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Research Paper**METHOD DEVELOPMENT AND ANALYTICAL VALIDATION FOR THE SIMULTANEOUS DETERMINATION OF REMOGLIFLOZIN AND METFORMIN****Priyanka Choudhary*, Dilip Agrawal, Rakesh Goyal**

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A simple, rapid, affordable, precise, and accurate RP-HPLC technique for simultaneous quantification of Remogliflozin Etabonate and Metformin HCl in their synthetic mixture and tablet dosage form has been devised. A reverse-phase high-performance liquid chromatographic method has been devised to simultaneously quantify Remogliflozin Etabonate and Metformin HCl in their Synthetic Mixture. Chromatographic separation was obtained using a Hypersil™ Thermo Scientific "ODS-C18 (250 mm × 4.6 mm, i.d.2.5 µm) column with a mobile phase consisting of Acetonitrile: 20 mM ammonium formate (pH adjusted to 3.5 with formic acid) in a ratio of 40:60 % (v/v). Detection was carried out at 243nm. The retention time of Remogliflozin Etabonate and Metformin HCl was 3.2 min and 4.9 min, respectively. The method devised for quickly, precisely, and accurately quantifying Metformin HCl and Remogliflozin Etabonate in their synthetic mixture was effective. The suggested technique, which worked well for simultaneously quantifying both drugs in a commercial synthetic mixture.

Keywords: Remogliflozin Etabonate, Metformin HCl, RP-HPLC, Development of method, validation.**INTRODUCTION**

Remogliflozin Etabonate is a medication of the gliflozin class used to treat type 2 diabetes and non-alcoholic steatohepatitis ("NASH"). IUPAC name was Ethyl [(2R,3S,4S,5R,6S)-3,4,5-trihydroxy-6-[[5-methyl-1-(propan-2-yl)-4-[[4-(propan-2-yloxy)phenyl]methyl]-1H-pyrazol-3-yl]oxy]oxan-2-yl]methyl carbonate.¹

Remogliflozin is being developed by BHV Pharma, a fully owned subsidiary of Avolynt in North Carolina, USA, and Glenmark Pharmaceuticals through a partnership with BHV. It was initially discovered by the Japanese company Kissei Pharmaceutical. In May 2019, Glenmark launched Remogliflozin commercially in India for the first time.²⁻³

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Metformin is a member of the biguanide class of anti-diabetics with antihyperglycemic action. Lactic acidosis is an infrequent side effect of Metformin. IUPAC's name was N, N-Dimethyl imidodicarbonimidicdiamide. In 1922, Metformin was discovered.³ The research on people was started in 1950 by French physician Jean Sterne. It was first made available as a medicine in France in 1957 and the US in 1995¹⁰⁻²².⁴

According to a survey of the literature, there are two methods available for determining Remogliflozin Etabonate and Metformin HCl using UV spectroscopy and two RP-HPLC techniques has been published for the estimation of Remogliflozin Etabonate and Metformin HCl in their pharmaceutical dosage



form or API for stability, suggesting an analytical method and validation.⁵⁻⁶ The goal of the current work was to develop a stability-indicating RP-HPLC method for the estimation of Remogliflozin Etabonate and Metformin HCl in their dosage forms. The proposed RP-HPLC detection method was validated in accordance with International Conference on Harmonisation (ICH) guidelines⁷⁻⁸ because analytical methods must be approved before use by the pharmaceutical industry. This method's selectivity, linearity, accuracy, and precision, as well as its limit of detection and limit of quantification, were evaluated.

EXPERIMENTAL

Chemicals and Reagents:

Double distilled water was used. AR grade solvents were used during the whole study. HPLC grade Ortho Phosphoric Acid (Merck) was used for the mobile phase. Potassium dihydrogen ortho phosphate, Ammonium formate were of also AR grade (Rankem).

Instrument:

HPLC system (Shimadzu LC-20AD) equipped with inbuilt autosampler and quaternary gradient pump with an on-line degasser was used. The column compartment having temperature control and photodiode array (PDA) detector was employed throughout the analysis. Chromatographic data was acquired using empower software.

Drug Standard Standard Solution:

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The primary standard stock solution was prepared by adding 10 mg Remogliflozin and 50 mg Metformin in to 80 ml of diluent and then make the final volume of volumetric flask up to the 100 ml with the same diluent, sonicated for 10 min with the help of sonicator for complete dissolve the drugs and after sonication, volume makes up 100 ml "with the same solvent. Take the volume of primary standard stock solution (0.25, 0.5, 1, 1.25, 1.5, and 2.5) make up to 10 ml with the same diluent. The final concentration of Remogliflozin and Metformin was found to be 2.5 to 25 $\mu\text{g ml}^{-1}$ and 12.5 to 125 $\mu\text{g ml}^{-1}$, respectively for linearity and other analytical methods. The final solution was filtered through a 0.45 μm Millipore membrane filter."

Preparation of sample Solution:

20 tablets of different brands of Remogliflozin and Metformin "were accurately weighed and then crushed to form the powder equivalent to 10 mg Remogliflozin and Metformin 50 mg which was then transferred into a cleaned and dried 100 ml volumetric flask. The powder was dissolved into the mobile phase using sonication, made up the volume up to 100 ml with the same solvent and filtered with using a Millipore membrane filter resulting in the concentrations 10 and 50 $\mu\text{g ml}^{-1}$ respectively. The working sample was repeatedly injected with 20 μl solution by using the flow rate of 1 ml min⁻¹. The optimum wavelength for detection

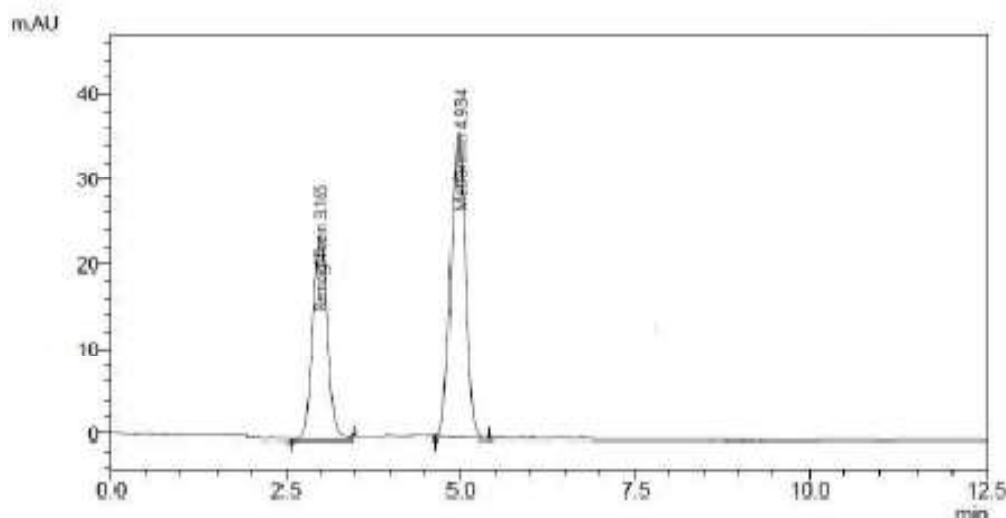


Figure 1: Chromatogram showing the separation of drugs

was set at 243 nm.”

Method Development and Validation:

The process was optimized and validated by changing multiple parameters like mobile phase composition, pH, elution technique, flow rate,

Table 1: Optimized Chromatographic Conditions

S. No	Parameter	Description
1.	Column	Hypersil TM Thermo Scientific “ODS-C18 (250 mm × 4.6 mm, i.d. 2.5 µm) columns”
2.	Mobile Phase	Acetonitrile: 20 mM ammonium formate (pH adjusted to 3.5 with formic acid) in a ratio of 40:60 % (v/v)
3.	Flow rate	1.0 mL / min
4.	Run time	10 minutes
5.	Column Temperature	28 ± 5°C
6.	Injection Volume	20 µL
7.	Detection Wavelength	243 nm
8.	Retention times	
	• Remogliflozin	3.2 minutes
	• Metformin	4.9 minutes

and appropriate columns to achieve sharp peaks, maximum theoretical plates, less tailing factor, and short analysis time. A typical chromatogram found by the same condition mentioned above is illustrated in Figure 1.

RESULTS AND DISCUSSION

System suitability:

The system suitability test is essential in validating analytical techniques and confirmation of resolution amongst numerous peaks of interest. All perious parameters (theoretical plates, retention time, and tailing factor) in the study met complete acceptance every time. % RSD for peak area of six replicate was found to be 1.01 and 0.88 for Remogliflozin and Metformin, respectively.

Specificity:

Good resolution and no interference from blank and excipients were observed that this method is specific for simultaneous analyzing of



Remogliflozin and Metformin. The commonly present excipients did not pose any interference at the retention time of the drug as they were not identified.

Linearity:

The method for linearity was evaluated from the calibration curve data, and the linear value was observed between the range from 2.5- 25 µg ml⁻¹ and 12.5- 125 µg ml⁻¹ for Remogliflozin and Metformin, respectively. The results revealed a strong link between detector response and drug concentration levels within the concentration range.

Precision:

For the precision study, the overall % RSD of system method precision was found to be less than 2, which indicates that the precision achieved successfully within the limit.

Accuracy:

Then recovery was estimated at 80 %, 100 % and 120 % of the selected concentrations. Remogliflozin and Metformin recovery values were determined to be 99.93-100.76 percent and 100.11 to 100.40 percent, respectively.

Robustness:

The robustness of the analytical procedure was established & developed by changing flow rate, pH, wavelength, and mobile phase composition. The results indicate that the present method is robust (% RSD < 1.00).

CONCLUSION:

According to ICH guidelines, the RP-HPLC and UV spectrophotometric techniques mentioned above were developed and validated for determining remogliflozin and Metformin. Comparing the procedures to those already set, they were straightforward, precise, accurate, and affordable. One advantage of these newly created methods is that they are far more sensitive than those in use. The RP-HPLC method might also report the Remogliflozin and Metformin stability characteristics under various stress situations. As a result, it can be used to determine the stability of medications in tablet form. Due to the absence of excipients or degradants, both techniques were precise.

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Conflict of Interest

The authors declare that they have no conflict of interest