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Original Article

Spectroscopic Determination of Glimepiride and Linagliptin in Combined Synthetic Blends

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ABSTRACT

Background: Glimepiride along with Linagliptin have been commonly utilized in combination for treatment of type 2 diabetes mellitus. For routine analysis and quality control, it is essential to develop a straightforward, precise, as well as accurate Ultraviolet spectroscopic approach for their simultaneous quantification in synthetic mixture. **Materials and Methods:** Glimepiride and Linagliptin were developed using the Ultraviolet Spectroscopic Method at 228 and 296 nm, respectively. The absorbance correction method revealed linearity with a correlation coefficient of 0.9983 in 2-10 µg/mL concentration ranges for Glimepiride as well as 5-25 µg/mL for Linagliptin. Validation parameters, that includes accuracy, linearity, robustness, precision, specificity, along with limit of detection/quantitation, had been evaluated in accordance with International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use recommendations. **Results:** The developed approach showed excellent linearity for both drugs over selected concentration range. Accuracy and precision were within acceptable limits, confirming the reliability of the method. Specificity studies demonstrated no interference from impurities or excipients. The method was robust and reproducible, with detection and quantitation limits adequate for routine analysis. **Conclusion:** The simultaneous measurement of Glimepiride, as well as Linagliptin in their synthetic mixture, had been achieved through successful development as well as validation of a straightforward, accurate, and precise Ultraviolet spectroscopic approach. The procedure is appropriate for routine quality control and pharmaceutical analysis since it complies with International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use Q2 (R2) guidelines.

Keywords: Glimepiride, Linagliptin, Simultaneous Estimation, Synthetic Mixture, Ultraviolet Spectroscopy, Validation.

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INTRODUCTION

Diabetes has been a chronic metabolic disorder characterized through raised blood sugar levels triggered by either inadequate insulin synthesis or action, or both. It has been classified primarily into Type 1 diabetes, resulting from beta cells' autoimmune destruction that synthesize insulin, and Type 2 diabetes, which rises from insulin resistance along with inadequate insulin secretion. Diabetes is a growing global health concern, associated as well as difficulties that include neuropathy, retinopathy, cardiovascular disease, and nephropathy. Understanding its underlying mechanisms, risk factors, and effective management strategies is crucial for addressing its impact on public health (Tripathi, 2019; Beckett & Stenlake, 2007; Indian Pharmacopoeia Commission, 2022).

The oral anti-diabetic medication Glimepiride is categorized as a sulfonylurea. It mainly functions by inducing emit of insulin from pancreatic β-cells. Glimepiride accomplishes this by attaching to sulfonylurea receptors on ATP-sensitive potassium channels (K-ATP channels). As a result of the ensuing cell depolarization, calcium channels open, allowing calcium to enter and triggering the release of insulin. Glimepiride chemical structure shown in Figure 1, also promotes glucose uptake by increasing insulin sensitivity in the peripheral tissues like liver, muscles, and adipose tissue. It also lessens glucose production from liver. CYP2C9 enzyme primarily breaks down the medication in the liver before it is eliminated through urine (NCBI, 2023a).

Linagliptin chemical structure shown in Figure 2, is a reversible, competitive inhibitor of Di peptidyl peptidase-4 (DPP-4). When this enzyme is inhibited, GLP-1 along with Glucose-dependent Insulinotropic Polypeptide (GIP) break down more slowly. While Glocagon-Like Peptide-1 (GLP-1) along with Glucose-dependent Insulinotropic Polypeptide (GIP) stimulate insulin release from pancreatic β-cells, they minimize glucagon release. Together,

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these effects raise synthesis of insulin in response to glucose along with minimize breakdown of glycogen by liver (NCBI, 2023b).

The main objective behind this study to develop new, simple, specific, precise, accurate and economical analytical method for the estimation of Glimepiride and Linagliptin by using UV-visible Spectrophotometer.

To validate the developed method according to ICH Q2 (R2) Guidelines.

To apply validated method on synthetic mixture.

MATERIALS AND METHODS

The study was conducted using a double beam UV-1800 spectrophotometer (Shimadzu, Japan) to ensure accurate and precise spectral measurements. the study utilized a double beam UV-1800 spectrophotometer (Shimadzu, Japan). Samples were precisely weighed using an analytical balance (Model AP225WD, Shimadzu, Japan), and an ultrasonicate (FS 4, Frantline, India) was used to improve the solubility of the analytes. Standard and sample solutions were prepared using various volumetric flasks (10 mL, 50 mL, and 100 mL) and pipettes (1 mL, 2 mL, and 5 mL). Moreover, beakers with varying capacities (50 mL, 100 mL, 250 mL, and 500 mL) were used for managing reagents and preparing solutions. The reference standards for Glimepiride and Linagliptin were sourced from Glenmark Life Sciences Ltd. In the ultraviolet spectroscopic analysis, acetonitrile utilized as both the solvent and the diluent. The spectrophotometer was used in spectrum mode, with a scanning range of 200 to 400 nm established to record the absorbance characteristics of the analytes. To ensure precise absorbance measurements and remove any background interference, baseline correction was carried out with acetonitrile.

The standard stock solutions of Glimepiride and Linagliptin were prepared by, an accurately weighed quantity of 10 mg of each drug was transferred into a 100 mL volumetric flask. Acetonitrile was added, and the volume was adjusted appropriately. The solution underwent sonication for 15 min to ensure complete dissolution.

The selection of the analytical wavelength was performed by preparing solutions of Glimepiride and Linagliptin at concentrations of 2 µg/mL and 5 µg/mL, respectively as shown in the Figure 3. This was achieved by pipetting 0.2 mL from the standard stock solution of Glimepiride and 0.5 mL from the standard stock solution of Linagliptin into separate 10 mL volumetric flasks, followed by dilution with acetonitrile. The prepared solutions were scanned between 200 nm and 400 nm using a UV-visible spectrophotometer, with acetonitrile as the blank. The overlay spectra of both solutions were analysed, and 261 nm was identified as the isosbestic point, which was selected as the analytical wavelength for simultaneous estimation.

The binary mixture of Glimepiride and Linagliptin was prepared by, aliquots of 0.2 mL from the standard stock solution of Glimepiride and 0.5 mL from the standard stock solution of Linagliptin were transferred into a single volumetric flask. The volume was adjusted to 10 mL using acetonitrile as the diluent, resulting in a final concentration of 2 µg/mL for Glimepiride and 5 µg/mL for Linagliptin. The prepared binary mixture was used for subsequent analytical studies to evaluate the performance of the developed method.

The calibration curves for Glimepiride and Linagliptin were calculated by using standard solutions at five distinct concentration levels to ensure precision and reliability. For Glimepiride, from a standard stock solution of 100 µg/mL was prepared previously, from which aliquots of 0.2, 0.4, 0.6, 0.8, and 1.0 mL were accurately transferred into individual 10 mL volumetric flasks and subsequently diluted with acetonitrile to obtain final concentrations of 2, 4, 6, 8, and 10 µg/mL, respectively. Similarly, the calibration curve for Linagliptin was developed by pipetting aliquots of 0.5, 1.0, 1.5, 2.0, and 2.5 mL from a 100 µg/mL standard stock solution into a series of 10 mL volumetric flasks, followed by dilution with acetonitrile to achieve final concentrations of 5, 10, 15, 20, and 25 µg/mL, respectively. Each prepared solution was subjected to spectrophotometric analysis using a UV-1800 spectrophotometer, with acetonitrile serving as the blank. The absorbance values for Glimepiride were recorded at 228 nm, while those for Linagliptin were measured at 295 nm. The calibration curves were constructed by plotting absorbance against concentration, ensuring the linearity, accuracy, and robustness of the analytical method.

The absorption correction method is based on the principle of absorbance additivity, allowing for the simultaneous estimation of two components without prior separation. Subsequently, various Synthetic mixture solutions of Glimepiride and linagliptin were analysed across the full spectrum of 200 to 400 nm.

The quantitative assessment of these drugs was determined using the following formulas:

$$A = abc$$

$$C_G = A1/ab$$

$$C_G = A1/ ax1*b\ldots\ldots\ldots\ldots\ldots\ldots$$

$$A2 = A\ Glim + A\ Lina$$

$$A2 = (ay2 * C_L * b) + (ax2 * C_G * b)$$

$$A2 = (ay2 * C_L) + (ax2 * C_G)$$

$$C_L = [A2 - (ax2 * C_G)] / ay2\ldots\ldots\ldots$$

Where A1 and A2 Represent the Absorbance of the mixture at 228 nm (λ1) and 296 nm (λ2), respectively. The Parameters ax1 and ax2 denote the absorptivity of Linagliptin at λ1 and λ2, while ay1 and ay2 correspond to the absorptivity of Glimepiride at the same wavelengths. Additionally, CG and CL indicate the concentrations of Glimepiride and Linagliptin Respectively.

This method allows accurate quantification by correcting for overlapping absorbances and minimizing spectral interference. It is a simple, rapid, and cost-effective technique suitable for routine pharmaceutical analysis.

Validation of the Ultraviolet Spectroscopic Method have been performed by using different analytical validation parameters.

The proposed method's specificity was evaluated by analysing standard solutions of Glimepiride and Linagliptin to guarantee distinct identification without interference from excipients. The results confirmed that the excipients in the formulation did not significantly affect the analytical outcomes, thereby establishing the method's specificity.

Five concentration levels were used to assess linearity: Glimepiride (2-10 µg/mL) and Linagliptin (5-25 µg/mL). The calibration curves demonstrated outstanding linearity within these ranges, with a percent relative standard deviation value below 2%, confirming the method's appropriateness for quantitative analysis.

Three concentration levels were used in a recovery study involving synthetic mixtures and the standard addition method to ascertain accuracy. A weight sample of synthetic mixture equivalent to one tablet (average weight 130 mg) containing 2 mg and 5 mg of active ingredients was prepared. The resulting solution concentrations were 200 µg/mL and 500 µg/mL, respectively. These solutions was further diluted up to 10 mL. The accuracy assessment, carried out using standard addition method, showed satisfactory recovery rates, confirming the method's reliability for quantification.

Precision was assessed based on intraday and interday reproducibility. To ascertain intraday precision, three concentration levels of Glimepiride (2, 4, and 6 µg/mL) and Linagliptin (5, 10, and 15 µg/mL) were analysed in triplicate within the same day under the same spectroscopic conditions. Results are tabulated in Table 5. The assessment of interday precision involved analysing the same concentrations across three consecutive days, all the while ensuring that spectroscopic conditions remained unchanged. Results are tabulated in Table 6. The low percent relative standard deviation values obtained indicated high precision and repeatability.

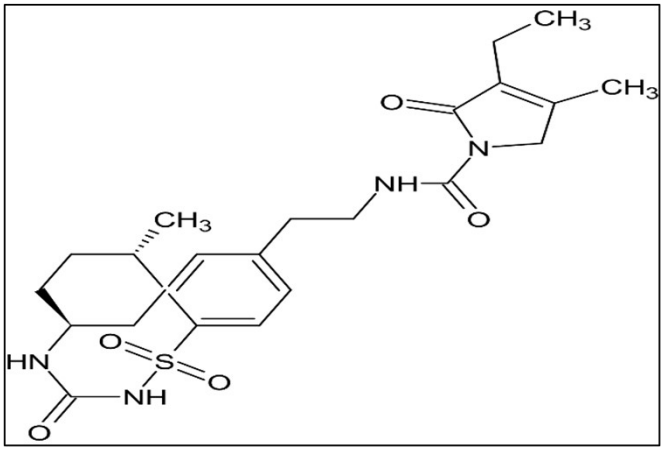

Figure 1: Chemical Structure of Glimepiride.

Using calibration curves to establish the method's sensitivity, detection and quantitation limits were set. Using the standard deviation of Y-intercepts from three calibration curves and the mean slope of those curves, the detection limit and quantitation limit were determined. The determined values validated the developed method's high sensitivity for detecting and quantifying Glimepiride and Linagliptin.

The method's robustness was assessed by making slight adjustments to the analytical conditions, especially concerning the detection wavelength. The method proved to be robust, as the analytical results were consistent despite these changes, indicating its reliability under slightly altered experimental conditions.

The validated method was successfully applied for the quantitative analysis of a synthetic mixture comprising both Glimepiride and Linagliptin.

RESULTS

Absorbance correction method Result

The absorption correction method enables the simultaneous estimation of Glimepiride and Linagliptin by eliminating spectral interference. Two specific wavelengths were selected for accurate quantification:

1. **Primary Wavelength (λ1):** At 296 nm, Linagliptin exhibits maximum absorbance, while Glimepiride shows negligible interference.

Table 1: Linearity of Glimepiride.

Conc. (µg/mL)	Mean Absorbance ± SD	%RSD
2	0.141 ± 0.00096	0.68
4	0.238 ± 0.00098	0.41
6	0.341 ± 0.00094	0.27
8	0.452 ± 0.00163	0.36
10	0.571 ± 0.00098	0.17
Correlation Coefficient	0.9983	
Regression Equation	Y= 0.0537x + 0.0264	

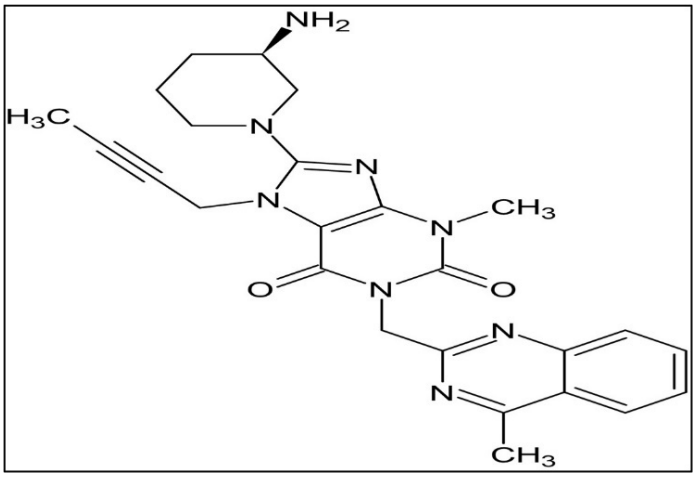

Figure 2: Chemical Structure of Linagliptin.

2. **Secondary Wavelength (λ2):** At 228 nm, both Glimepiride and Linagliptin absorb, necessitating absorbance correction.

For Glimepiride, the difference in absorbance at 228 nm and 296 nm (A {228-296}) corrects for the interference caused by Linagliptin, ensuring precise measurement. Similarly, for Linagliptin, the absorbance at 296 nm is used to determine its concentration without interference from Glimepiride.

The purpose of my study is to develop and validate innovative analytical methods that can accurately detect and quantify pharmaceutical compounds, ensuring compliance with regulatory requirements and enhancing patient safety. This research is relevant to the pharmaceutical industry, regulatory agencies, and ultimately, patients who rely on safe and effective medications.

The selection of an appropriate wavelength is fundamental in Ultraviolet spectroscopic analysis, as it ensures optimal absorbance and minimizes interference from other components. Figure 3 demonstrates the importance of this parameter, highlighting the maximum absorbance of the analytes at their respective wavelengths. The calibration curves for Glimepiride and Linagliptin, depicted in Figures 4-7, establish a direct correlation between concentration and absorbance, confirming the method's linearity and suitability for quantitative analysis.

The specificity assessment confirmed that the developed method effectively distinguished Glimepiride and Linagliptin from other potential interferences. This was achieved by analysing standard drug samples and ensuring that no overlapping peaks were present, demonstrating the method's ability to selectively quantify the target compounds.

The linearity and range were evaluated by constructing five independent calibration curves within the concentration ranges of 2-10 µg/mL for Glimepiride. Results are tabulated in Table 1 and 5-25 µg/mL for Linagliptin. Results are tabulated in Table 2, as illustrated in Figures 6 and 7. The strong correlation coefficients obtained confirm the method's reliability for accurate quantification.

Table 2: Linearity of Linagliptin.

Conc. (µg/mL)	Mean Absorbance ± SD	%RSD
5	0.2198 ± 0.00165	0.75
10	0.4333 ± 0.00112	0.25
15	0.5825 ± 0.00187	0.32
20	0.8532 ± 0.00285	0.33
25	0.9897 ± 0.00229	0.23
Correlation Coefficient	0.9982	
Regression Equation	y = 0.0392x + 0.0278	

Accuracy was assessed through recovery studies, which yielded percent recoveries between 95.33% and 98.16% for Glimepiride. Results are tabulated in Table 3, while Linagliptin exhibited recoveries ranging from 97.86% to 98.93%. Results are tabulated in Table 4. These results demonstrate the method's high accuracy, ensuring minimal deviations from true values. The precision of the method was evident in the low Relative Standard Deviation (%RSD) values obtained, reflecting consistency and reproducibility in repeated measurements.

Robustness was evaluated by analysing minor variations in experimental conditions, with %RSD values of 0.63-0.64% for Glimepiride, results are tabulated in Table 8. and 0.13-0.15% for Linagliptin, results are tabulated in Table 9. confirming the stability of the method under slight modifications.

The Detection Limit (DL) and Quantitation Limit (QL) were determined to assess the sensitivity of the method. Results are tabulated in Table 7. Additionally, the assay results revealed high purity levels for both analytes, with Glimepiride showing a percentage purity of 99.333 ± 0.0057% and Linagliptin demonstrating 99.610 ± 0.0010%, Results are tabulated in Table 10. These values indicate the method's suitability for routine pharmaceutical analysis, ensuring precise and reliable quantification of the drugs.

DISCUSSION

The development and validation of an analytical method require rigorous evaluation to ensure its suitability for pharmaceutical applications. This research is relevant to the pharmaceutical industry, regulatory agencies, and ultimately, patients who rely on safe and effective medications.

Ultraviolet spectrophotometry remains a widely utilized technique due to its simplicity, cost-effectiveness, and high sensitivity for drug quantification. The selection of an appropriate wavelength

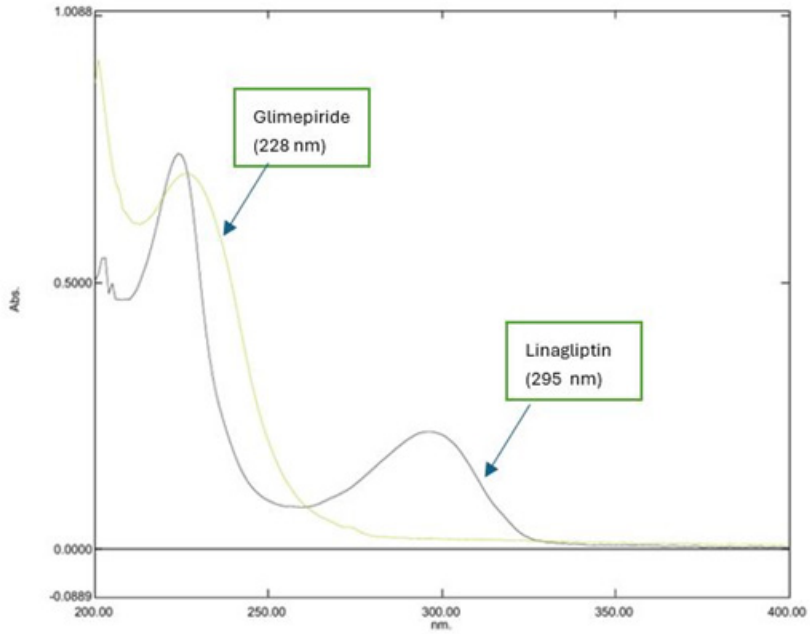

Figure 3: Selection of Wavelength (261nm).

Table 3: **Accuracy Data of Glimepiride.**

% Level	Target Conc. (µg/mL)	Std. Spiked conc. (µg/mL)	Total conc. (µg/mL)	Standard conc. (µg/mL)	% Recovery	Mean %Recovery ± SD	% RSD
50 %	2	1	3	0.97	97.00	95.33 ± 1.52	1.60
	2	1	3	0.95	95.00		
	2	1	3	0.94	94.00		
100 %	2	2	4	1.98	99.00	98.16 ± 0.76	0.77
	2	2	4	1.95	97.50		
	2	2	4	1.96	98.00		
150 %	2	3	5	2.92	97.33	98.11 ± 0.69	0.70
	2	3	5	2.95	98.33		
	2	3	5	2.96	98.66		

Table 4: **Accuracy Data of Linagliptin.**

% Level	Target Conc. (µg/mL)	Std. Spiked conc. (µg/mL)	Total conc. (µg/mL)	Standard conc. (µg/mL)	% Recovery	Mean %Recovery ± SD	% RSD
50 %	5	2.5	7.5	2.48	99.20	98.26 ± 0.8	0.84
	5	2.5	7.5	2.45	98.00		
	5	2.5	7.5	2.44	97.60		
100 %	5	5	10	4.87	97.40	97.86 ± 0.5	0.51
	5	5	10	4.89	97.80		
	5	5	10	4.92	98.40		
150 %	5	7.5	12.5	7.42	98.93	98.93 ± 0.4	0.40
	5	7.5	12.5	7.39	98.53		
	5	7.5	12.5	7.45	99.33		

Table 5: **Intraday Precision of Glimepiride and Linagliptin.**

Name of Drug	Conc. (µg/mL)	Mean Abs.± SD	%RSD
Glimepiride	2	0.3889 ± 0.00167	0.42
	4	0.5843 ± 0.00223	0.38
	6	0.7683 ± 0.00212	0.27
Linagliptin	5	0.4378 ± 0.00246	0.56
	10	0.6458 ± 0.00369	0.57
	15	0.8745 ± 0.00358	0.40

Table 6: **Interday Precision of Glimepiride and Linagliptin.**

Name of Drug	Conc. (µg/mL)	Mean Abs.± SD	%RSD
Glimepiride	2	0.3885 ± 0.00195	0.50
	4	0.5847 ± 0.00258	0.44
	6	0.7673 ± 0.00248	0.32
Linagliptin	5	0.4568 ± 0.00331	0.72
	10	0.6825 ± 0.00457	0.66
	15	0.8162 ± 0.00534	0.65

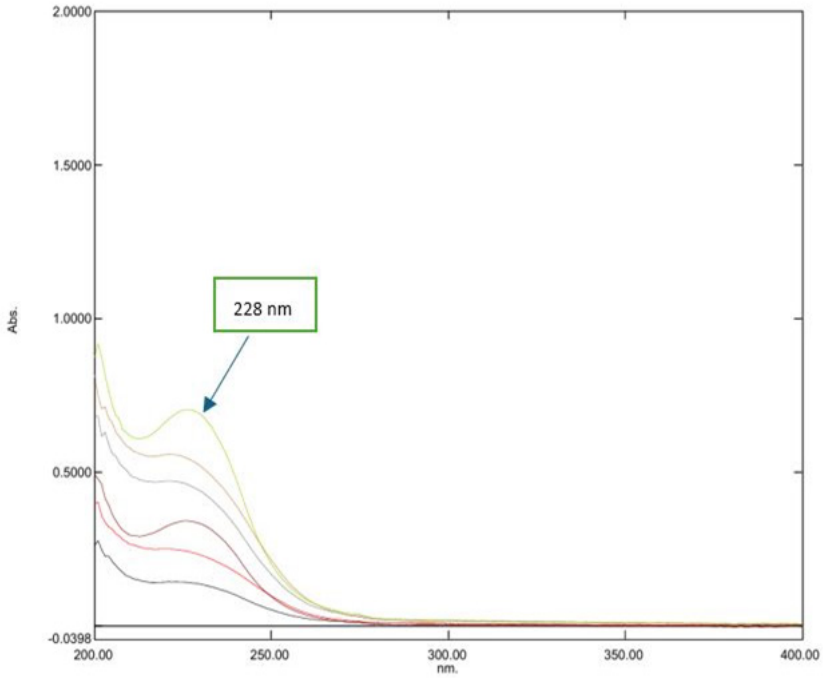

Figure 4: Overlain Spectra of Glimepiride.

plays a critical role in ensuring accurate absorbance readings and minimizing potential interferences. The maximum absorbance wavelengths chosen for Glimepiride and Linagliptin were based on their spectral characteristics, ensuring optimal detection and quantification. Wavelength selection directly influences the method's sensitivity and accuracy, as improper selection can lead to erroneous results and compromised analytical performance (Beckett & Stenlake, 2007).

The calibration curves constructed for both drugs demonstrated a linear response within the selected concentration ranges, indicating the method's robustness for quantification. A strong linear relationship is essential for ensuring that the analytical method provides consistent and proportional responses to varying concentrations. Linearity is a fundamental requirement in method validation, as it establishes the range within which the method produces reliable and reproducible results. According to International Council for Harmonisation (ICH) guidelines, a well-validated method should exhibit high linearity with correlation coefficients approaching unity (ICH, 2023). The high correlation values obtained in this study confirm the reliability of the method for quantitative analysis.

Accuracy is a crucial parameter in method validation, ensuring that the analytical technique provides results close to the true value. The recovery studies performed demonstrated excellent accuracy for both Glimepiride and Linagliptin, with percent recoveries within acceptable limits. These findings align with previous studies that emphasize the importance of accuracy in pharmaceutical analysis, as even minor deviations can impact clinical outcomes (Tripathi, 2019). The high accuracy values obtained suggest that the method can be confidently employed for routine quality control assessments in pharmaceutical formulations.

Precision, evaluated through repeatability and intermediate precision, further confirmed the method's reliability. The low

%RSD values indicate that the method produces consistent results upon repeated measurements. Precision is a key parameter in ensuring that variations in experimental conditions, such as instrument performance and analyst proficiency, do not significantly impact the results. The method's robustness was assessed by introducing slight variations in parameters, such as solvent composition and wavelength, and the results remained consistent, further supporting the method's stability. A robust method is essential for ensuring reliable results across different laboratory conditions, reinforcing its applicability in real-world scenarios (Mohan, 2019).

The determination of Detection Limit (DL) and Quantitation Limit (QL) is essential for understanding the method's sensitivity. The DL represents the lowest concentration of the analyte that can be detected but not necessarily quantified, while the QL indicates the minimum concentration that can be accurately quantified. A sensitive analytical method ensures that even trace amounts of the drug can be detected, which is particularly important for pharmacokinetic and bioavailability studies (Ojo *et al.*, 2023). The obtained values suggest that the method is highly sensitive, making it suitable for detecting low concentrations of Glimepiride and Linagliptin in pharmaceutical samples.

The assay results revealed high purity levels for both Glimepiride and Linagliptin, confirming the method's effectiveness in determining drug content in formulations. The high purity values obtained align with pharmacopeial standards, ensuring that the drugs meet regulatory requirements for safety and efficacy (Indian Pharmacopoeia Commission, 2022). Pharmaceutical assays play a crucial role in drug quality control, as they ensure that formulations contain the intended amount of active pharmaceutical ingredients. The obtained purity percentages demonstrate the method's accuracy and reliability, making it a valuable tool for pharmaceutical quality assessment.

Overall, the validated Ultraviolet spectroscopic method demonstrates excellent performance in terms of specificity, linearity, accuracy, precision, robustness, and sensitivity. These findings align with regulatory guidelines, reinforcing the method's applicability for routine pharmaceutical analysis. The ability to accurately quantify Glimepiride and Linagliptin using a simple and cost-effective spectroscopic technique highlights its potential for widespread adoption in quality control laboratories. Future research could explore further refinements, such as method optimization using advanced chemometric techniques, to enhance sensitivity and selectivity (ICH, 2023).

Comparison of Developed UV Spectroscopic Method with Existing HPLC Methods

The analytical landscape for the simultaneous estimation of Glimepiride and Linagliptin includes several HPLC methods. A notable RP-HPLC method developed by Godal *et al.*, utilizes a Shim-pack solar C_{18} column (250 mm × 4.6 mm, 5 µm) with a mobile phase composition of Acetonitrile: Methanol: Water (80:10:10 v/v/v, pH 3.0 adjusted with 1% OPA). The detection

Table 7: DL and QL of Glimepiride and Linagliptin.

Name of Drug	DL(µg/mL)	QL(µg/mL)
Glimepiride	0.16	0.38
Linagliptin	0.25	0.70

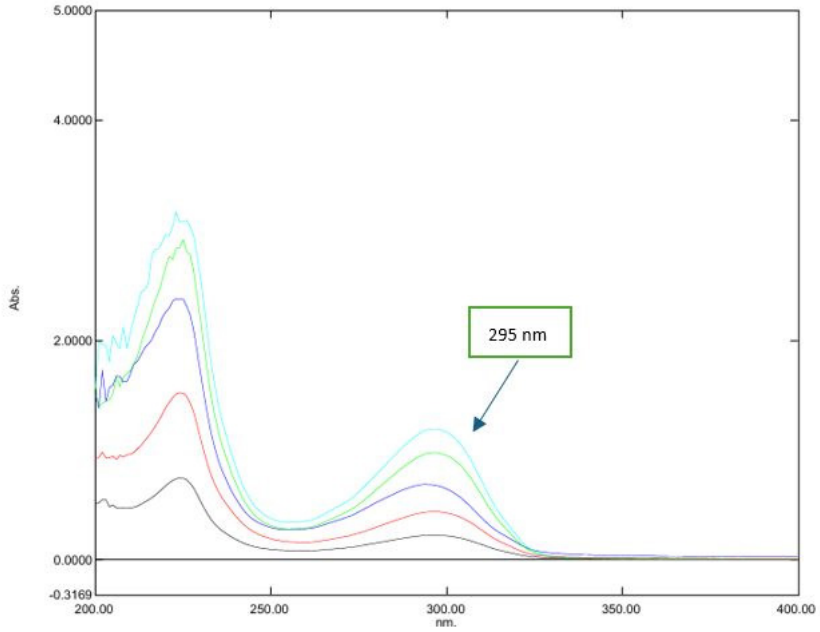

Figure 5: Overlain Spectra of Linagliptin.

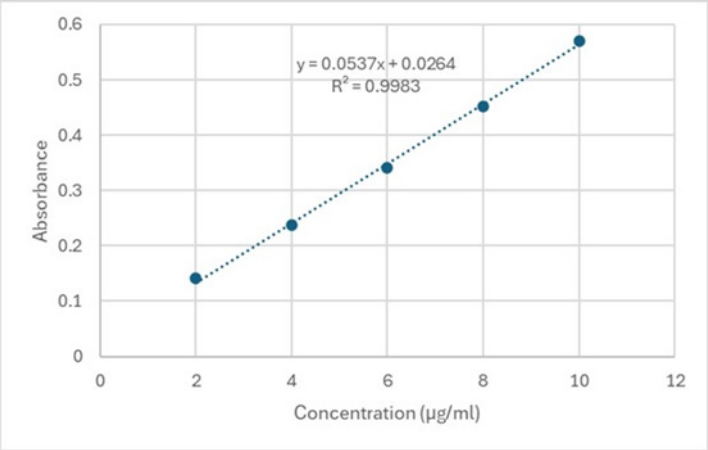

Figure 6: Calibration Curve of Glimepiride.

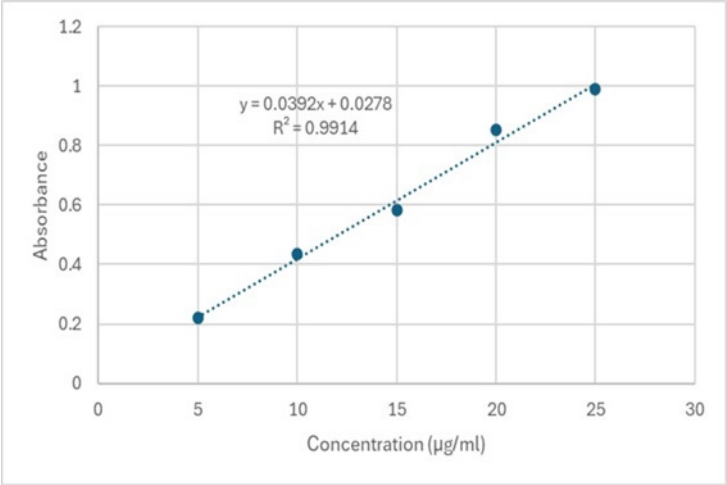

Figure 7: Calibration Curve of Linagliptin.

was performed at 228 nm, with retention times of 4.970 min for Glimepiride and 2.451 min for Linagliptin. The method exhibited excellent linearity in the range of 2-6 µg/mL for Glimepiride and 5-15 µg/mL for Linagliptin, with correlation coefficients close to 0.999. Accuracy and precision values demonstrated compliance with ICH guidelines, making this method suitable for pharmaceutical analysis. Another HPLC method, developed by Dasila *et al.*, employs Acetonitrile: Methanol: Water (35:35:30 v/v) as the mobile phase on a Hibar ODS C18 column, with detection at 245 nm. The method achieved retention times of 3.198 min for Glimepiride and 7.401 min for Linagliptin, with an LOD of 0.035 µg/mL for Glimepiride and 0.08 µg/mL for Linagliptin, and LOQ values of 0.10 µg/mL and 0.08 µg/mL, respectively.

In contrast, the developed UV spectroscopic method presents a cost-effective and rapid alternative, requiring minimal instrumentation. This method employs methanol as a solvent, with detection wavelengths at 228 nm for Glimepiride and 296 nm for Linagliptin. Linearity was observed within 2-10 µg/mL for Glimepiride and 5-25 µg/mL for Linagliptin, with correlation coefficients of 0.9983 and 0.9982, respectively. The accuracy and precision values were within acceptable limits, with recovery rates between 95.33%-98.16% for Glimepiride and 97.86%-98.93% for Linagliptin. Unlike HPLC, this UV method does not require expensive solvents, mobile phase preparation, or extensive sample handling, making it highly suitable for routine quality control in resource-limited settings.

Advantages of the Developed UV Spectroscopic Method

The developed UV spectroscopic method offers significant advantages over conventional HPLC methods. It is a cost-effective alternative as it eliminates the need for expensive HPLC instrumentation and mobile phases, making it accessible for routine quality control. The method is simple, as it does not require complex sample preparation or chromatographic conditions, reducing the possibility of errors and ensuring ease of use. Additionally, it allows for rapid analysis by significantly reducing the time required for estimation compared to HPLC methods. While the sensitivity of the UV method is slightly lower than that of HPLC, it still meets the pharmaceutical validation requirements for routine drug analysis. Moreover, the method minimizes solvent usage, reducing the environmental impact

Table 8: Robustness of Glimepiride.

Sl. No.	Standard Absorbance	Glimepiride (228 nm)	
		+2 nm	-2 nm
1	0.5822	0.5819	0.5825
2	0.5883	0.5881	0.5886
3	0.5889	0.5887	0.5892
Mean	0.5864	0.5862	0.5867
SD	0.0037	0.0037	0.0037
% RSD	0.6321	0.64	0.63

Table 9: Robustness of Linagliptin.

Sl. No.	Standard Absorbance	Linagliptin (295 nm)	
		+2 nm	-2 nm
1	0.7592	0.7589	0.7595
2	0.7589	0.7585	0.7589
3	0.7572	0.7569	0.7572
Mean	0.7584	0.7581	0.7585
SD	0.0010	0.0010	0.0011
% RSD	0.1422	0.13	0.15

Table 10: Analysis of Synthetic Mixture.

Total Amount (mg)		Amount Found (mg)		%Purity (%)	
Glimepiride	Linagliptin	Glimepiride	Linagliptin	Glimepiride	Linagliptin
2	5	1.99	4.98	99.333 ± 0.0057	99.610 ± 0.0010
2	5	1.98	4.99		
2	5	1.99	4.97		

associated with organic solvent consumption in chromatographic techniques.

While HPLC remains the gold standard for high-precision and trace-level analysis, the developed UV method provides a practical alternative, particularly for regular pharmaceutical quality control.

The novelty of this research lies in the development and validation of a simple, precise, and cost-effective UV spectroscopic method for the simultaneous estimation of Glimepiride and Linagliptin in synthetic mixtures. Unlike existing methods, this approach minimizes the need for expensive reagents and complex chromatographic systems while maintaining high accuracy and reproducibility. The method adheres to ICH Q2 (R2) guidelines, making it a viable alternative for routine pharmaceutical analysis, especially in settings where HPLC resources are limited.

CONCLUSION

The simultaneous measurement of Glimepiride along with Linagliptin in their synthetic mixture has been accomplished through effective development and validation of an Ultraviolet spectroscopic technique. Each validation parameters were conducted in compliance with International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use Q2 (R2) guidelines, yielding results within the acceptable range. This confirms the suitability of the method for routine quantitative analysis. The method demonstrates high specificity, with no observed interference from impurities. Overall, proposed approach has been straightforward, accurate, as well as precise, making it highly suitable for practical applications.

CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

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