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Review Article

Review on Method Development and Validation of Remogliflozin Etabonate and Teneligliptin by RP-HPLC and UV Spectroscopy

Kedar Sneha Sanjay*, Dr. Gaware Vinayak M.

Pravara Collage of Pharmacy (for women) Chincholi, Nashik. Maharashtra

A B S T R A C T

The increasing global prevalence of Type 2 Diabetes Mellitus has driven the demand for safer and more effective therapeutic strategies, notably those combining novel antidiabetic agents. This study focuses on Remogliflozin Etabonate, a selective SGLT2 inhibitor, and Teneligliptin, a third-generation DPP-4 inhibitor, both offering complementary mechanisms for improved glycemic control. The research emphasizes the urgent need for robust analytical methods to ensure quality, safety, and efficacy of these drugs in pharmaceutical formulations. Various validated techniques including UV Spectroscopy, HPTLC, and RP-HPLC have been developed to accurately quantify these compounds. Among these, RP-HPLC stands out for its precision, reproducibility, and adaptability in routine analysis. Detailed method validation parameters such as linearity, accuracy, LOD, and LOQ are examined, supporting their compliance with ICH guidelines. This paper also compares the performance and suitability of existing methods while proposing optimal conditions for simultaneous estimation. The combination of Remogliflozin and Teneligliptin not only enhances therapeutic outcomes but also poses analytical challenges that are addressed through methodical development. The review underscores the significance of validated techniques in regulatory submissions and quality assurance, paving the way for advanced pharmacological monitoring. This comprehensive overview contributes to the evolving landscape of diabetes treatment and analytical innovation.

Keywords: Remogliflozin Etabonate, Teneligliptin, RP-HPLC, SGLT2 Inhibitor, Type 2 Diabetes Mellitus, DPP-4 Inhibitor, Analytical Method Development

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*Address for Correspondence:

Kedar Sneha Sanjay, Pravara Collage of Pharmacy (for women) Chincholi, Nashik. Maharashtra

INTRODUCTION

Remogliflozin Etabonate (REM) is chemically Ethyl[(2R,3S,4S,5R,6S)-3,4,5-trihydroxy-6 Remogliflozin -[5-methyl-1-propan-2-yl-4-[(4-propan-2-yloxyphenyl) methyl] pyrazol-3-yl] oxyoxan-2-yl] methyl carbonate. According to Figure S1, REM has a molecular weight of 522.6 g/mol and the formula C26H38N2O9. The fact that is an inactive prodrug which upon the administration and absorption is converted to its active form remogliflozin which acts particularly on the sodium-glucose co-transporter subtype 2 (SGLT2) and used for treatment of Diabetes Mellitus Type-2 (1)A literature survey regarding quantitative analysis revealed that various analytical methods have been reported for the estimation of REM. Estimation of REM in human plasma has been reported by LC MS-MS methods. UV Spectroscopy and HPTLC have been developed for the analysis of REM in bulk and tablet dosage form. REM is not official in any pharmacopoeia. Analytical method submitted to drug authority as a part of new drug application or abbreviated new drug application should be specific and it must have stability indicating nature(2)SGLT1, a high affinity, low capacity glucose cotransporter, and SGLT2, a low affinity, high capacity glucose cotransporter, are the two varieties of sodium-glucose cotransporters that have been identified and shown to exhibit the glucose reabsorption in the proximal tubules of the kidney.(3)Numerous acute and chronic problems can result from persistent hyperglycemia in uncontrolled diabetes mellitus caused by inadequate therapy or non-adherence to treatment. Hypoglycemia, diabetic ketoacidosis, hyperglycemic hyperosmolar condition, and hyperglycemic diabetic coma are examples of acute consequences. Nephropathy, neuropathy, and retinopathy are examples of chronic microvascular complications; coronary artery disease (CAD), peripheral artery disease (PAD), and cerebrovascular disease are examples of chronic macrovascular consequences.(4).A safer anti-diabetic

medication is required due to the increase in side effects; the most important side effects to take into account are hypoglycemia, long-term side effects, and the potential for weight gain with this medication.(5)Patients with glucose/galactose malabsorption, which is caused by mutations in the SGLT1 gene, have severe gastrointestinal problems but only minor renal glucosuria (6)A new medication called remogliflozin etabonate is an oral bioavailable prodrug of the powerful and specific SGLT2 inhibitor remogliflozin. Single dosages of remogliflozin etabonate have been shown to cause a significant excretion of glucose in the urine. Comparing dapagliflozin, canagliflozin, and empagliflozin with other authorized SGLT2 inhibitors,whereas have longer half-lives, remogliflozin etabonate needs to be administered twice daily (BID) in order to produce 24-hour glucose-lowering effects because it has a short elimination half-life (7).The intricate process of glucose homeostasis is regulated by renal filtration/reabsorption, hepatic/renal gluconeogenesis, tissue usage, and gastrointestinal absorption, elimination. The active sodiumdependent glucose transporter 2 (SGLT2), which is found on the apical or luminal membrane of the epithelial cell in the S1 segment, is principally responsible for the reabsorption of glucose when the glomerular filtrate enters the proximal tubule under normal physiological conditions (8).Monitoring the progression of this worldwide epidemic is crucial. (9)A second co-transporter (SGLT1) found in the S3 distal portion of the proximal tubule facilitates the reabsorption of leftover glucose. (10)In 1990, there were 26.0 million diabetics in India; by 2016, that number had grown to 65.0 million, a 2.5-fold increase (11).

Teneligliptin is a third generation DPP-4 inhibitor licensed for treatment of type 2 diabetes

(12).Teneligliptin (Tenelia) is chemically 3- [(2S,4S) -4-[4-(3-methyl-1-phenyl-1H-pyrazol-5-yl) piperazin-1-yl [pyrrolidin-2-ylcarbonyl] Teneligliptin is safe and effective for people with type 2 diabetes who have renal impairment or even end-stage renal disease. Illness without modifying dosage (13).Five rings make up the extremely stiff "J-shaped" structure of teneligliptin. Since DPP-4 is directly connected to four of these rings, the highest Comparing DPP-4 enzyme binding to various gliptins (14).Teneligliptin functions by preventing the DPP-4 enzyme from becoming active (15).Teneligliptin is beneficial in terms of pharmacological features since the dosage is constant regardless of renal function (16).Teneligliptin has a 24.2-hour half-life, which results in reduction of postprandial hyperglycemia following all three daily meals and inhibition of DPP-4 throughout the day (17).To reach the appropriate glycemic target levels, patients with insufficient glycemic control frequently need extra combination therapy or treatment with more recent anti-diabetic medications or insulin (18).An incretin hormone called glucagon-like peptide-1 (GLP-1) is released from the digestive system in reaction to meal consumption (19).GLP-1 has a crucial function in controlling postprandial insulin secretion because it inhibits glucagon secretion and raises it in a glucose-dependent manner (20).

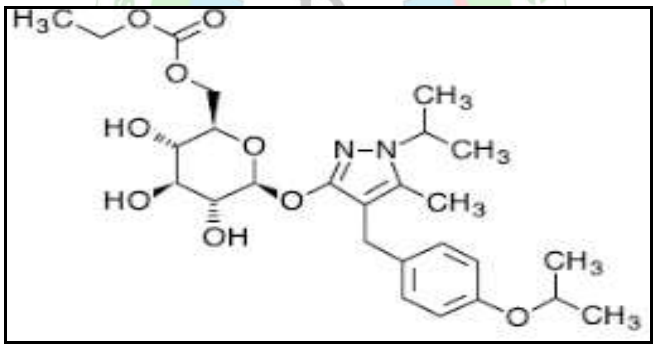

Figure 1: Chemical structure of Remogliflozin etabonate

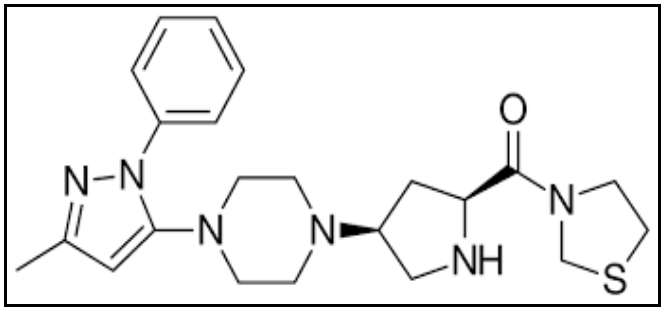

Figure 2: ***Chemical structure of Teneligliptin***

The development of analytical techniques

Analytical methods ensure that the drugs are identified, effective, potent, and pure. Drug development and manufacturing depend on the development of analytical techniques. Due to patent regulations, a suitable analytical approach for the drugs cannot be published in the literature. According to no pharmacopeia, these are the basic prerequisites for creating new drug analysis techniques. More and more drugs are being introduced to the market each year. The pharmacopeia may therefore not

contain the standards and testing methods for these drugs. Therefore, new methods of analysis for these types of drugs must be grown. The analytical process is often described in detail as part of the scope of the analytical technique's development.

HPLC METHOD

Applications for reversed phase chromatography in the field of biochemistry include both analytical and preparatory uses. separation as well as purification. Reversed phase chromatography can separate molecules with a high degree of recovery and resolution that have certain hydrophobic properties, such as proteins, peptides, and nucleic acids (21).

Analytical technique Development and Validation presents the topic of creating and refining an HPLC technique, which leads to a detailed guideline. It then discusses the validation procedure, which begins with instrument qualification and ends with system appropriateness (22).The development, enhancement, and production of pharmaceuticals all benefit greatly from the refinement and validation of analytical approaches. The primary goal of an analytical measure is to obtain reliable, accurate, realistic information. The use of validated analytical techniques is crucial to accomplishing this aim (23).In order to guarantee adherence to safety and quality regulations, the US, Europe, Compendia, or pharmacopeia, have been issued by Japan and other nations that outline the official testing procedures for a large number of marketed pharmaceutical goods (24).When examining pharmaceutical formulations and bulk medications for quality assurance and control, pharmaceutical analysis is extremely important. A sharp rise in prescription Sectors (25).These chromatographic principles' primary benefits include low detection limits, the capacity to produce structural details, the need for little sample preparation, and the ability to cover a large variety of analytes with varying polarity (26).

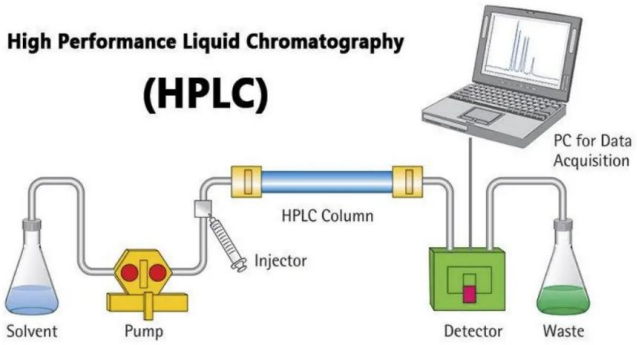

Figure 3: HPLC technique

Validation parameters of HPLC

The objective of an analytical procedure is to determine its suitability for the intended purpose. Validation is crucial in proving compliance under particular conditions for any process, method, equipment, material, or activity. The ICH harmonized guideline Q2(R1) offers guidance for validating analytical methods, which aims to guarantee that the methods used to analyze pharmaceutical products are accurate, dependable, and consistent. Method development can be a difficult and time-consuming process. For all activities, method development labs must estimate the appropriate mobile phase, temperature, pH, column, and gradient to achieve precise and separation.

Herearethevalidationparametersforanalytical methods

1. Specificity
2. Accuracy
3. Linearity
4. Precision
5. Quantitationlimit
6. Detectionlimit
7. Range
8. Robustness

Reversed-phase High-Performance liquid chromatography

It is the most widely used technique for chemical analysis and preparative separations of compounds of interest. the sciences of biology, pharmacology, food, and medicine. This techniqueinvolves a polar solvent as the mobile phase and a non-polar hydrophobic packing with an octal or octa decyl functional group attached to silica gel as the stationary phase. In this phase, the polar component elutes first, while the non-polar compounds are held steady for a duration. The majority of medications and pharmaceuticals elute more quickly because they are polar in nature and are not maintained for extended periods of time. The several columns that are utilized include Octa Decyl Silane (ODS) or C18, C8, and C4 (in the stationary phase's rising polarity sequence) as per table 1. It is possible to employ secondary solute chemicals with an aqueous mobile phase (27).

UV Spectroscopy

Ultraviolet (UV) spectroscopy is a physical technique of the most often used method for analytical and preparative separations of compounds of interest. Using visible, ultraviolet, and near-infrared light, optical spectroscopy is based on the Beer-Lambert rule, which asserts that a solution's absorbance is exactly proportional to the path length and the absorbing species' concentration in the solution. Consequently, it can be used to ascertain the absorber concentration in a solution for a certain path length.It is important to understand how quickly absorbance varies with concentration. After being widely used over the past 37 years, UV-VIS spectroscopy has emerged as the most crucial analytical tool in a modern laboratory. In a multitude of applications,UV-VIS spectroscopy is superior to other methods in terms of its ease of use, adaptability, precision, speed, and affordability (28). All the recent study related to

method development and validation of Remogliflozin Etabonate and Teneligliptin are mention in below table. 1

Table 1: Reported method

Sr.No	Drug	Method	Description	Wavelength	Ref.No.
1	Remogliflozin Etabonate	UV spectroscopy	Solvent: Methanol Linearity: 2-10 µg/ml r2: 0.999 LOD: 0.037 µg/ml LOQ: 0.113 µg/ml	229 nm	29
2	Remogliflozin Etabonate	RP-HPLC	Column: C18 (250 mm × 4.6 mm, 5 µm) Mobile phase: Methanol:Water (70:30% v/v) Flow rate: 1.0 ml/min Linearity: 1-25 µg/ml R2: 0.997 LOD: 0.21 µg/ml LOQ: 0.66 µg/ml	229 nm	30
3	Remogliflozin Etabonate	HPTLC	Stationary Phase: Silica gel 60 F254 (100 mm × 100 mm, 250µm) Mobile Phase: Toluene: Methanol (8.5:1.5% v/v) Rf value: 0.35±0.03 Linearity: 50-250 ng/band	224nm	31
4	Teneligliptin	HPLC	Column :Cosmosil C18 (250mm x 4.6ID, Particle size: 5 micron) Mobile Phase 70 : 30 (Methanol: Phosphate buffer pH-3). Flow Rate 0.8 ml/min Linearity: 10 to 50 µg/ml (Injection Volume 20 µl Detector UV-3000-M	246nm	32
5	Teneligliptin	UV Spectroscopy	Solvent :Distiled water Linearity:linear in the range of 5-70 µg/mL for zero order and AUC techniques, while 5-80 µg/mL regression coefficient (R2) 0.999 The accuracy of the drug was ranged in between 98.54-101.80 . The percentage RSD values for method precision for all the methods were within the limit of ≤ 2	244nm	33
6	Teneligliptin	RP-HPLC	Mobile phase : mixture of 0.05M Potassium dihydrogen phosphate PH 4.0 and Acetonitrile 80:20 % v/v flow rate : 1 ml/min r. The retention time of Teneligliptin, Impurity B and Impurity G were 7.443 min, 6.650 min and 8.473 min respectively. Linearity for Teneligliptin, Impurity B and Impurity G were found in the range of 500-3000 µg/ml (R2 = 0.998), 5-15 µg/ml (R2 = 0.994) and 5-15 µg/ml (R2 = 0.998) respectively. The accuracy of the present method was evaluated at 50%, 100% and 150%. The % recoveries of drug were found to be in range of 99.315 ± 0.283 for Teneligliptin. Precision studies were carried out and the RSD values were less than two	242nm	34
7	Teneligliptin	UV Spectroscopy	Solvent : methanol Linearity:2-12 µg/ml (PPM) LOD : 5.88 ug/ml LOQ: 17.29 ug/ml	248nm	35
8	Teneligliptin	RP- HPLC	Solvent : Methanol Column: Inertsil C18(250 mm × 4.6ID,5 um) Mobile phase : Methanol: Water (90:10)	248nm	36

			Flow rate : flow rate of 0.8 ml/min Linearity: 10–50 µg/mL. Run time : 30 min Retention time : 6.36 min LOD: 0.956 ug/m LOQ: 0.171 ug/ml		
9	Remogliflozin And Teneligliptin	RP- HPLC	Column :Ascentis 150 x 4.6 mm, 5m column. 0.01N Kh2:30 is present in the mobile phase. Acetonitrile in the 70:30 ratio flow rate : 1.0ml/min. retention time: Remogliflozin - 2.271 minutes Teneligliptin 2.706 Percent RSD of Remogliflozin: 0.6 Teneligliptin : 0.5 Remogliflozin and Teneligliptin recovered at 99.73% and 99.63%, respectively. LOD: REMO-0.01 TENE- 0.04 LOQ: REMO- 0.48 TENE- 1.47	254nm	37
10	Remogliflozin And Teneligliptin	HPLC	Column : C 18 column of dimensions 150 x 4.6 mm and 5µm Mobile phase: ammonium acetate and Acetonitrile ratio of 65:35. Flow rate : 1 ml/min Run time : 5.0 min Buffer: 0.1N Ammonium acetate RSD : Remogliflozin and Teneligliptin was found at 2.206 and 2.646 min. %RSD of the drugs found at 0.6 % and 0.6%	210nm	38
11	Remogliflozin And Teneligliptin	UPLC	Column: C18 100 mm × 3.5 mm, 2.1 mm column with an economical flow rate : 0.2 mL/ min. Mobile phase: acetonitrile,triethylamine and methanol. RT : Remogliflozin-1.3ml/min Teneligliptin-1.6ml/min	248nm	39
12	Remogliflozin And Teneligliptin	RP-HPLC	Mobile phase: Acetonitrile: KH2 ,ratio (35:65) Retention time: remogliflozin:2.263 min teneligliptin :2.994 min r2 : 0.999 flow rate: 1ml/min column temperature of 30°C, injection volume : 10µL run time : 6min LOD : Remogliflozin- 0.42 Teneligliptin- 0.02 LOQ : Remogliflozin-1.26 Teneligliptin-0.05	240nm	40
13	Remogliflozin and Vildagliptin	Second derivative spectroscopy	Mobile phase: Ethanol Linearity: REM: 5-75 µg/ml VLD: 2-50 µg/ml r2: REM: 0.9997 VLD: 0.9993 LOD: REM: 1.38 µg/ml VLD: 0.31 µg/ml LOQ: REM: 4.12 µg/ml VLD: 0.94 µg/ml	REM: 243 nm VLD: 221 nm	41
14	Remogliflozin Etabonate And Metformin Hydrochloride	RP-HPLC	Column: C18 (250mm x 4.6mm, 5 µm) Mobile phase: Buffer (pH 4.0): methanol (60:40 % v/v) Flow rate: 1 ml/min Linearity: MET: 20-60 µg/ml REM: 5-15 µg/ml LOD: MET: 0.785 µg/ml REM: 0.764 µg/ml LOQ: MET: 2.380 µg/ml REM: 2.314 µg/ml	241 nm	42
15	Remogliflozin Etabonate	RP-HPLC	Column: C18 (250 mm × 4.6 mm, 5 µm)	210nm	43

	and Vildagliptin		Mobile phase: Water:Acetonitrile (60:40 % v/v) Flow rate: 1.0 ml/min Linearity: VLD: 5-40 µg/ml REM: 10-80 µg/ml r2: VLD: 0.9992 REM:0.9997 LOD: VLD: 0.029 µg/ml REM: 0.010 µg/ml LOQ: VLD: 0.088 µg/ml REM: 0.031 µg/ml		
16	Remogliflozin Etabonate and Metformin Hydrochloride	UHPLC/DAD	Column: C18 (5 µm, 4.6 mm x 150 mm) Mobile phase: Phosphate buffer (pH:4.5): Acetonitrile (60:40% v/v) LOQ: REM: 10 µg/ml MET: 50 µg/ml LOD: REM: 5 µg/ml MET: 10 µg/ml	230nm	44
17	Metformin and Remogliflozin	UV Derivative Spectrophotometric	Model: Shimadzu 1700 Solvent: Methanol, Water Linearity: RGE: 1-24µg/mL MFH: 2.5-30µg/m	Third derivative Absorbance Method RGE:234.8nm MFH:240.1nm Zero cross point: RGE: 240.1nm MET: 234 nm Ratio Second derivative Method: Zero crossing point: RGE: 277.2nm MFH: 246.6nm	45
18	Remogliflozin and Vildagliptin	RP-HPLC	Stationary Phase: Luna C18 (250mm ×4.6mm, 5µm) Mobile Phase: Acetate Buffer (pH 5.6): Methanol (30:70%v/v) Flow Rate: 1.0 mL/min Retention Time: REM: 4.881 VDG: 6.334 Linearity: REM: 10-200µg/mL VDG: 10-200µg/mL	210 nm	46
19	Teneligliptin	UV Spectroscopy	Linearity :10-50ug/ml R2 : 0.9952% LOD:2.25 ug/ml LOQ: 6.83 ug/ml	246 nm	47
20	Remogliflozin and Teneligliptin	HPLC	Column :Discovery C 18 column of dimensions 150 x 4.6 mm and 5µm Flow rate: 1 ml/min Run time 5.0 min Buffer: 0.1N Ammonium acetate Mobile phase :ammonium acetate and Acetonitrile (65:35). RT: Remogliflozin: 2.206 min Teneligliptin 2.646 min. %RSD :Remogliflozin: 0.6 % Teneligliptin: 0.6% RT : Teneligliptin 2.206 Remogliflozin 2.646	210nm	48
21	Remogliflozin and Teneligliptin	HPLC	Column :Inertsil C18 (4.6 x 150mm, 4.8µm) Mobile phase : Acetonitrile: OPA buffer with pH 4.4 ratio (70:30) flow rate : 1.0 ml/min Linearity: Remogliflozin 12.5-75µg/ml Teneligliptin :1.25- 7.5ug/ml LOD: Remogliflozin :0.22, Teneligliptin :0.68 LOQ: Remogliflozin:0.05 Teneligliptin :0.15	210 nm	2

CONCLUSION

The comprehensive study of Remogliflozin Etabonate and Teneligliptin highlights their significant role in the effective management of Type 2 Diabetes Mellitus. As a selective SGLT2 inhibitor and a DPP-4 inhibitor respectively, both drugs offer distinct mechanisms of action that complement each other when used in combination therapy. The increasing need for accurate, reliable, and cost-effective analytical methods has driven the development and validation of various techniques including UV Spectroscopy, HPTLC,

HPLC, and RP-HPLC. These methods have been proven to be robust, precise, and sensitive for the qualitative and quantitative estimation of these antidiabetic agents in pharmaceutical formulations. Among them, RP-HPLC remains the most versatile and widely used due to its high resolution and reproducibility. Overall, the study supports the continued innovation and optimization of analytical techniques for better therapeutic monitoring and quality control in the pharmaceutical industry**.**

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