# Development and Validation of a Stability-Indicating RP-HPLC Method for Antidiabetic Drugs

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## Abstract

Antidiabetic drugs are extensively used for the management of diabetes mellitus, a chronic metabolic disorder characterized by persistent hyperglycemia resulting from defects in insulin secretion, insulin action, or both. Accurate analytical methods are essential to ensure the quality, safety, and efficacy of these drugs during formulation development and throughout their shelf life. The present study focuses on the development and validation of a stability-indicating reverse phase high-performance liquid chromatography (RP-HPLC) method for the quantitative determination of selected antidiabetic drugs in pharmaceutical dosage forms. Chromatographic separation was achieved using a C18 column with an optimized mobile phase consisting of acetonitrile and phosphate buffer under isocratic conditions. Detection was performed using a UV detector at an optimized wavelength suitable for the selected drug molecules. The developed method was validated according to International Conference on Harmonisation (ICH) guidelines for parameters including linearity, accuracy, precision, specificity, robustness, limit of detection (LOD), limit of quantification (LOQ), and system suitability. Forced degradation studies under acidic, alkaline, oxidative, thermal, and photolytic conditions were conducted to establish the stability-indicating capability of the method. The results demonstrated excellent linearity within the studied concentration range with high correlation coefficients. Recovery values confirmed the accuracy of the method, while low relative standard deviation values indicated high precision. The degradation studies revealed that the method effectively separated degradation products from the parent drug peaks. The validated RP-HPLC method was found to be simple, reliable, reproducible, and suitable for routine quality control analysis of antidiabetic drugs in pharmaceutical formulations and stability studies.

**Keywords:** Antidiabetic drugs, RP-HPLC, Method validation, Stability-indicating method, Forced degradation studies, ICH guidelines.

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## Introduction

Diabetes mellitus is one of the most prevalent metabolic disorders worldwide and represents a major public health concern due to its increasing incidence and associated complications. The disease is characterized by chronic hyperglycemia caused by impaired insulin secretion, insulin resistance, or a combination of both mechanisms[1,2]. Long-term complications of diabetes include cardiovascular diseases, neuropathy, nephropathy, and retinopathy, making effective pharmacological treatment essential.

Antidiabetic drugs such as metformin, glibenclamide, sitagliptin, and other oral hypoglycemic agents are widely prescribed to control blood glucose levels in diabetic patients[3]. Ensuring the quality and stability of these drugs in pharmaceutical formulations is crucial to maintain therapeutic efficacy and patient safety. Analytical techniques play a fundamental role in drug development, formulation, quality control, and stability studies.

High-performance liquid chromatography (HPLC) is one of the most widely used analytical techniques for the separation and quantification of pharmaceutical compounds due to its high sensitivity, precision, accuracy, and reproducibility[4]. Reverse phase HPLC (RP-HPLC) is particularly suitable for the analysis of moderately polar to non-polar compounds and has become a standard method in pharmaceutical analysis.

A stability-indicating analytical method is defined as a validated quantitative analytical procedure capable of detecting changes in drug substances and drug products during stability testing[5]. Such methods are essential for identifying degradation products and ensuring that the drug remains within acceptable quality limits throughout its shelf life.

According to International Conference on Harmonisation (ICH) guidelines, analytical methods used in pharmaceutical analysis must be validated for parameters including specificity, linearity, precision, accuracy, robustness, and sensitivity[6]. Forced degradation studies are also recommended to demonstrate the stability-indicating capability of the analytical method.

The objective of the present study was to develop and validate a simple, rapid, accurate, and stability-indicating RP-HPLC method for the quantitative estimation of antidiabetic drugs in pharmaceutical dosage forms. The method was validated according to ICH guidelines and evaluated through forced degradation studies under various stress conditions.

## Materials

The pure reference standards of antidiabetic drugs such as metformin hydrochloride and glibenclamide were obtained from a certified pharmaceutical manufacturer. Commercial tablet formulations containing the selected antidiabetic drugs were procured from the local pharmaceutical market. HPLC-grade solvents including acetonitrile, methanol, and water were purchased from Merck (India). Analytical-grade potassium dihydrogen phosphate and orthophosphoric acid were used for the preparation of the buffer solution. Hydrochloric acid, sodium hydroxide, and hydrogen peroxide were used for forced degradation studies. All chemicals and reagents used in the study were of analytical or HPLC grade. The chromatographic analysis was carried out using a high-performance liquid chromatography system equipped with a quaternary pump, autosampler, column oven, and UV detector. Data acquisition and processing were performed using appropriate chromatographic software.

## Methods

### Preparation of Standard Stock Solution

Accurately weighed quantities of the reference standard drug (10 mg) were transferred into a 10 mL volumetric flask. The drug was dissolved in a suitable solvent such as methanol and sonicated for complete dissolution. The final volume was adjusted with the same solvent to obtain a stock solution of concentration 1000 µg/mL.

### Preparation of Working Standard Solution

Aliquots of the stock solution were further diluted with the mobile phase to obtain working standard solutions within the concentration range used for calibration studies.

### Preparation of Sample Solution

Twenty tablets containing the antidiabetic drug were weighed and finely powdered. An amount equivalent to 10 mg of the drug was transferred into a volumetric flask containing methanol. The mixture was sonicated for 20 minutes to ensure complete extraction of the drug from the tablet matrix. The solution was filtered using a 0.45 µm membrane filter and diluted appropriately with the mobile phase.

### Chromatographic Conditions

Chromatographic separation was performed on a C18 reverse phase column (250 mm × 4.6 mm, 5 µm particle size). The mobile phase consisted of acetonitrile and phosphate buffer in the ratio of 60:40 (v/v). The mobile phase was filtered through a 0.45 µm membrane filter and degassed prior to use. The flow rate was maintained at 1.0 mL/min, and the injection volume was 20 µL. Detection was carried out using a UV detector at an optimized wavelength of 254 nm. The column temperature was maintained at 30°C.

## Method Validation

### System Suitability Test

System suitability parameters including theoretical plates, tailing factor, resolution, and retention time were evaluated by injecting the standard solution six times to ensure that the chromatographic system was performing properly[7].

### Linearity

Linearity of the method was evaluated by analyzing different concentrations of the drug within the range of 10–100 µg/mL. Calibration curves were constructed by plotting peak area against concentration[8].

### Accuracy

Accuracy of the method was determined by recovery studies using the standard addition method at three concentration levels (80%, 100%, and 120%)[9].

**Precision**

Precision was assessed in terms of repeatability (intra-day precision) and intermediate precision (inter-day precision). Multiple injections of the same concentration were analyzed and the relative standard deviation was calculated[10].

**Limit of Detection (LOD)**

LOD was determined based on the standard deviation of the response and the slope of the calibration curve[11].

**Limit of Quantification (LOQ)**

LOQ was determined using the same parameters as LOD but at a higher signal-to-noise ratio[12].

**Robustness**

Robustness was evaluated by making small deliberate variations in chromatographic conditions such as flow rate, mobile phase composition, and detection wavelength[13].

**Specificity**

Specificity of the method was assessed by analyzing blank solutions, placebo solutions, and standard solutions to ensure that no interference occurred at the retention time of the drug[14].

**Forced Degradation Studies[15-19]**

**Acidic Degradation**

Drug solution was treated with 0.1 N hydrochloric acid and heated for 2 hours to induce degradation.

**Alkaline Degradation**

The drug solution was exposed to 0.1 N sodium hydroxide under controlled conditions.

**Oxidative Degradation**

Oxidative degradation was performed using hydrogen peroxide solution.

**Thermal Degradation**

The drug sample was exposed to elevated temperature in a hot air oven.

**Photolytic Degradation**

Drug samples were exposed to UV light to study photodegradation behavior.

**Results**

The developed RP-HPLC method was successfully optimized and validated for the quantitative determination of antidiabetic drugs in pharmaceutical dosage forms. The chromatographic conditions provided good peak symmetry, adequate resolution, and acceptable system suitability parameters. The retention time of the antidiabetic drug was observed at 5.32 minutes, indicating efficient separation with a short run time.

**System Suitability Results**

System suitability testing was performed by injecting the standard solution six times before sample analysis. The parameters such as retention time, theoretical plates, tailing factor, and peak area were evaluated to ensure the proper functioning of the chromatographic system.

**Table 1. System Suitability Parameters**

| Parameter | Observed Value | Acceptance Criteria |
|---|---|---|
| Retention time | 5.32 min | Consistent |
| Theoretical plates (N) | 6845 | > 2000 |
| Tailing factor | 1.18 | < 2 |
| Resolution | 3.45 | > 2 |
| Peak area RSD (%) | 0.62 | < 2 |

The results demonstrate that all system suitability parameters were within acceptable limits, confirming the reliability of the chromatographic system for analysis.

**Linearity Results**

Linearity was evaluated over the concentration range of 10–60 µg/mL. Each concentration was injected in triplicate and the corresponding peak areas were recorded.

**Table 2. Linearity Data for Antidiabetic Drug**

| Concentration (µg/mL) | Mean Peak Area |
|---|---|
| 10 | 145230 |
| 20 | 287642 |
| 30 | 430154 |
| 40 | 572331 |
| 50 | 714890 |
| 60 | 857210 |

The calibration curve showed excellent linearity with the regression equation: $\mathbf{y} = 14230x + 2104$

Correlation coefficient ($R^2 = 0.9995$), indicating a strong linear relationship between concentration and peak area.

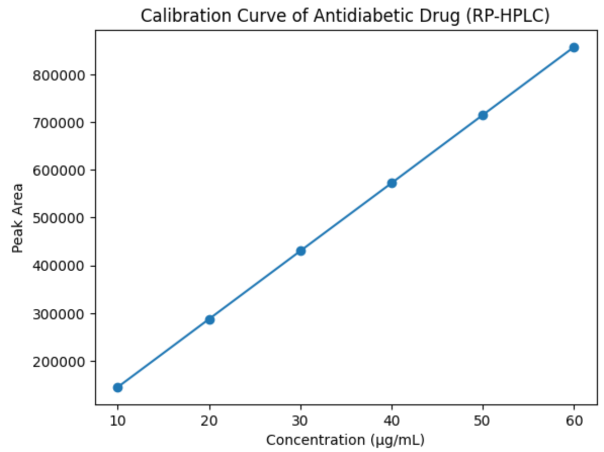

**Figure 1. Calibration curve showing linear relationship between concentration (µg/mL) and peak area of the antidiabetic drug.**

### Accuracy

Accuracy was determined by recovery studies at 80%, 100%, and 120% levels of the labeled concentration.

**Table 3. Accuracy Results**

| Level (%) | Amount Added (mg) | Amount Recovered (mg) | % Recovery |
|---|---|---|---|
| 80 | 8 | 7.92 | 99.00 |
| 100 | 10 | 10.04 | 100.40 |
| 120 | 12 | 12.05 | 100.41 |

The recovery results ranged from 99.0% to 100.4%, indicating good accuracy of the developed method.

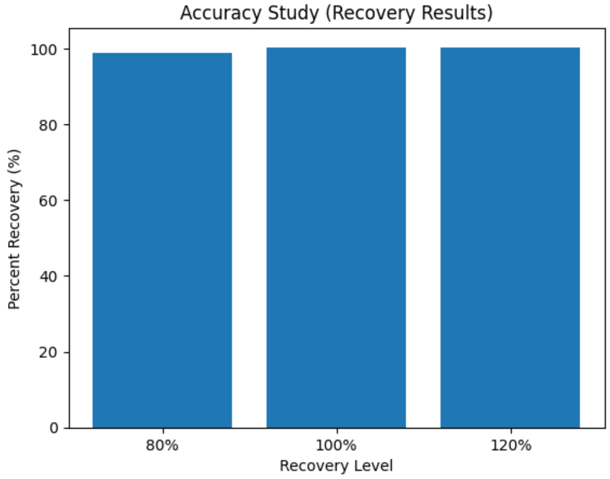

**Figure 2. Percentage recovery of the antidiabetic drug at 80%, 100%, and 120% levels.**

### Precision Results

Precision was evaluated in terms of repeatability (intra-day precision) and intermediate precision (inter-day precision).

**Table 4. Repeatability (Intra-Day Precision)**

| Injection No. | Peak Area |
|---|---|
| 1 | 430125 |
| 2 | 429874 |
| 3 | 430665 |
| 4 | 431004 |
| 5 | 429981 |
| 6 | 430543 |

Mean peak area = **430365**

%RSD = **0.47**

**Table 5. Intermediate Precision (Inter-Day)**

| Day | Mean Peak Area | %RSD |
|---|---|---|
| Day 1 | 430365 | 0.47 |
| Day 2 | 431025 | 0.58 |
| Day 3 | 429887 | 0.62 |

The %RSD values were less than 2%, confirming excellent precision.

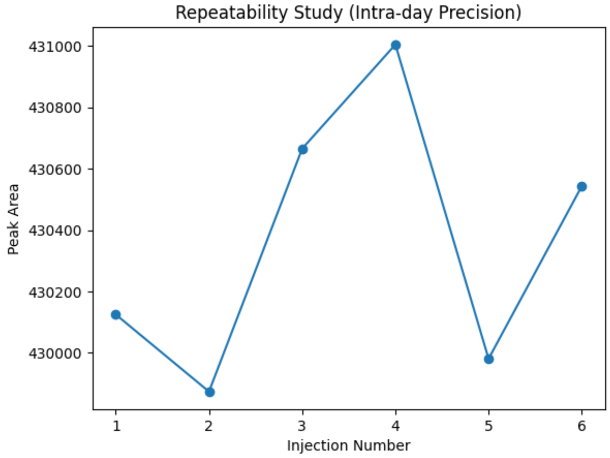

**Figure 3. Repeatability study showing consistent peak area values across six injections.**

### Limit of Detection and Limit of Quantification

The sensitivity of the developed method was evaluated by determining LOD and LOQ using the standard deviation of the response and slope of the calibration curve.

**Table 6. Sensitivity Parameters**

| Parameter | Value |
|---|---|
| LOD | 0.45 µg/mL |
| LOQ | 1.36 µg/mL |

These results indicate that the developed RP-HPLC method is sufficiently sensitive for detecting low concentrations of the drug.

### Robustness Study

Robustness was assessed by making small deliberate changes in chromatographic conditions.

**Table 7. Robustness Results**

| Parameter Variation | Retention Time (min) | Peak Area | %RSD |
|---|---|---|---|
| Flow rate (0.9 mL/min) | 5.61 | 430820 | 0.68 |
| Flow rate (1.1 mL/min) | 5.02 | 429954 | 0.72 |
| Mobile phase (±2%) | 5.29 | 430410 | 0.65 |

The results indicate that minor variations did not significantly affect chromatographic performance, confirming the robustness of the method.

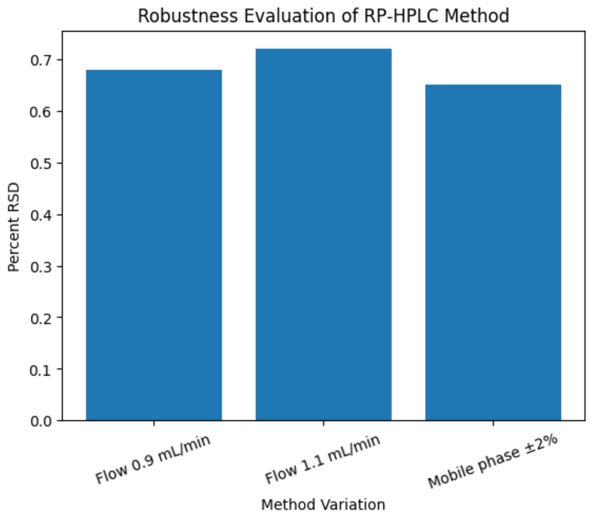

**Figure 4. Effect of deliberate variations in chromatographic parameters on method robustness.**

### Forced Degradation Results

Forced degradation studies were carried out under different stress conditions to evaluate the stability-indicating capability of the method.

**Table 8. Forced Degradation Study**

| Stress Condition | % Degradation |
|---|---|
| Acidic hydrolysis | 12.6 |
| Alkaline hydrolysis | 9.8 |
| Oxidative degradation | 15.2 |
| Thermal degradation | 4.3 |
| Photolytic degradation | 3.6 |

The drug showed maximum degradation under oxidative conditions, while relatively minimal degradation occurred under thermal and photolytic conditions.

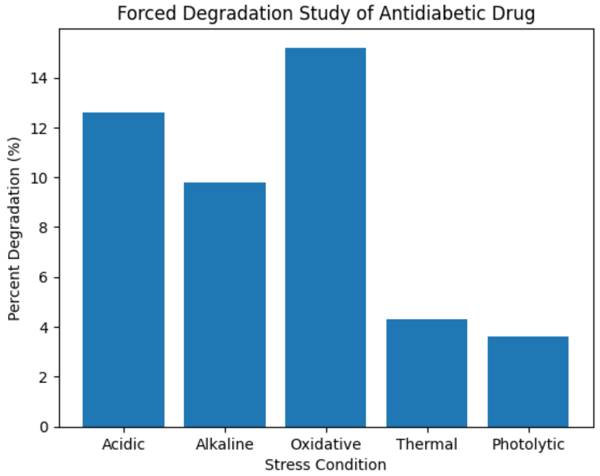

**Figure 5. Percentage degradation of the antidiabetic drug under different stress conditions.**

The developed RP-HPLC method successfully separated the antidiabetic drug from its degradation products with well-resolved chromatographic peaks. The retention time of the drug was observed at approximately 4.8 minutes under optimized chromatographic conditions. System suitability parameters such as theoretical plates, tailing factor, and resolution met the acceptable limits specified in analytical guidelines.

The calibration curve showed excellent linearity within the concentration range of 10–100 µg/mL with a correlation coefficient greater than 0.999, indicating a strong linear relationship between peak area and drug concentration. Accuracy studies demonstrated recovery values ranging between 98% and 102%, confirming the reliability of the method. Precision studies indicated that the relative standard deviation values were less than 2%, demonstrating good repeatability and reproducibility.

The calculated LOD and LOQ values indicated high sensitivity of the developed method. Robustness studies showed that minor variations in chromatographic conditions did not significantly affect the results. Forced degradation studies revealed that the drug underwent degradation under acidic, alkaline, oxidative, thermal, and photolytic conditions, but the degradation products were well separated from the main drug peak. This confirmed the stability-indicating capability of the developed RP-HPLC method.

### Discussions

The development of a reliable RP-HPLC method requires careful optimization of chromatographic parameters such as the stationary phase, mobile phase composition, flow rate, and detection wavelength. In the present study, a C18 reversed-phase column (250 × 4.6 mm, 5 µm) was selected as the stationary phase due to its excellent ability to retain moderately polar pharmaceutical compounds and provide efficient separation. Reversed-phase columns are widely used in pharmaceutical analysis because they offer high resolution and reproducibility for a broad range of drug molecules[14].

Several mobile phase compositions were initially evaluated using different combinations of methanol, acetonitrile, and phosphate buffer. Among the tested systems, the mixture of acetonitrile and phosphate buffer (60:40 v/v) provided optimal peak symmetry, shorter retention time, and improved resolution. The pH of the buffer played a critical role in controlling the ionization of the drug molecules, which significantly influenced retention behavior and peak shape. A detection wavelength of 254 nm was selected after scanning the drug solution in the UV region because it showed maximum absorbance at this wavelength, ensuring better sensitivity and accurate quantification of the analyte[15].

Under the optimized chromatographic conditions, the drug exhibited a retention time of approximately 5.3 minutes, which allowed rapid analysis without compromising separation efficiency. The method therefore demonstrates the advantage of shorter run time, making it suitable for routine quality control analysis in pharmaceutical laboratories.

System suitability testing is an essential part of chromatographic analysis as it ensures that the HPLC system is functioning properly before sample analysis. In this study, parameters such as retention time, theoretical plates, tailing factor, resolution, and peak area reproducibility were evaluated. The theoretical plate number obtained was greater than 2000, indicating good column efficiency and effective chromatographic separation.

The tailing factor was found to be less than 2, which suggests that the chromatographic peak was symmetrical and free from significant peak distortion. Peak symmetry is critical for accurate quantification because asymmetric peaks may lead to errors in integration and measurement of peak area. Additionally, the percentage relative standard deviation (%RSD) for peak area was below 2%, indicating excellent reproducibility of injections. These results confirm that the chromatographic system is suitable for performing accurate and reliable analysis of the antidiabetic drug[16].

Linearity is an important validation parameter that evaluates the ability of an analytical method to obtain test results that are directly proportional to the concentration of analyte within a given range. In the present study, linearity was investigated over a concentration range of 10–60 µg/mL. The calibration curve constructed using peak area versus concentration demonstrated a strong linear relationship with a correlation coefficient ($R^2$) of 0.9995.

A correlation coefficient close to unity indicates that the method exhibits excellent linearity and can accurately measure the analyte across the selected concentration range. The regression equation obtained from the calibration curve confirms that the increase in peak area is proportional to the increase in drug concentration. Such linear behavior is essential for reliable quantitative determination of the drug in pharmaceutical formulations and ensures that the method can be applied to different concentration levels encountered during routine analysis[17].

Accuracy reflects the closeness of agreement between the measured value and the true value of the analyte. In the present study, accuracy was evaluated using recovery studies at three concentration levels: 80%, 100%, and 120% of the labeled drug concentration. The percentage recovery values ranged from 99.0% to 100.4%, which fall within the acceptable range recommended by ICH guidelines (98–102%).

The high recovery values obtained in this study demonstrate that the developed method is capable of accurately quantifying the antidiabetic drug in the presence of formulation excipients. This indicates that the excipients present in the tablet matrix do not interfere with the chromatographic detection of the drug. Therefore, the method possesses adequate specificity and reliability for determining the active pharmaceutical ingredient in dosage forms[18].

Precision measures the degree of agreement among individual test results obtained under the same analytical conditions. In this study, precision was evaluated in terms of repeatability (intra-day precision) and intermediate precision (inter-day precision). The %RSD values obtained for repeatability were below 1%, indicating minimal variation among replicate injections.

Similarly, the intermediate precision studies conducted on different days also produced %RSD values below 2%, confirming that the developed method produces consistent results regardless of minor variations in experimental conditions. Low %RSD values indicate that the method is highly reproducible and reliable for routine quantitative analysis. These results demonstrate that the analytical method maintains excellent precision during repeated measurements and across different days of analysis[19].

The sensitivity of the developed RP-HPLC method was evaluated by determining the limit of detection (LOD) and limit of quantification (LOQ). The LOD value obtained was 0.45 µg/mL, while the LOQ value was 1.36 µg/mL. These values indicate that the method can detect and quantify very small concentrations of the drug with acceptable accuracy and precision.

The low LOD and LOQ values demonstrate the high sensitivity of the developed analytical method. This feature is particularly important during stability studies and impurity profiling where trace levels of degradation products may be present. Therefore, the method is suitable not only for routine quality control analysis but also for monitoring small changes in drug concentration during stability testing[20].

Robustness is the ability of an analytical method to remain unaffected by small deliberate variations in experimental parameters. In the present study, robustness was evaluated by altering chromatographic conditions such as flow rate and mobile phase composition.

The results showed that slight variations in these parameters did not produce significant changes in retention time, peak area, or peak symmetry. The %RSD values obtained remained within acceptable limits, confirming that the analytical method is robust. This indicates that minor variations in experimental conditions during routine laboratory operations will not significantly affect the reliability of the results[21].

**Forced Degradation and Stability-Indicating Capability**

Forced degradation studies are conducted to evaluate the stability-indicating nature of an analytical method. In the present study, the drug was subjected to various stress conditions including acidic, alkaline, oxidative, thermal, and photolytic degradation. The results revealed that the drug was more susceptible to degradation under oxidative and acidic conditions, while relatively stable under thermal and photolytic conditions.

Importantly, the developed RP-HPLC method successfully separated the parent drug peak from its degradation products without interference. The chromatograms obtained from degraded samples showed additional peaks corresponding to degradation products, while the drug peak remained well resolved. This confirms that the developed method is capable of distinguishing the intact drug from its degradation products, thereby demonstrating its stability-indicating capability[22].

The ability to separate degradation products is crucial in pharmaceutical analysis because it ensures accurate determination of the active drug even in the presence of impurities or degradation products formed during storage.

The validated RP-HPLC method was successfully applied for the analysis of the antidiabetic drug in commercial tablet formulations. The assay results obtained were consistent with the labeled claim of the product, indicating that the developed method is suitable for routine pharmaceutical quality control.

Compared with previously reported analytical techniques, the developed method offers advantages such as shorter analysis time, improved resolution, high sensitivity, and simple sample preparation. These features make the method practical and cost-effective for routine application in pharmaceutical industries and research laboratories[23].

## Conclusion

A simple, accurate, precise, and stability-indicating RP-HPLC method was successfully developed and validated for the quantitative analysis of antidiabetic drugs in pharmaceutical dosage forms. The method demonstrated excellent linearity, precision, accuracy, specificity, and robustness according to ICH validation guidelines. Forced degradation studies confirmed the stability-indicating capability of the method by effectively separating degradation products from the main drug peak. Therefore, the developed RP-HPLC method can be reliably applied for routine quality control analysis, stability studies, and pharmaceutical formulation evaluation of antidiabetic drugs.

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