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RESEARCH ARTICLE
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Development of an RP-HPLC Method to estimation Glimepiride in Bulk and Solid Dosage Form

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ABSTRACT

Aim: Two straightforward and touchy RP-HPLC techniques for the quantitative estimation of Glimepiride in mass and drug portion structures have been contrived in this review.

Material & Methods: Glimepiride was resolved utilizing a RP-HPLC technique using a C-18 evenness section and a portable period of methanol: phosphate support pH 4.0 (50:50 V/V). The versatile stage was siphoned at a pace of 0.5 ml/min, and the location was done at a frequency of 239 nm.

Results: 2.470 minutes was discovered to be the retention time. Linearity, Accuracy, Precision, System Suitability, LOD, LOQ, Ruggedness, and Robustness are all validated for this approach. The proposed method is an excellent way to get accurate results and has been demonstrated to be suitable for regular Glimepiride analysis in bulk and dose forms.

Conclusion: The method was used to find out how much of a compound was included in commercial pharmaceutical dosage forms. The approach is straightforward, repeatable, and accurate, and it is a better option for routine quality control than other chromatographic techniques.

Keywords: *RP-HPLC Method, Estimation of Glimepiride, Bulk & Solid Dosage Form, Linearity, Accuracy, Precision, System suitability*

INTRODUCTION

HPLC is the most adaptable and generally utilized chromatographic procedure. It is an actual division procedure in the fluid stage where an example is isolated into its constituent parts (or analytes) by conveying between the portable stage (a streaming fluid) and the fixed stage (a fixed strong) (sorbents pressed inside a segment). A web-based identifier creates a chromatogram by checking the centralization of each isolated part in the segment gushing. For the quantitative examination of drugs, biomolecules, polymers, and other natural substances, HPLC is the most broadly utilized insightful innovation [1, 2]. HPLC works by constraining dissolvable through shut sections containing tiny particles under high tension, bringing about high goal detachments. In a scope of natural, inorganic, and organic materials, the system is utilized to isolate and decide species. The motivation behind this study is to make an UV/noticeable Spectrophotometric and RP-HPLC technique for assessing Glimepiride in mass and drug definitions [3-6].

MATERIAL & METHODS

We concocted a straightforward and delicate RP-HPLC technique for quantitative estimation of Glimepiride in mass medications and drug plans in the ongoing review.

Chromatographic system and conditions

The proposed procedure was carried out under the aforementioned chromatographic conditions.

Mobile phase selection

Glimepiride was put into the HPLC system as a pure drug and ran in various solvent systems. In order to discover the optimal conditions for the separation of Glimepiride, different portable stages, for example, methanol and water, methanol and different phosphate cushions with pH of 6, 5.5, and 3.5 were investigated. In comparison to other mobile phases, methanol and potassium dihydrogen orthophosphate buffer (pH: 4) yielded good results. At long last, methanol and phosphate cushion were demonstrated to be the best versatile stage parts (pH: 4). The medication had high resolution, a moderate retention period, and adequate peak symmetry in this mobile phase [7].

Preparation of phosphate buffer

7.0 gm KH2PO4 was weighed into a 1000 ml volumetric flask, dissolved, and diluted with HPLC water to 1000 ml. Ortho phosphoric acid was used to get the pH to 4.0 [8].

Preparation of mobile phase

Blend 500 mL of the previously mentioned cushion (half) with 500 mL of methanol HPLC (half) and degas in a ultrasonic water shower for 5 minutes. Under vacuum filtration, channel through a 0.45 channel [9].

Preparation of working standard stock solution

Around 10 mg of Glimepiride was painstakingly gauged and disintegrated in 50 ml of methanol in a 100 ml volumetric jar, then, at that point, weakened to the ideal focus with methanol. Whatman channel paper No. 41 was utilized to channel the subsequent arrangement.

Sample Solution Preparation

Twenty tablets were painstakingly pummeled and unequivocally weighted. In a 100 ml volumetric flagon containing methanol (around 50 ml), tablet powder comparable to 10 mg of Glimepiride was broken down by sonication and separated utilizing Whatman channel paper (No. 41). The filtrate was gathered by washing the channel paper with extra dissolvable. To accomplish a centralization of 100 g/ml, the filtrate volume was changed in accordance with the imprint with a similar dissolvable. Whatman channel paper was utilized to channel the resultant arrangement [10].

Columns must be cleaned

Molding of the segments was performed before to the following HPLC show to streaming HPLC grade methanol through them at a stream pace of 1 ml/min for 30 minutes. In order to erase any remainders of the earlier run that might be available in the segment.

Mobile phase loading

The pipe was filled with filtered and degassed mobile phase. Each channel was primed separately with newly prepared mobile phase.

Validated RP-HPLC method

An insightful technique's approval is the most common way of laying out through research facility examinations that the strategy's exhibition trademark meets the prerequisites for the expected logical application. Analytical parameters are used to express performance characteristics [11, 12].

Linearity

Proper aliquots of standard Glimepiride stock arrangements (100 g/ml) were set in different 10 ml volumetric flagons, and the subsequent arrangement was weakened sufficient with diluent to get a last centralization of 10-50 g/l. The chromatographic apparatus was injected with these solutions. The Glimepiride calibration curve was created by graphing peak area vs. Glimepiride applied concentration [13].

Precision

Between day and intra-day difference tests demonstrated the technique's accuracy. Six rehashed infusions of standard arrangement were done in the intra-day tests, and the reaction component of medication pinnacle and percent RSD were determined. A chromatogram was shown. Six rehashed infusions of standard arrangement were finished six successive days in the between day variety preliminaries, and the reaction component of meds pinnacle and percent RSD were figured. The made technique was viewed as exact in light of the information got [14].

Accuracy

The method's accuracy refers to how near the test findings are to the genuine value. Twenty tablets of each formulation were weighed and pulverised, and the results were analysed to see how accurate they were. Recuperation examinations were led out utilizing the standard option strategy, which included adding a known measure of standard medication answer for the example arrangement (50, 100, and 150 percent).

Limit of detection (LOD)

Utilizing the made RP-HPLC technique, the fostered strategy's Limit of Detection not entirely set in stone by infusing progressively lower measures of standard arrangements. The LOD is the analyte focus at which a perceptible reaction can be gotten (sign to commotion proportion of 3:1) [15, 16].

Limit of quantitation (LOQ)

The LOQ values were derived using a three-fold multiplication method based on the LOD strength.

Ruggedness

Glimepiride tests weighing 10 mg were gauged and broken down in a 100 ml volumetric cup containing portable stage (50 ml), then sonicated for 30 minutes prior to making the last volume with versatile stage. 3 ml of the standard stock arrangement was pipette out and saved into a 10 ml volumetric cup, which was then loaded up with versatile stage to the ideal volume. Infusions of the examples were made into the segment [15].

Robustness

Various technique boundaries, for example, pH, stream rate, segment temperature, infusion volume, and versatile stage creation, are changed inside a practical reach to test a strategy's vigor, and the quantitative impact of the not set in stone. There were no massive changes in the chromatograms, exhibiting the heartiness of the RP-HPLC strategy laid out [16].

RESULTS

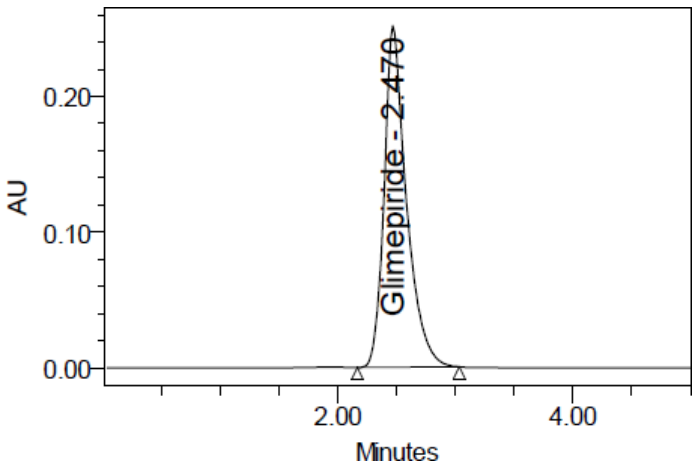

FIG 1: Standard HPLC Chromatogram of Glimepiride at 239 nm

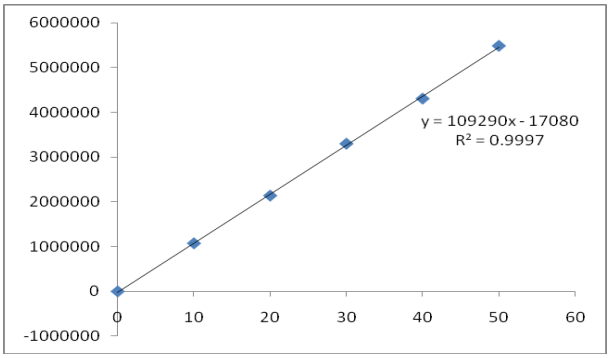

FIG 2: RP-HPLC Calibration curve of Glimepiride

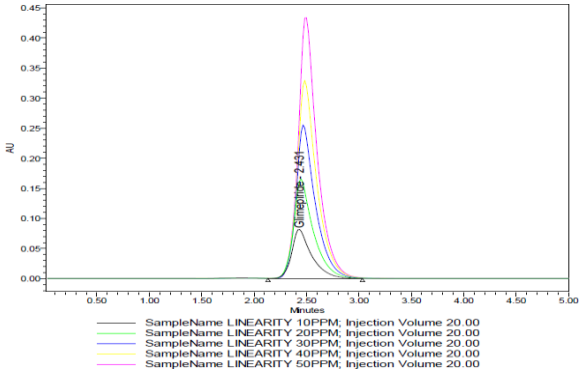

FIG 3: Overlain chromatogram of Glimepiride by RP-HPLC method

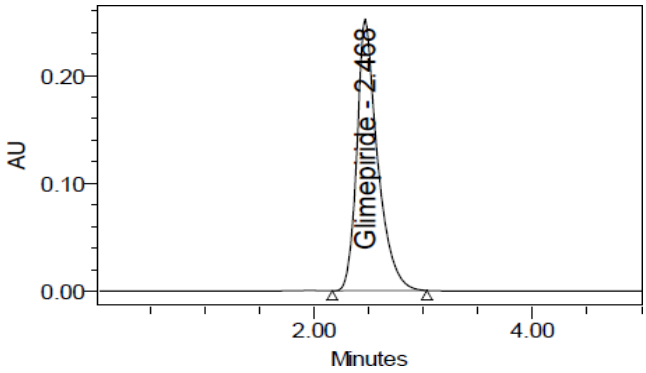

FIG 4: Chromatogram of precision

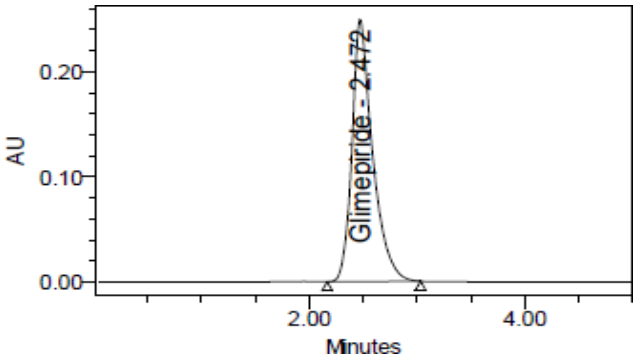

FIG 5: Chromatogram of standard drug i.e. Glimepride solution

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TABLE 1: Adjustment information of Glimepiride by RP-HPLC strategy

S. No.	Concentration (µg/ml)	Area
1	0	0
2	10	10734
3	20	21576
4	30	32967
5	40	43029
6	50	54803

TABLE 2: Glimepiride characterization parameters

Parameter	RP-HPLC
Calibration range (µg/ml)	10-50
Detection wavelength (nm)	239
Mobile phase (methanol: 0.051 M) phosphate buffer) (v/v; pH: 4.0)	50:50
Retention time (min)	2.470±0.035
Regression equation (Y*)	Y=109290 X -17080
Slope (m)	109293
Intercept (c)	-17082
Correlation coefficient (r2)	0.9961
Limit of detection (µg/ml)	0.02
Limit of quantitation (µg/ml)	0.07

TABLE 3: RP-HPLC technique precision results for Glimepiride

S. No.	Concentration (µg/ml)	Intraday	Interday
1	30	3305558	3305441
2	30	3292266	3297255
3	30	3293512	3302419
4	30	3285834	3302324
5	30	3296448	3302637
6	30	3298422	3299541
Avg.	-	3295355	3301622
SD*	-	6606.34	2836.59
%RSD*	-	0.21	0.084

TABLE 4: Glimepiride recovery data using the RP-HPLC method

Level of recovery (%)	Amount of drug added (µg)	Amount of drug Recovered (µg)*	% Recovery ± SD*
50	5	4.96	99.3±0.42
100	10	9.99	99.4±0.38
150	15	14.79	98.1±0.49

TABLE 5: Robustness studies of Glimepiride by changing the flow rate

Sl. No	Flow Rate (ml/min)	System Suitability Results		
		Plate Count	Tailing	Retention Time (tR)
1	0.4	2812	1.2	2.736
2	*0.5	2874	1.3	2.473
3	0.6	2798	1.2	2.224

TABLE 6: RP-HPLC technique was utilized to decide the roughness of Glimepiride

Samples	Label Claim (mg)	Analyst I		Analyst II	
		Amount found (mg)	% Recovery ± SD**	Amount found (mg)	% Recovery ± SD**
Amryl	1	1.0037	100.38±0.0732	1.0027	100.27± 0.0916
Glemstar	1	1.0025	100.26±0.1146	1.0024	100.24±0.0794

DISCUSSION

Due to their significance in quality control of prescriptions and medication items, the improvement of a logical technique for deciding medications by RP-HPLC has drawn in a ton of consideration lately. The objective of this work was to make a RP-HPLC technique for dissecting Glimepiride in mass drug and drug portion structure using the most normally utilized RP-C 18 section with UV discovery [17].

Each example was infused multiple times, with a 5-minute run span. 2.470 0.035 min was viewed as the maintenance time. In the fixation scope of 10-50 g/ml, when the centralizations of Glimepiride and their particular pinnacle regions were exposed to relapse examination utilizing the least squares strategy, a decent direct relationship (r2= 0.9997) was seen between the convergence of Glimepiride and their separate pinnacle regions. Glimepiride's relapse condition was found to be Y= 109290 X-17080, where 'Y' addresses the pinnacle region and 'X' addresses the grouping of Glimepiride.

In the focus scope of 10-50 g/ml, linearity was found. The coefficient of relationship (r2) was viewed as 0.9997. Accuracy was applied to the mass medicine. For intra-day and between day accuracy, the normal was taken and percent RSD was determined, yielding 0.20 and 0.086, separately. The percent RSD readings were all within two standard deviations, indicating that the procedure was accurate. Glimepiride in tablet formulations was quantified using the RP-HPLC method described in this work. Different analysts examined glimepiride tablets (containing 1 mg of the medication). We took the average area and calculated the percent accuracy. The findings are frequently within the range, i.e., 98-102 percent. Glimepiride assays were done by separate analysts on different occasions (days). The percent assay was determined, and the findings were found to be within the acceptable range, i.e., 98-102 percent [18].

The chromatograms of medication arrangement were recorded with differed stream rates like 0.4 ml/min, 0.5 ml/min, and 0.6 ml/min while keeping the portable stage proportion consistent (methanol: phosphate cushion (pH: 4) in the proportion of 50:50, v/v). The pinnacles were sharp at a stream pace of 0.5 ml/min; in any case, aside from that stream rate, the remainder of the stream still up in the air to be unacceptable. Accordingly, the stream pace of 0.5 ml/min was kept up with all through the review. The chromatograms of medication arrangement were recorded by changing portable stage proportions like methanol: phosphate support (0.051 M, pH: 4) = 60:40, 50:50, and 40:60 v/v while keeping the stream rate consistent (0.5 ml/min). The pinnacles were fresh with the portable stage (50:50 v/v methanol: phosphate cradle). For the investigation, the portable stage proportion (methanol: phosphate support, 50:50 v/v) was kept consistent [19,20].

CONCLUSION

The British Pharmacopoeia lists glimepiride as an official drug. Glimepiride is an anti-diabetic medication of the sulfonyl urea group that has a long-lasting impact and maintains a more natural regulation of insulin secretion during physical activity. The objective of this study was to create a fresher, less difficult, more exact, and more affordable HPLC strategy for deciding Glimepiride as a functioning drug fixing and in drug arrangements without impedance from different constituents in the definitions.

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