International Journal of Pharmacy and Pharmaceutical Research (IJPPR)
Volume 31, Issue 3, March 2025 **ijppr.humanjournals.com** ISSN: 2349-7203

Quantitative Spectrophotometric Estimation of Lobeglitazone and Glimepiride from the Combined Formulation by Vierordt's and Q Absorption Technique

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Received: 2025-3-05 Revised: 2025-3-16 Accepted: 2025-3-23

ABSTRACT

Present research study was focused on concurrent estimation of Lobeglitazone and Glimepiride from their combined dosage form utilizing sustainable simple solvent and common methods of UV-VIS spectrometry. Technique for the estimation of Lobeglitazone (LGZ) and Glimepiride (GMP) was developed by using solvent 0.1 N NaOH and suitable wavelengths 251 nm and 228 nm and was validated as per ICH Q 2 R1regulatory guidelines. Critical parameters were selected by studying effect of input variables on spectrum characteristics. Linearity of the drugs was ascertained over the conc range 2 to 30µg/ml and 1 to 24µg/ml for LGZ and GMP respectively. The accuracy was found within acceptable limit with standard deviation 1.8031 to 5.7134 for LGZ and 0.4759 to 2.5857 for GMP; and the assay study data was found 99.54% for LGZ and 99.78% for GMP. The stability of the method was calculated by minor variation in the wavelength, scan speed. The developed method is rigid, robust and efficient for the determination of LGZ and GMP from their combined dosage form.

Keywords : *Sustainable method, Lobeglitazone, Glimepiride, Validation, Vierordt's method, Q method*

INTRODUCTION

Due to a growing awareness of the impact of solvents on pollution, environment; sustainable solvents are a topic of growing interest in both the research community and the chemical industry. Present studies the major objective was to practice sustainable common solvent for analytical method development which facilitates approach towards environmentally safe and economical. Numerous literature article highlighted on restrict use of organic solvent in method development [1] purposely shows significance and utility of agents like hydrotropes in solubilisation of very poor water soluble drug [2, 3]. The development of eco-friendly method by avoiding organic solvent could be called as economical green method [4]. Environmental department is consistently giving pressure to minimise hazardous and volatile solvent content in the waste which seriously affects environment. Use of hydrotropic solutions, supercritical fluids in the organic synthesis curbs use of organic solvent in view point of green chemistry [5]. Hydrotropes are capable of increasing the solubility of organic compounds up to 200 times in water. In literature review it is revealed that green FT-IR method [6], eco-friendly methods [7, 8] are suitable for analytical purpose; and green analytical methods are preferred over analytical methods using harmful organic solvent for environment [9]. Drugs Lobeglitazone and glimepiride were intentionally selected for this research purpose study due to their poor water solubility [10].

Lobeglitazone chemically is 5-[(4-[2-([6-(4-Methoxyphenoxy) pyrimidin-4-yl]-methylamino) ethoxy] phenyl) methyl]-1,3-thiazolidine-2,4-dione. This drug provides a safer and more effective alternative to existing TZDs. It works similarly to pioglitazone on glycemic control but requires lower doses [11].

Literature survey revealed that few analytical methods have been reported for the estimation of LGZ alone or in combination with other anti-diabetic agents in pharmaceutical dosage form includes HPLC methods [12, 13], bio analytical HPLC method [14], with glimepiride HPLC method [15] were reviewed.

Glimepiride (GMP) is chemically 1-[[4-[2-(3-ethyl-4 methyl-2-oxo-3-pyrroline-1-carboxamido) ethyl] phenyl] sulphonyl]-3-*trans*-(4-methyl cyclo hexyl) urea [16, 17] and is oral antidiabetic II generation sulfonylurea drug promotes insulin release at ATP-sensitive potassium channels on pancreatic β-cells via binding to a 65 kDa subunits of the sulfonyl urea receptor [16] . Glimepiride act at the

molecular level primarily as insulin secratagogues that is these compounds elicit insulin secretion from pancreatic β islet cells. It is used for the treatment of type 2 diabetes mellitus and has duration of action of upto 24 Hrs [18, 19].

Various analytical methods have been reported for the estimation of GMP alone or in combination with other antidiabetic agents in pharmaceutical dosage form includes RP-HPLC methods [20-22], with ezetimibe HPLC method [23], with lobeglitazone HPLC methods [24, 25], stability indicating HPLC method with lobeglitazone[26] with metformin [27] and Densitometric detection HPTLC method [28] were reviewed. Glimepiride is official in IP and BP [17, 19] and chemical structure is shown in Fig No 1.

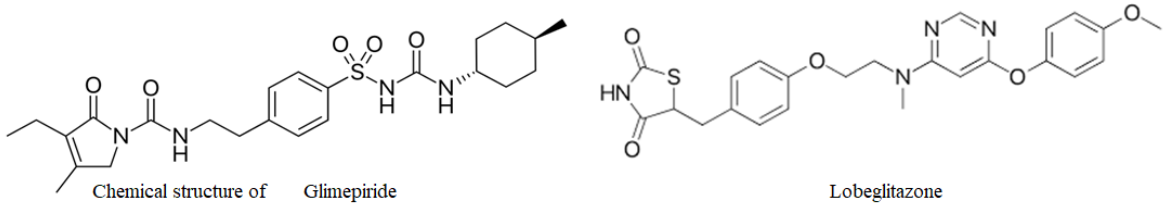

Fig No 1: Chemical structure of Drug molecule

For analytical method validation ICH Q2 (R1) has given various method performance characteristics [29, 30].

MATERIALS AND METHODS

Instrumentation

Advanced UV-1900i Shimadzu Double beam spectrophotometer (Shimadzu, Kyoto, Japan) with 1 nm spectral bandwidth, wavelength accuracy of ± 0.3 nm and 10 mm matched Quartz cells was utilised to carry out analysis. For weighing of drugs electronic balance 'Afcoset' Model No. ER 200A (The Bombay Burmah Trading corpo Ltd) with accuracy ± 0.1 mg and for degassing the solutions Digital Ultrasonic cleaner 1.8 Ltr (Labman scientific Instruments Chennai) was used.

Reagents, Chemicals and Solvent

Pharmaceutically pure samples of Lobeglitazone from Akums Drugs and Pharmaceuticals Ltd Haridwar UK and Glimepiride from BLD pharmatech Co Hyderabad were procured as a gift samples and the commercial formulation containing 0.5 mg LGZ and 1 mg GMP were procured from local market. NaOH-AR grade and laboratory distilled purified water were utilised for making the solvent.

Research article [31] was focused on techniques to be adopted while selection of suitable solvent**.** LGZ is freely soluble in DMSO and slightly soluble in water. Similarly GMP is freely soluble in DMF, DMSO, dichloromethane, and chloroform; soluble in ethanol, slightly soluble in methanol, acetone, acetonitrile and dil alkali, dil acids, practically insoluble in water [18].

Although solubility of the procured drug was studied in 0.1 N HCL, water and 0.1 N NaOH; and to understand characteristic nature of spectra each solution of known conc of analyte was scanned in UV range. The recorded spectra in these solvents are shown in (Fig No 2 and 3). It was found that both drugs have appreciable solubility in 0.1 N NaOH and greater absorbance as compare to other solvents.

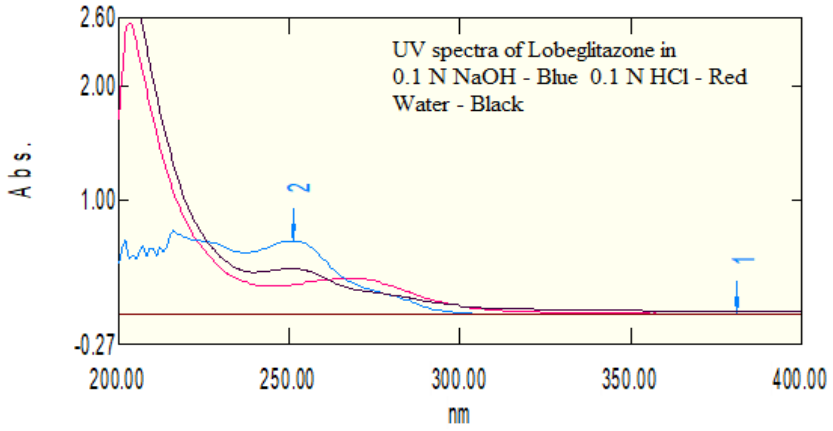

Fig 2: UV-VIS spectra of Lobeglitazone in solvent selection study

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Volume 31, Issue 3, March 2025 ijppr.humanjournals.com ISSN: 2349-7203

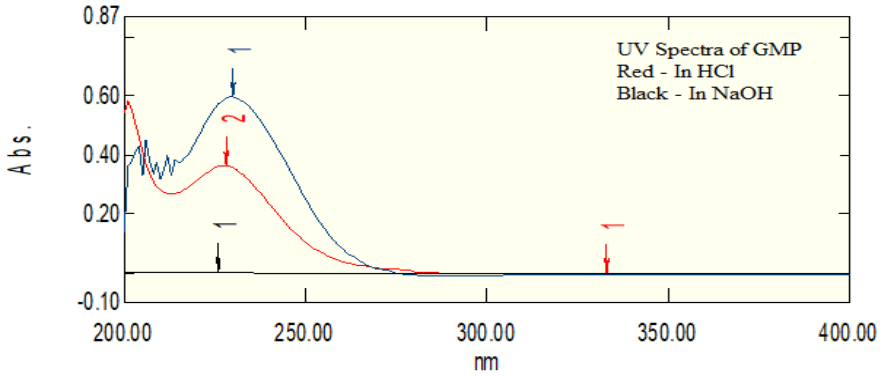

Fig 3: UV-VIS spectra of Glimepiride in solvent selection study

Selection of wavelength and conc range

From UV spectra it was found that LGZ and GMP have measurable absorbance at 251 and 228 nm respectively in 0.1 N NaOH. From the nature of spectra working conc range 2 to 30µg/ml and 1 to 24µg/ml was selected in solvent for LGZ and GMP respectively.

Above discussed observations was guided to select critical parameters listed in Table No 1 and by using these; method was validated as per ICH guidelines and by analysing marketed preparations.

Preparation of stock solutions and standard solutions

10 mg of pure drug each of LGZ and GMP were accurately and separately weighed; and transferred into separate 25 ml volumetric flask. Dissolved into 0.1 N NaOH solution and volume was made to 25 ml with solvent. Working standard solution of LGZ 12µg/ml and GMP 12µg/ml was obtained by diluting aliquot of stock solution.

Table No 1: Selected critical parameter for UV-VIS analytical method of LGZ and GMP

Parameter	Selected variables For LGZ	Selected variables For GMP
Wavelength range	400-200 nm	400-200 nm
Wavelength	251 nm	228 nm
Solvent	0.1 N NaOH	0.1 N NaOH
Scan speed	Fast	Fast
Sampling interval	± 0.2 nm	± 0.2 nm
Conc Range	2 to 30µg/ml	1 to 24µg/ml
Absorption Range	1.2 Unit	1.2 unit

Experimental Method for estimation

From the overlain spectra it was found that many approaches of multicomponent analysis are suitable for simultaneous estimation of both the drugs. Among of this Vierordt's method and absorption ratio method were selected for estimation of LGZ and GMP from the combined dosage form.

Method-I: Vierordt's method

LGZ was shown absorbance at 251 nm; and GMP has maximum absorbance at 228. At 251 nm negligible absorbance of GMP was found hence this wavelength was suitable for exclusive measurement of LGZ; and 228 nm where LGZ shows interference, which was corrected by vierordt's method. LGZ of different conc was made and absorbance measured, from 3 sets of measurement, wavelength of maximum absorbance of LGZ and GMP decided. The equation A= abc was applied for x (GMP) and y (LGZ) determination. Working standard solutions of GMP and LGZ having conc each of 10mcg/ml were separately prepared and used for the method.

The wavelength 228 and 251 nm was considered as 1 (λ_1) and 2 (λ_2) respectively. On rearranging the 2 generated equations, the conc of x and y was calculated by following formula.

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$$Cx = \frac{A2\ .ay1 - \ A1.ay2}{ax2.ay1 - \ ax1.ay2}$$

$$Cy = \frac{A1\ .ax2 - \ A2.ax1}{ax2.ay1 - \ ax1.ay2}$$

Where Cx and Cy = Conc of GMP and LGZ in sample solution

A_1 and A_2 = absorbance of sample solution at 1 and 2 wavelength

ay_1 and ay_2 = absorptivity of LGZ at 1 and 2 wavelength of standard solution

ax_1 and ax_2 = absorptivity of GMP at 1 and 2 wavelength of standard solution

Method-II Q Absorption ratio method

The absorption ratio method is modification of simultaneous equation method. It is based upon fact that the ratio of absorbances at any two wavelengths is constant value independent of conc or pathlengths. Two different dilute solutions of same drug give the same absorption ratio A_1/ A_2. Two wavelengths are being selected as λ_1 (where absorptivity of both the drug remains constant) and λ_2 (λ_{max} of one of the drug). The wavelength at which two drugs show similar absorptivity is known as iso-absorptive point (shown in the figure). There should not interference of any other component like excipients, other drug except X and Y.

The absorptivity of X Glimepiride at λ_1 and λ_2 are a_{X1} and a_{X2} respectively.

The absorptivity of Y Lobeglitazone at λ_1 and λ_2 are a_{Y1} and a_{Y2} respectively.

$$Cx = \frac{Qm - Qy}{Qx - Qy}\ \frac{A}{a\ x1} \qquad Cy = \frac{Qm - Qx}{Qy - Qx}\ \frac{A}{aY1}$$

$$Q_m = \frac{A_2}{A_1} \qquad Q_X = \frac{ax_2}{ax_1} \qquad Q_Y = \frac{aY_2}{aY_1}$$

Where

Cx and C_Y - are concentrations of LGZ and GMP respectively. (g/100 ml)

Qx - Ratio of absorptivity of LGZ at 251 and 240 nm

Q_Y - Ratio of absorptivity of GMP at 251 and 240 nm

Qm - Ratio of absorbance of sample solution at 251 and 240 nm

A - Absorbance of sample solution at Isobestic point

a_{X1}- Absorptivity of LGZ at Isobestic point

a_{Y1}- Absorptivity of GMP at Isobestic point

Validation of the Method

Selected critical parameters should meet the performance characteristics of the analytical method so as to attain analytical target profile of the method. An ICH guideline Q2 R1 was applied to study methods performance with critical parameters in order to implement part of AQbD approach. The method was validated as per ICH guidelines.

System suitability

System suitability is studied to demonstrate the suitability of the developed procedure under consideration for the analytical method. Six replicates of working standard solutions with conc16 and 12mcg/ml each of GMP and LGZ were prepared separately and absorbance was recorded, and SD and % RSD of the response was calculated.

Linearity

The linearity of an analytical method is its ability to obtain response i.e. absorbance which is directly proportional to the conc of analyte. Series of working standard solutions were prepared in conc. range of 1-24µg/ml for GMP and 2-30µg/ml for LGZ and scanned in 200 to 400 nm range in spectrum mode of the spectrophotometer, absorbance of the standard solutions were recorded at their respective wavelength; i.e. 228 for GMP and 251 nm for LGZ in spectrum order. Microsoft office excel software tool was used to obtain the standard regression curve and its analysis as slope, intercept, and correlation coefficient.

Assay of formulation

Assay was carried out by proposed methods and assay was validated by statistical parameters.

Estimation of formulations by Vierordt's and Q method

Tablets were powdered and powder equivalent to 10 mg GMP and 5 mg LGZ was weighed and transferred into 50 ml volumetric flask. Dissolved into 0.1 N NaOH and volume was made to 50ml with solvent. Solution was filtered through what man filter paper and aliquots of solution were further diluted to obtain tablet solution. Solution was scanned in the range of 200 to 400 nm to obtain absorbance of tablet solution at 228 and 251 nm in spectrum order. Also 240 nm where both drugs has constant absorptivity was selected for Q method. Obtained absorbance were utilised to estimate unknown conc of formulation; and results were statistically validated to obtain % of nominal conc, standard deviation and % of RSD.

Accuracy and Precision

The accuracy of an analytical method expresses the closeness of an agreement between test result and true result. Accuracy study was performed by recovery study i.e. standard addition method; diluted standard solutions of GMP and LGZ were prepared and standard solutions added in 80,100 and 120% proportionate to the tablet solution. Three replicates at each of these three levels were prepared and measured and % of conc, SD and RSD were calculated.

The precision study was carried out by performing assay of tablet six times; also the reproducibility in result was studied by inter day and intraday precision.

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

The LOD and LOQ of GMP and LGZ by the proposed method were determined using calibration graph method and calculated as 3.3σ/s and 10 σ/s for LOD and LOQ respectively; σ is the standard deviation of calibration curve and s is the slope of regression line.

Robustness and Ruggedness

It is measure of capacity of analytical procedure to remain unaffected by small but deliberate variations in method parameter.

RESULTS AND DISCUSSION

Method development comprises numerous steps; of which solvent selection, method for measurement selection are significant one. Uses of eco-friendly solvents have got remarkable weightage due to low cost, readily available and environmentally sound. Drugs underlying analysis must have appreciable solubility in the selected solvent. Chemical structure of the drug and physico-chemical properties available in the literature guides about use of appropriate solvent in the method. Solubility of GMP and LGZ was studied in each solvent; and in 0.1 N NaOH solvent both drugs were shown maximum and consistent absorbance as compare to other solvent.

System Suitability

The absorbances (Fig No 4) of five replicates of standard solutions (12 and 16 µg/ml) are reported in Table No 2. The SD was found for LGZ and GMP within acceptable limit and meets the system suitability requirements indicates method was suitable for analysis.

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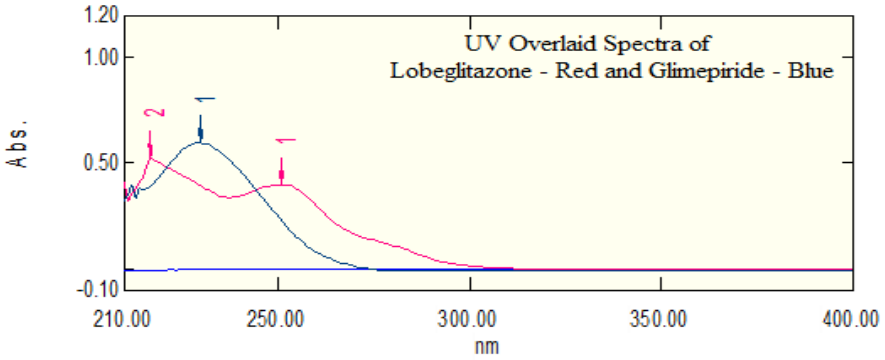

Fig 4: Overlaid spectra of LGZ and GMP in spectrum menu

Table No 2: System suitability study of LGZ and GMP

Sr No	Conc in µg /ml	Absorbance of LGZ	Conc in µg /ml	Absorbance of GMP
1	12µg /ml	0.478	16µg /ml	0.724
2	12µg /ml	0.473	16µg /ml	0.692
3	12µg /ml	0.485	16µg /ml	0.707
4	12µg /ml	0.502	16µg /ml	0.706
5	12µg /ml	0.468	16µg /ml	0.667
	SD	0.01748	SD	0.02127

Linearity

The overlay spectra obtained in linearity study was shown in Fig No 5 and 6 and the obtained calibration curve of both analytes was found to be linear in the selected conc range as shown in Fig No 7. The regression equation of line and its parameters slope, r^2 value and intercept are tabulated in Table No 3, which proved the linear relationship between conc and obtained response.

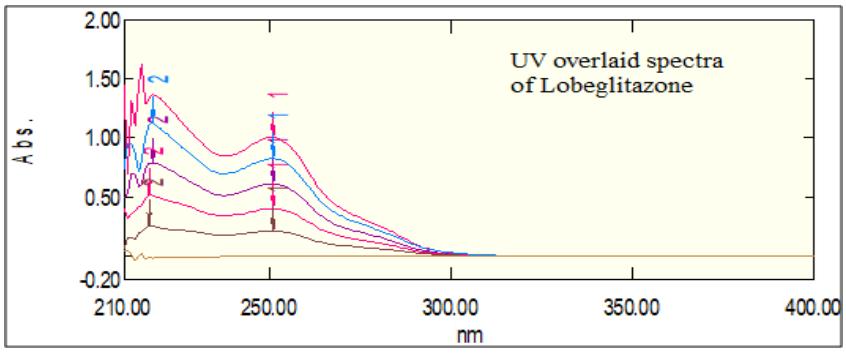

Fig 5: UV-VIS overlain spectra of LGZ in linearity study

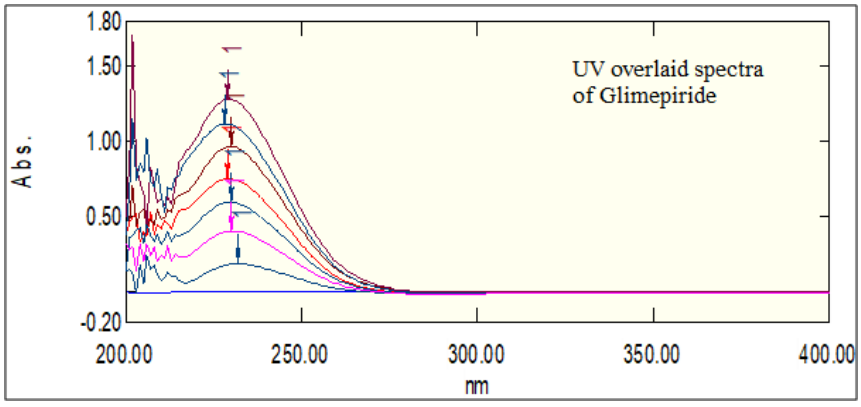

Fig 6: UV-VIS overlain spectra of GMP in linearity study

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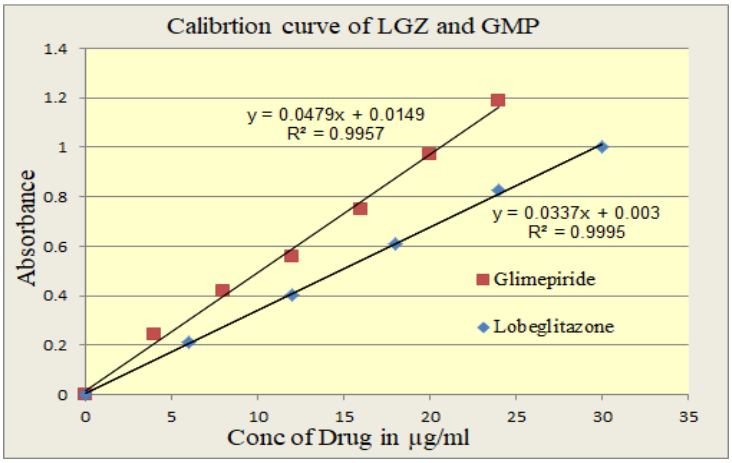

Fig 7: Calibration curve of Lobeglitazone and Glimepiride

Table No 3: Parameters of regression equation obtained in Microsoft excel office

Parameters	LGZ	GMP
Detection wavelength	251 nm	228 nm
Beer's law limit (µg/ml)	1-30µg/ml	1-24 µg/ml
Correlation coefficient (r^2)	0.9995	0.9957
Regression equation (y = mx + c)	Y=0.0337 x +0.003	Y=0.0479 x +0.0149

Assay

The assay was carried out by both the method. The spectra of formulation was obtained and calculated % of nominal conc and SD, data was found within acceptable limits are summarized in Table No 4. The results indicated applicability of the method for estimation of Formulation.

Table No 4: Results of assay of formulation by proposed method

Formulation	Drug	Label Claim (mg/Tablet)	Amount found/mg; n=6	Drug Content %	Std Deviation	% RSD
Lobg G 1 Tablet	LGZ	0.5 mg	0.4977	99.54	3.1521	3.1671
	GMP	1 mg	0.9978	99.78	4.0771	4.0861

Accuracy and Precision

The results of accuracy are summarised in Table No 5, the obtained results were within acceptable limit; and methods accuracy was justified by calculating % drug content. The precision study was carried out by performing assay of solutions; further the reproducibility in result was studied by interday and intraday precision. The values obtained SD and % RSD was shown methods precision and are summarised in Table No 6.

Table No 5: Results of accuracy

Sr No	Parameter	Level of study	Data Title	Obtd Data	S.D.	RSD
2	Accuracy study of LGZ	80%	% Purity found	103.71	1.8031	1.7385
		100%		99.41	5.7134	5.7473
		120%		99.21	3.3658	3.3929
	Accuracy study of GMP	80 %	% Purity	98.97	2.5857	2.6126
		100 %		105.94	1.2053	1.1469
		120 %		97.77	0.4759	0.4867

Table No 6: Results of precision

Sr No	Parameter	Level of study	Data Title	Obtd. Data	S.D.	RSD
1	Precision study of LGZ	Intraday Precision	Mean of Abs n= 6	103.58	0.8443	0.8152
		Interday precision		98.92	0.6175	0.6242
1	Precision study of GMP	Intraday Precision	Mean of Abs n= 6	104.71	4.7511	4.5369
		Interday precision		103.01	4.0729	3.9539

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

The LOD and LOQ of DGZ and GMP by the proposed method were found within acceptable limit.

Robustness and Ruggedness

Robustness was studied and capacity of analytical procedure to measure analyte was remain unaffected by small but deliberate variations in method parameter like variation in the wavelength ± 1 nm, variation in the solvent strength by ± 0.1 %. The analytical method was found rugged during development; similarity the result was produced by performing the analysis by different analyst.

CONCLUSION

The method was developed with eco-friendly and readily available aqueous 0.1 N NaOH solvent. Lobeglitazone and Glimepiride were estimated from the formulation by the method and satisfactory results were obtained. The Q absorption method was given reproducible results; however obtained results of the both methods were within acceptable limits given in the pharmacopoeia. The validated method is economical, precise, accurate, robust and reproducible hence can be routinely used for estimation of both the drugs from the dosage form.

CONFLICT OF INTEREST

All Authors declared that there is no conflict of interest.

ACKNOWLEDGEMENT

Authors are thankful to Akums Drugs and Pharmaceuticals Ltd Haridwar UK for supply pharmaceutically pure sample of Lobeglitazone and BLD pharmatech Co Hyderabad for supply of Glimepiride as a gift sample. Authors are thankful to Management, Principal SVPM'S College of Pharmacy Malegaon BKII Baramati Dist. Pune Maharashtra for providing facilities for research.

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International Journal of Pharmacy and Pharmaceutical Research (IJPPR)
Volume 31, Issue 3, March 2025 **ijppr.humanjournals.com** ISSN: 2349-7203

How to cite this article:
Mansi M. Kulkarni et al. Ijppr.Human, 2025; Vol. 31 (3): 493-502.

Conflict of Interest Statement: All authors have nothing else to disclose.