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ORIGINAL ARTICLE

Development and Validation of RP-HPLC Method for Simultaneous Estimation of Remogliflozin and Vildagliptin in Bulk and Marketed Formulation

Irshad Ahmed[1]*, Kesari Malwar[2] , Mudabbirul Haque[3], Mohd. Shoeb[4], Bilal Sufi[5] , Mohd. Vaqqas[6]
[1]*Associate Professor, Department of Pharmaceutics, New Montfort Institute of Pharmacy, Ashti
[2]Student , Department of Quality Assurance, New Montfort Institute of Pharmacy, Ashti
[3]Principal , Department of Pharmaceutics, New Montfort Institute of Pharmacy, Ashti
[4]Assistant Professor**,** Department of Pharmacology, New Montfort Institute of Pharmacy, Ashti
[5]Assistant Professor**,** Department of Pharmaceutics, New Montfort Institute of Pharmacy, Ashti
[6]Assistant Professor, Department of Pharmaceutics, New Montfort Institute of Pharmacy, Ashti
Corresponding Author Email : irshadzaki.radiff1996@gmail.com

ABSTRACT

Remogliflozin and Vildagliptin are two commonly prescribed antidiabetic agents with complementary mechanisms of action used in the management of Type 2 Diabetes Mellitus. Their simultaneous determination is essential for routine quality control of combined formulations. The present work focuses on the development and validation of a simple, precise, accurate, and stability-indicating RP-HPLC method for the simultaneous estimation of Remogliflozin and Vildagliptin in bulk and marketed tablet dosage forms. Chromatographic separation was achieved using a C18 column with an optimized mobile phase consisting of Methanol and Phosphate buffer, delivered at a flow rate of 1.0 mL/min. Detection was carried out using a UV detector at the selected wavelength. The method was validated according to ICH Q2(R1) guidelines by evaluating system suitability, linearity, accuracy, precision, specificity, robustness, ruggedness, limit of detection (LOD), and limit of quantification (LOQ). The results demonstrated good separation with satisfactory retention times and system suitability parameters. Linearity was observed in the respective concentration ranges with correlation coefficients (r^2) greater than 0.999 for both drugs. Recovery studies confirmed accuracy, with percentage recovery values falling within acceptable limits. Precision results showed %RSD values less than 2%, indicating good repeatability. Forced degradation studies performed under acidic, alkaline, oxidative, thermal, neutral, and photolytic conditions confirmed the stability-indicating nature of the developed method, as significant degradation peaks were successfully resolved from the analyte peaks. Thus, the proposed RP-HPLC method is reliable, sensitive, rugged, and suitable for routine quality control analysis and stability assessment of Remogliflozin and Vildagliptin in pharmaceutical formulations.

Keywords: *Remogliflozin, Vildagliptin, RP-HPLC, Method validation, Stability-indicating method, ICH Q2(R1).*

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INTRODUCTION

Diabetes mellitus (DM) is a chronic metabolic disorder characterised by persistent hyperglycemia resulting from impaired insulin secretion, insulin action, or both. The origin of the term "diabetes mellitus" reflects its historical description, derived from the Greek word *diabetes* meaning "to pass through" and the Latin word *mellitus* meaning "sweet", referring to the sweet taste of urine observed in patients with uncontrolled diabetes. The disease has been recognised since ancient times, with early descriptions documented between 250–300 BC in Greek, Egyptian, and Indian civilisations [1]. A turning point in diabetes management occurred in 1922 when Banting and Best isolated insulin from bovine pancreas, enabling therapeutic insulin administration and revolutionising diabetes treatment. Over the decades, numerous advancements have been made in understanding disease pathophysiology, refining

diagnostic criteria, and improving therapeutic approaches. However, diabetes remains one of the most prevalent chronic diseases worldwide.

Diabetes mellitus encompasses a spectrum of disorders including Type 1 diabetes mellitus (T1DM), Type 2 diabetes mellitus (T2DM), maturity-onset diabetes of the young (MODY), gestational diabetes mellitus (GDM), neonatal diabetes, and secondary diabetes caused by drugs such as steroids or endocrine abnormalities [2]. Clinically, three major forms—Type 1, Type 2, and gestational diabetes—are most commonly encountered. Type 1 diabetes is characterised by autoimmune destruction of pancreatic β-cells, resulting in absolute insulin deficiency and lifelong dependence on exogenous insulin therapy. It often manifests in childhood or adolescence, though it may occur at any age [3-4]. In contrast, Type 2 diabetes, the most prevalent form, involves insulin resistance and gradually declining insulin secretion. It is commonly associated with obesity, sedentary lifestyle, poor dietary habits, genetic predisposition, and ageing.[3–4] Gestational diabetes develops during pregnancy, usually in the second or third trimester due to hormonal changes that impair insulin action. Despite often resolving postpartum, GDM significantly increases the long-term risk of developing Type 2 diabetes in both the mother and offspring [5-6].

Diagnosis of diabetes is based on biochemical parameters that assess plasma glucose levels and long-term glycaemic control. The common diagnostic tests include fasting plasma glucose (FPG), oral glucose tolerance test (OGTT), random plasma glucose, and glycated haemoglobin (HbA1c). A fasting blood glucose level of ≥126 mg/dL (7.0 mmol/L), OGTT value ≥200 mg/dL (11.1 mmol/L), or random glucose ≥200 mg/dL with classical symptoms are diagnostic of diabetes [7-9]. HbA1c, which reflects average blood glucose over the preceding two to three months, is considered diagnostic when ≥6.5%. Early identification of gestational diabetes is essential to limit adverse maternal and fetal outcomes and reduce risks such as neuropathy, nephropathy, and cardiovascular complications [9-10].

The management of diabetes involves an integrated plan including lifestyle modification—dietary regulation, physical activity of at least 150 minutes per week, and patient education—alongside pharmacological therapy and periodic monitoring. Optimal glycaemic targets include fasting glucose of 90–130 mg/dL and HbA1c below 7% [10-11]. Type 1 diabetes requires lifelong insulin therapy, while Type 2 diabetes can be managed using oral hypoglycaemic agents such as metformin, sulfonylureas, meglitinides, thiazolidinediones, DPP-4 inhibitors, GLP-1 receptor agonists, SGLT-2 inhibitors, and insulin when necessary [12]. These agents differ in their mechanisms of action and offer additional benefits such as weight loss, cardiovascular protection, and reduced hypoglycaemia risk. Regular monitoring for long-term complications—including retinopathy, nephropathy, neuropathy, dyslipidaemia, and hypertension—is essential, with therapeutic strategies involving ACE inhibitors, ARBs, statins, and agents for neuropathic pain [12].

Combination therapy is increasingly preferred in Type 2 diabetes management due to its ability to target multiple pathophysiological pathways simultaneously. The fixed-dose combination of Remogliflozin etabonate (an SGLT-2 inhibitor) and Vildagliptin (a DPP-4 inhibitor) offers complementary and synergistic benefits [14]. Remogliflozin promotes urinary glucose excretion by inhibiting renal tubular SGLT-2 transporters, thereby lowering blood glucose independent of insulin [15-16]. Vildagliptin inhibits the DPP-4 enzyme, prolonging the action of incretin hormones and enhancing insulin secretion while reducing glucagon release in a glucose-dependent manner. Their combined use improves glycaemic control, reduces insulin resistance, supports moderate weight reduction, and lowers the risk of hypoglycaemia.

Analytical chemistry is essential in pharmaceutical quality control, enabling accurate estimation of active pharmaceutical ingredients (APIs), impurities, degradation products, excipients, and components in formulations [16]. High-Performance Liquid Chromatography (HPLC) is widely employed due to its sensitivity, accuracy, reproducibility, rapidity, and suitability for complex mixtures [18-20]. The development of an RP-HPLC method requires systematic optimisation of chromatographic parameters including column selection, mobile phase composition, pH, buffer strength, flow rate, wavelength, and diluent properties. Method validation ensures reliability and includes assessment of precision, accuracy, specificity, linearity, robustness, ruggedness, limit of detection (LOD), and limit of quantification (LOQ) [21-30]. A validated RP-HPLC method for simultaneous estimation of Remogliflozin and Vildagliptin is crucial for routine quality control, formulation analysis, and regulatory compliance.

MATERIAL AND METHODS

Materials

Procurement of Drug, Formulation, and Solvents

Table 1: Procurement Details of Remogliflozin, Vildagliptin, Formulation and Chemicals

Sr. No.	Chemicals / Formulations	Supplier
1	Remogliflozin	Swapnroop Drugs and Pharmaceuticals, Aurangabad, India
2	Vildagliptin	Swapnroop Drugs and Pharmaceuticals, Aurangabad, India
3	Zomelis SG (Marketed formulation)	Eris Lifesciences Ltd.
4	Methanol (HPLC grade)	Merck Ltd., India
5	0.1% Acetic Acid (HPLC grade)	Merck Ltd., India
6	Acetonitrile (HPLC grade)	Merck Ltd., India
7	Water (HPLC grade)	Merck Ltd., India

Instrumentation and Chromatographic Conditions

Table 2: Chromatographic Conditions

Parameter	Details
Instrument	Agilent 1100 HPLC Gradient System
Detector	PWD Detector
Software	ChemStation
Column	Agilent RP-C18 (4.6 × 250 mm, 5 µm)
Flow rate	0.9 mL/min
Detection wavelength	222 nm
Mobile phase	Methanol : 0.1% Acetic Acid (40:60, v/v)
Temperature	25°C
Injection volume	20 µL
Formulation analysed	ZOMELIS SG

Table 3: HPLC Pump Unit Specification

Parameter	Details
Pump unit	G1310A IsoPump
Maximum pressure	400 bar
Discharge rate	0.001–5 mL/min
Pressure limit range	400 bar
Pressure display accuracy	±5%
Number of mobile phases supported	4
Mixing ratio range	0–100%
Pump type	HP-1100 Reciprocating Pump

UV Spectroscopy

A. Preparation of Standard Stock Solutions

Accurately weighed:

- 20 mg Remogliflozin
- 10 mg Vildagliptin

Each transferred into separate 100 mL volumetric flasks, dissolved in ~20–30 mL methanol, sonicated for 10 minutes, and diluted to volume with methanol.

Final stock concentrations:

- Remogliflozin: **200 µg/mL**
- Vildagliptin: **100 µg/mL**

B. Preparation of Working Standard Solutions

- Remogliflozin: 10 mL of 200 µg/mL → dilute to 100 mL → 20 µg/mL
- Vildagliptin: 10 mL of 100 µg/mL → dilute to 100 mL → 10 µg/mL

C. Determination of λmax

Working solutions were scanned over 200–400 nm using methanol as blank.

λmax values for each drug were recorded.

Preparation of Mixed Standard Solutions

10 mg Remogliflozin + 5 mg Vildagliptin transferred to 25 mL flask, dissolved in methanol → 400 µg/mL and 200 µg/mL, respectively.

Working standards prepared at:

4+2, 8+4, 12+6, 16+8, and 20+10 µg/mL

Filtered through 0.45 µm membrane filter prior to injection.

Mobile Phase Optimization

Various combinations of methanol, acetonitrile, and 0.1% acetic acid were tested at ratios between 90:10 and 40:60 (v/v) under identical chromatographic conditions.

Table 4: Trial Table

Trial No.	Mobile Phase Composition (v/v)	Flow Rate
1	MeOH 90% : 0.1% Acetic Acid 10%	0.7 mL/min
2	MeOH 80% : 0.1% Acetic Acid 20%	0.7 mL/min
3	MeOH 70% : 0.1% Acetic Acid 30%	0.7 mL/min
4	MeOH 60% : 0.1% Acetic Acid 40%	0.7 mL/min
5	MeOH 50% : 0.1% Acetic Acid 50%	0.7 mL/min
6	MeOH 40% : 0.1% Acetic Acid 60%	0.9 mL/min
7	ACN 90% : 0.1% Acetic Acid 10%	0.7 mL/min
8	ACN 60% : 0.1% Acetic Acid 40%	0.7 mL/min

Method Validation (ICH Q2(R1))

The developed RP-HPLC method was validated in accordance with ICH Q2(R1) guidelines to assess linearity, accuracy, precision, ruggedness, robustness, specificity, and assay performance.

Linearity

Linearity was evaluated by preparing mixed standard solutions of Remogliflozin in the concentration range of 4–20 µg/mL and Vildagliptin in the range of 2–10µg/mL. Each solution was filtered through a 0.45 µm membrane filter and injected at a volume of 20µL. Calibration curves were constructed by plotting peak area against concentration for both analytes.

Accuracy (Recovery Studies)

Accuracy was assessed by the standard-addition method at 80%, 100%, and 120% of the test concentration. Pre-analyzed tablet samples containing 8µg/mL of Remogliflozin and 4µg/mL of Vildagliptin were spiked with standard drug solutions to achieve final concentrations of 6.4, 8.0, and 9.6 µg/mL for Remogliflozin, and 3.2, 4.0, and 4.8µg/mL for Vildagliptin. Percent recovery was calculated from measured peak areas.

Precision

a) Repeatability

Repeatability was determined by six replicate injections of mixed standard solutions containing 20µg/mL Remogliflozin and 10µg/mL Vildagliptin. The percentage relative standard deviation (%RSD**)** of peak areas was calculated.

b) Intraday Precision

Intraday precision was assessed by analyzing three different concentrations—8, 12, and 16 µg/mL for Remogliflozin and 4, 6, and 8µg/mL for Vildagliptin. Each concentration level was injected in duplicate at different times within the same day.

c) Interday Precision

Interday precision was evaluated using the same concentration levels over three consecutive days**.** Fresh stock solutions were prepared each day and %RSD values were calculated.

Ruggedness

Ruggedness was examined by introducing variations such as change of analyst and change of instrument. Mixed standard solutions containing 16µg/mL Remogliflozin and 8µg/mL Vildagliptin were injected in duplicate under optimized chromatographic conditions, and %RSD of peak areas was recorded.

Robustness

Robustness was assessed by deliberately introducing minor variations in method conditions. The mobile phase composition was varied to 39:61 and 41:59 (methanol:buffer; ±1%)**,** and the detection wavelength was modified to 221 nm and 223 nm (±2 nm)**.** Chromatographic parameters including retention time, peak area, and theoretical plates were evaluated to determine method reliability.

Specificity

Specificity was established using mixed standard solutions of 16 µg/mL Remogliflozin and 8 µg/mL Vildagliptin**.** The chromatograms were examined for peak purity, absence of interference from excipients, and consistency of retention times, confirming that the method was specific for both analytes.

Assay of Marketed Formulation

The assay of the marketed formulation (ZOMELIS-SG) was performed using the optimized method. Twenty tablets were weighed, finely powdered, and extracted with methanol using sonication. The

extract was diluted to obtain stock solutions equivalent to 400µg/mL Remogliflozin and 200µg/mL Vildagliptin. A further dilution of 0.4mL of this stock was made to 10mL with the mobile phase to yield final assay concentrations of 16µg/mL Remogliflozin and 8µg/mL Vildagliptin. The solutions were filtered through a 0.45µm membrane filter and injected alongside standard solutions. The assay percentage was calculated by comparing sample peak areas with those of standards.

Forced Degradation Studies

Forced degradation studies were performed to evaluate the stability-indicating capability of the developed method. The API stock solutions were subjected to various stress conditions and analyzed under optimized chromatographic parameters.

Acidic Hydrolysis

For acid-induced degradation, 0.4 mL of stock solution was mixed with 5 mL of 0.1 N HCl, diluted with the diluent, and allowed to react for 1 hour and 3 hours. The samples were then neutralized, filtered, and analyzed.

Alkaline Hydrolysis

Alkaline degradation was performed by treating 0.4mL of stock solution with 5mL of 0.1 NNaOH, followed by standing for **1 hour and 3 hours**. Samples were neutralized, filtered, and injected into the HPLC system.

Oxidative Degradation

Oxidative stress testing was carried out by combining 0.4mL of stock solution with 5mL of 3% hydrogen peroxide**.** The mixture was maintained for 1hour and 3hours, filtered, and analyzed without neutralization.

Neutral Hydrolysis

Neutral hydrolytic degradation was assessed by mixing 0.5 mL of stock solution with 5 mL of water, diluting with diluent, and keeping the mixture at room temperature for 3 hours, followed by filtration and analysis.

Photolytic Degradation

Photolytic degradation was evaluated by exposing 100 mg of the API to direct sunlight for 24 hours. A stock solution was prepared from the exposed material, diluted to working concentrations (16 µg/mL Remogliflozin and 8 µg/mL Vildagliptin), filtered, and analyzed for light-induced degradation products.

RESULTS

Determination of Absorption Maxima

The UV absorption maxima (λmax) for Remogliflozin (RMG) and Vildagliptin (VLD) were found to be 224 nm and 213 nm, respectively, using methanol as solvent, confirming their suitability for UV detection.

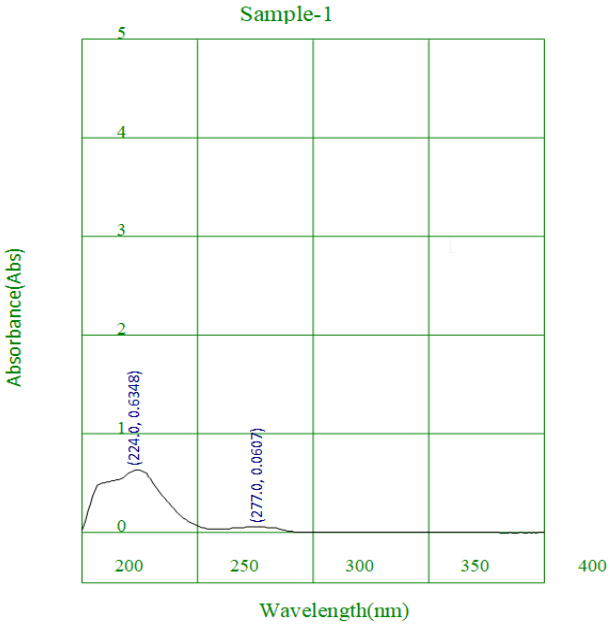

Fig 1: Absorption spectra of Remogliflozin

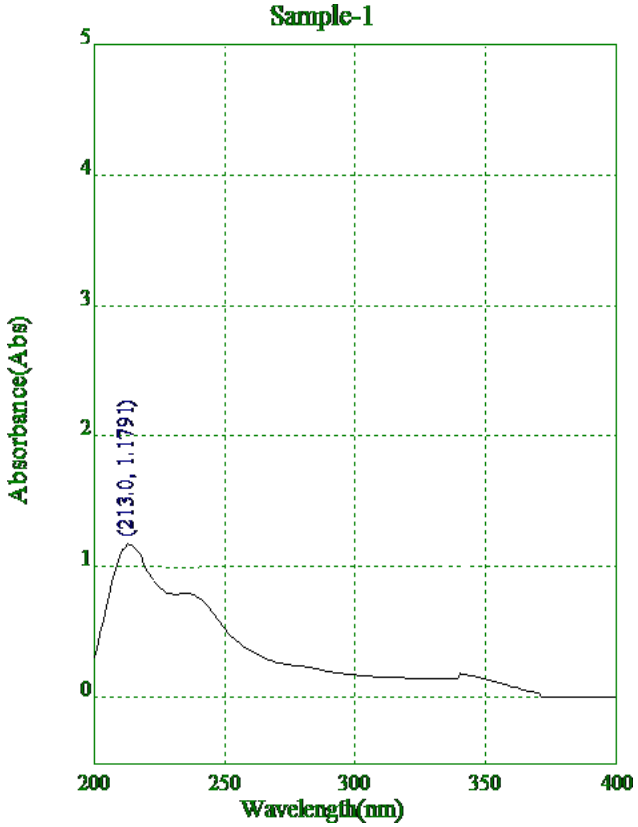

Fig 2 : Absorption spectra of Vildagliptin

Optimization of Chromatographic Conditions

A series of mobile phase trials were carried out for peak optimization. Trial-06 consisting of MeOH 40% + 0.1% Acetic acid 60% at 0.9 mL/min provided sharp, symmetrical peaks, adequate resolution and the best theoretical plate count, and was selected as the optimized chromatographic condition.

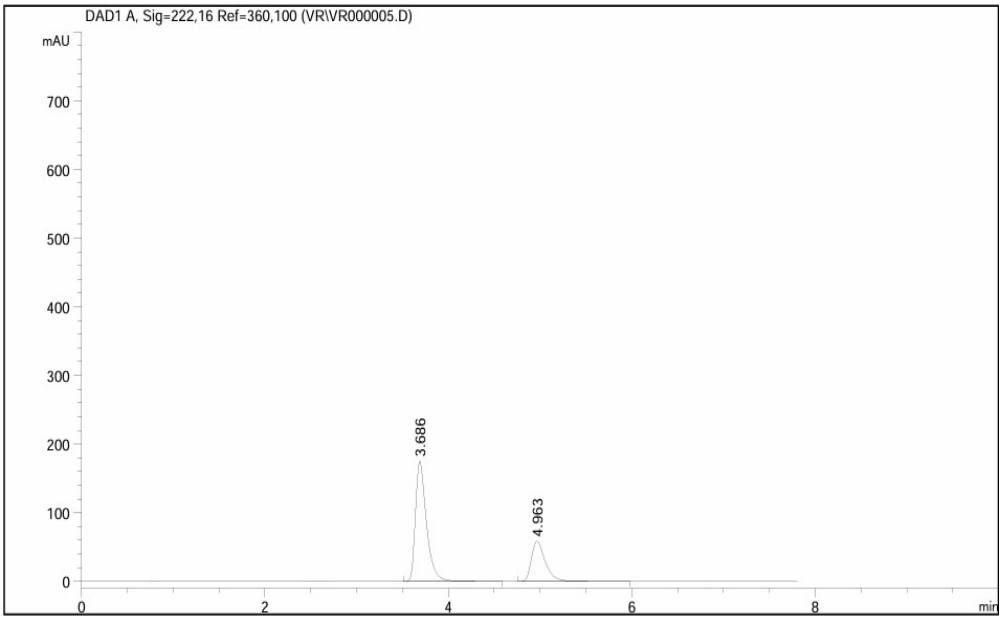

Fig 3: Chromatogram of Trial 06 optimized mobile phase composition

Linearity

The method exhibited excellent linearity over the ranges:

- RMG: 4–20 µg/mL (R^2 = 0.9999)
- VLD: 2–10 µg/mL (R^2 = 0.9997)

The %RSD values ranged from **0.05–1.20%** for RMG and **0.02–0.91%** for VLD, confirming a precise linear response.

Accuracy

Recovery studies at 80%, 100% & 120% levels showed:

- RMG: 100.49–101.98%
- VLD: 98.85–101.15%

All values were within the acceptable range (98–102%).

Precision

- **Repeatability**: Peak area %RSD
  - RMG: **0.030%**
  - VLD: **0.381%**
- **Intraday and Interday precision**: %RSD < **0.14%** for both drugs

These results confirmed an excellent degree of precision.

Sensitivity (LOD & LOQ)

LOD & LOQ were calculated per ICH-Q2(R1):

Drug	LOD (µg/mL)	LOQ (µg/mL)
RMG	**0.149 µg/mL**	**0.4515 µg/mL**
VLD	**0.0443 µg/mL**	**0.1342 µg/mL**

The values indicate high sensitivity of the developed method.

Ruggedness & Robustness

No significant change in peak area, retention time, or system suitability parameters under small method variations (different analysts, wavelength, and solvent composition). %RSD remained < **0.3%**, demonstrating rugged and robust performance.

Specificity

No interfering peaks were observed at the retention times of RMG and VLD.

Label claim results:

- **RMG: 99.35%**
- **VLD: 98.52%**

Thus confirming excellent specificity of the method.

Assay of Marketed Formulation

The developed HPLC method was successfully applied to the marketed tablet formulation:

- **RMG: 99.50%**
- **VLD: 99.76%**

Ensuring accuracy in routine quality evaluation

Table 5: Assay Results of Marketed Formulation

Drug	Conc (µg/mL)	Area (I)	C	M	CM	Amount Found (µg/mL)	% Label Claim	Mean % LC	SD	%RSD
RMG	16.00	2113.260	9.27	132.10	2103.99	15.9273	99.55	99.50	0.070	0.070
		2111.178	9.27	132.10	2101.91	15.9115	99.45			
VLD	8.00	905.120	11.15	111.80	893.97	7.9962	99.95	99.76	0.276	0.277
		901.630	11.15	111.80	890.48	7.9649	99.56			

Forced Degradation Study (Stability-Indicating Capability)

The degradation pattern was:

Oxidative > Basic > Acidic > Neutral

The method effectively separated degradation products from the analyte peaks, confirming strong stability-indicating capability.

Table 6: Summary of Method Validation Results for Remogliflozin and Vildagliptin

Validation Parameter	Remogliflozin (RMG)	Vildagliptin (VLD)	Acceptance Criteria	Status
Linearity Range	4–20 µg/mL	2–10 µg/mL	$r^2 \geq 0.999$	Meets
Linearity Regression (r^2)	0.99995	0.99979	Close to 1.0	Excellent
Accuracy (% Recovery)	100.49–101.98%	98.85–101.15%	98–102%	Within limits
Repeatability (%RSD)	0.030%	0.381%	≤ 1%	Highly precise
LOD (µg/mL)	0.1490	0.0443	As low as possible	Highly sensitive
LOQ (µg/mL)	0.4515	0.1342	As low as possible	Sensitive for quantification
Specificity	No interference	No interference	Analyte peak purity	Confirmed
Assay of Marketed Formulation	99.50% of label claim	99.76% of label claim	95–105%	Accurate & applicable
Stability-Indicating Capability	Degradation: 8.75% (H_2O_2, 1 h max)	7.71% (H_2O_2, 1 h max)	Degradants resolved	Confirmed

DISCUSSION

The present research work focused on the development of a simple, accurate, precise, and stability-indicating RP-HPLC method for the simultaneous estimation of Remogliflozin (RMG) and Vildagliptin (VLD) in bulk and pharmaceutical dosage forms. The optimized mobile phase of MeOH: 0.1% Acetic Acid (40:60 v/v) at 0.9 mL/min provided sharp, symmetrical, and well-resolved peaks with high theoretical plate counts and clean baseline separation, indicating optimum chromatographic conditions for the two analytes.

The linearity studies demonstrated excellent correlation within the concentration ranges **of** 4–20 µg/mL for RMG and 2–10 µg/mL for VLD, evidenced by regression coefficients (R^2) close to unity. The very low %RSD values (<1.20% for RMG and <0.91% for VLD) indicate the consistency and reliability of the detector response and robustness of the calibration model.

Accuracy results, expressed as percentage recovery, were within the pharmacopeial acceptance criteria of 98–102%, confirming the method's capability to measure the true analyte concentration without interference from excipients. RMG exhibited recovery values ranging 100.49–101.98%**,** while VLD showed 98.85–101.15%**,** demonstrating excellent trueness of the method.

Precision studies revealed significantly low variability in peak areas during repeatability, intraday, and interday experiments, with %RSD values well below the recommended limit of 2%, signifying strong reproducibility under both short-term and day-to-day analytical conditions.

The sensitivity of the proposed method was supported by low LOD and LOQ values for both drugs, confirming its applicability for detecting low concentration levels in samples. These values are suitable for routine analysis and possible trace-level detection in stability testing and pharmacokinetic studies.

Robustness and ruggedness tests ensured that minor variations in wavelength, mobile phase composition, and analyst handling did not significantly alter system suitability parameters, establishing the reliability of the method under diverse laboratory conditions.

Specificity results confirmed that no interfering peaks were observed at the retention times of RMG and VLD. Adequate separation of analytes from formulation excipients and degradation products validated the method's selective detection capabilities. The assay results (>99% label claim) confirmed successful application of the method to marketed formulation analysis.

Finally, forced degradation studies revealed degradation behavior consistent with known chemical instability patterns of antidiabetic drugs. The degradation trend (Oxidative > Basic > Acidic > Neutral) along with well-resolved degradant peaks demonstrated the method's strong stability-indicating performance, thereby fulfilling ICH Q2(R1) requirements for stress testing.

CONCLUSION

A simple, rapid, economical, and highly efficient RP-HPLC method has been successfully developed and validated for the simultaneous estimation of Remogliflozin and Vildagliptin in bulk and combined pharmaceutical dosage forms. The method demonstrated outstanding analytical performance in all validation parameters as per the guidelines of ICH Q2(R1), including specificity, linearity, accuracy, precision, robustness, ruggedness, and sensitivity. The excellent resolution with sharp and symmetrical peaks confirmed reliable chromatographic separation of both analytes without any interference from excipients or degradation products.

The accuracy and precision results were within the acceptable limits, indicating strong reproducibility and reliability of the method during repeated measurements. The low LOD and LOQ values reflected high sensitivity of quantification, enabling detection of both drugs even at trace levels. The method further proved to be stability-indicating, as it could efficiently distinguish parent drug peaks from various degradation products generated during forced degradation studies under acidic, alkaline, oxidative, thermal, and photolytic stress conditions.

Practical applicability of the method was confirmed by successful assay of marketed formulation with results close to the labeled claim. Due to its simplicity, short analysis time, and high sensitivity, the method is highly suitable for routine quality control analysis, regulatory submission requirements, dissolution profiling, and stability assessment during formulation development as well as post-marketing surveillance. Therefore, the developed RP-HPLC method can be confidently adopted in pharmaceutical industries and research laboratories for reliable evaluation of Remogliflozin and Vildagliptin in different analytical environments.

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