

In repeatability, six samples of the 100 µg/mL concentration were evaluated on the same day, as well as, under the same

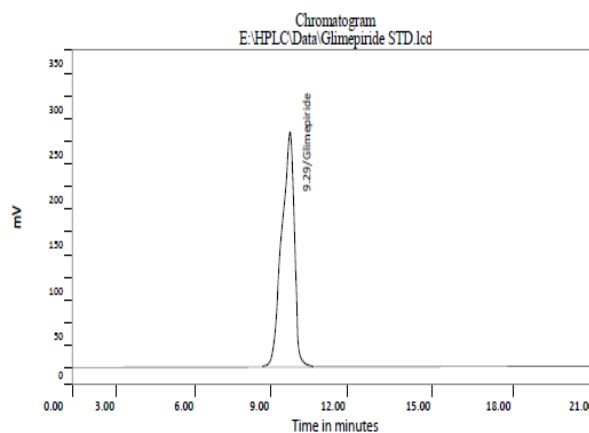


Figure 2: HPLC chromatogram for glimepiride standard solution

Table 2: Results of repeatability

Conc. (µg/mL)	Analyst 1	Average%	RSD	Analyst 2	Average%	RSD	Analyst 3	Average%	RSD
100	100.1	-	-	100.21	-	-	99.65	-	-
100	99.76	99.97	0.2	99.83	99.94	0.21	99.67	99.92	0.24
100	99.94	-	-	99.71	-	-	100.2	-	-
100	100.25	-	-	99.77	-	-	100.19	-	-
100	100.05	-	-	100.17	-	-	99.85	-	-
100	99.71	-	-	99.94	-	-	99.99	-	-

laboratory conditions (Table 2). In intermediate precision, the method was evaluated by performing the analysis on three different days (interday), using the same concentration, and for intra-precision, three analysts performed the analysis in the same laboratory (between-analysts) under the same conditions (Table 3).

In accuracy studies, drug/ analyte solutions of 80, 100, and 120 µg/mL concentrations corresponding to 80, 100, and 120% of the nominal drug concentration were analyzed (Table 4). The chromatogram obtained with 100µg/ml is shown as Figure 2.

Linearity and Range

Glimepiride solutions of concentrations ranging from 40 to 140 µg/mL were injected in six replicates into the HPLC

system. The R² was determined from the calibration plot of concentration against the peak area. The results of linearity are shown in Table 5, and the graph of correction as Figure 3.

Limit of Detection (LOD) and Limit of Quantitation (LOQ)

LOD, the lowest detectable concentration by HPLC, was found to be 0.354 µg/mL, while LOQ, the lowest concentration that could be quantified, was found to be 1.18 µg/mL. LOD and LOQ were determined by plotting a graph (Figure 4) between the area obtained against the concentration.

Robustness and Ruggedness

System robustness was assessed by applying the system suitability standards and evaluating the data generated by

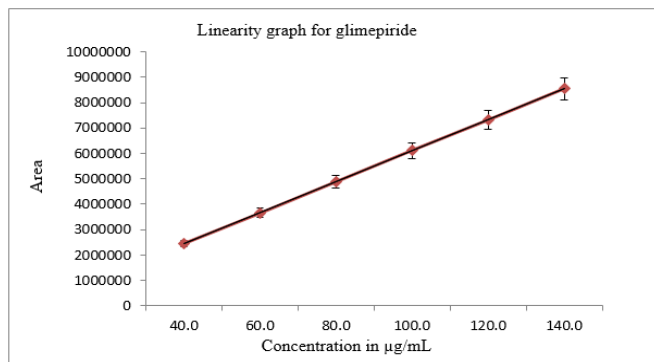


Figure 3: Graph for linearity

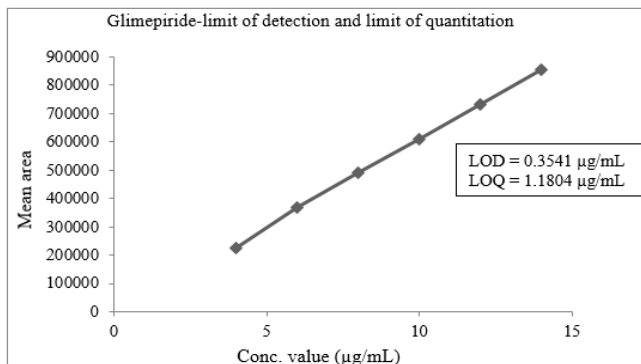


Figure 4: LOD and LOQ for glimepiride

Table 3: Results of inter- and intra-precision studies

Conc. (µg/mL)	Intraday			Interday One			Interday Two			Interday Three		
	Recovery%	Average%	RSD	Recovery%	Average%	RSD	Recovery%	Average%	RSD	Recovery%	Average%	RSD
100	99.89	-	-	100.05	-	-	99.65	-	-	99.97	-	-
100	100.19	-	-	99.84	-	-	99.85	-	-	100.17	-	-
100	99.75	99.98	0.21	99.7	99.95	0.21	100.11	99.98	0.21	99.86	99.98	0.19
100	99.75	-	-	100.22	-	-	99.95	-	-	100.25	-	-
100	100.22	-	-	100.07	-	-	100.23	-	-	99.75	-	-
100	100.06	-	-	99.91	-	-	100.05	-	-	99.87	-	-

Table 4: Results of accuracy study

Concentration of solution (µg/mL)	% mean recovery	% RSD
80	79.95	0.25
100	99.94	0.22
120	119.96	0.22

Table 5: Data for linearity studies

Sample No.	% recovery at different concentration levels					
	40%	60%	80%	100%	120%	140%
1	40.03	59.85	80.06	99.79	120.11	139.59
2	39.9	60.04	79.83	100.07	119.73	140.27
3	40.08	59.79	79.97	99.8	120.01	139.5
4	39.94	60.03	79.76	100.23	119.62	139.82
5	40.07	60.14	79.9	99.96	119.84	140.34
6	40.02	59.95	80.08	99.69	120.04	139.65
Average	40.01	59.97	79.93	99.92	119.89	139.86
RSD	0.18	0.22	0.16	0.21	0.16	0.26

Table 6: Robustness (change in flow rate)

Flow rate 0.95 mL/min (area)			Flow rate 1 mL/min (area)			Flow rate 1.05 mL/min (area)		
% recovery	Average		% recovery	Average		% recovery	Average	
100.1	99.98	6,117,859	99.97	99.93	6,110,449	99.81	99.93	6,100,315
99.81	RSD	6,100,612	99.71	RSD	6,094,206	100.09	RSD	6,117,315
100.04	0.15	6,114,182	100.1	0.2	6,118,408	99.91	0.18	6,106,318

Table 7: Change in mobile phase

Mobile phase I (initial) (area)			Mobile phase II (area)			Mobile phase III (area)		
% recovery	Average		% recovery	Average		% recovery	Average	
99.66	99.96	6,091,388	99.79	99.92	6,098,909	100.07	99.95	6,116,462
100.08	RSD	6,116,605	100.25	RSD	6,127,350	99.85	RSD	6,102,571
100.15	0.26	6,121,179	99.73	0.29	6,095,664	99.94	0.11	6,108,486

Table 8: Data for system suitability of glimepiride working standard solution

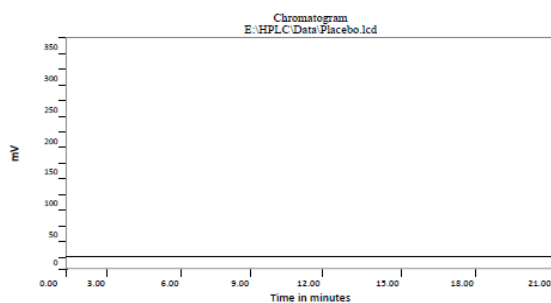
S. No.	Parameters	Active ingredient
1.	Linearity range	40–140 mcg/mL
2.	Correlation coefficient	1
3.	Slop	0.99
4.	Retention time	About 9.3 minutes
5.	Theoretical plate/ meter	More than 5,000
6.	LOD (µg/mL)	0.3541
7.	LOQ (µg/mL)	1.1804

Table 9: Data for specificity

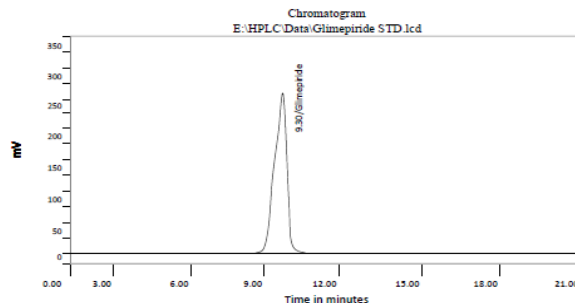
S. No.	Specificity (placebo) area	Specificity (100%)	Recovery%
1	0	4,302,422.1	99.64
2	0	4,308,283.6	99.78
3	0	4,322,387.78	100.11

Table 10: Assay data for marketed formulation

	Injection 1	Injection 2	Injection 3	Injection 4	Injection 5	Injection 6	% average	% RSD
Area	6,124,640.27	6,091,387.93	6,127,288.24	6,108,559.08	6,116,495.76	6,102,852.45	6,111,870.62	0.224
% recovery	100.21	99.66	100.25	99.94	100.07	99.85	100	



ID	RT in Minutes	Height	Area	Conc. in %	Tail.Factor	Theo.Plates	Res.
Glimepiride	0.00	0.00	0.00	0.00	0.00	0	----
Sum		0.00	0.00	0.00			

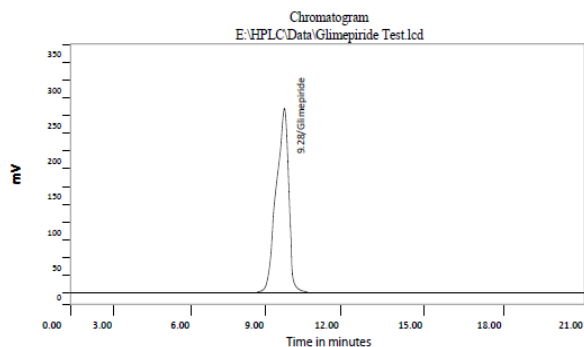


ID	RT in Minutes	Height	Area	Conc. in %	Tail.Factor	Theo.Plates	Res.
Glimepiride	9.30	270834.20	6115070.34	100.00	1.01	6598	----
Sum		270834.20	6115070.34	100.00			

Figure 5: Chromatogram for specificity placebo alone and with glimepiride

parameters of system suitability after changing the HPLC pump flow rate (± 0.05 mL) and composition of mobile phase (± 5 mL of acetonitrile). These alterations produced a change

in relative standard deviation (% RSD) and retention times of the glimepiride peak. The % recovery was more than 99% after analyzing the samples of glimepiride after 24 hours of



ID	RT in Minutes	Height	Area	Conc. in %	Tail.Factor	Theo.Plates	Res.
Glimepiride	9.28	269785.32	6091387.93	100.00	1.01	6572
Sum		269785.32	6091387.93	100.00			

Figure 6: Chromatogram for the marketed test product

preparation. The results of robustness are shown in Table 6 and Table 7.

System Suitability

The results of system suitability are shown in Table 8.

Specificity

To ascertain the specificity, a mixture of placebo was prepared by the same excipients as present in the marketed product without the active (glimepiride). The placebo injection was injected with and without glimepiride (Figure 5), to ensure the selectivity of the method for determination of glimepiride, and to check for any additional peak or presence, or interference of any other substance. Results obtained for specificity are shown in Table 9.

Assay of Test Product

The offered method was successfully applied to the analysis of marketed products (Amaryl). The results of the analysis are shown in Table 10 and chromatogram is shown in Figure 6.

CONCLUSION

The developed method offered the highest precision in quantitative chromatography of glimepiride in pharmaceutical dosage forms by RP-HPLC. The developed method is highly efficient, and it conforms to the modified system suitability test specifications of USP. The usage of the C18 column in the present method of analysis has shown better elution of analyte/drug with better resolution, plate count, and capacity factor. The present RP-HPLC method of estimation requires a simple approach for the preparation of drug samples and shorter run times for analysis (less than 21 minutes). Several samples can be concurrently and suitably analyzed for routine analysis of assay of glimepiride in bulk and tablet formulations. The proposed method does not suffer from any interference due to common excipients present in pharmaceutical preparations and

can be suitably adopted for quality control purposes for assay of glimepiride in glimepiride tablets dosage forms.

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