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Original Article

Development and Validation of a Gradient RP-HPLC Method for Concurrent Analysis of Mirabegron and Silodosin in Bulk and Pharmaceutical Tablets

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ABSTRACT

Objectives: To quickly and easily identify and quantify Mirabegron and Silodosin in both pure and pharmaceutical dosage forms, a gradient Reverse-Phase High Performance Liquid Chromatography (RP-HPLC) technique was described. **Materials and Methods:** The separation was accomplished using a gradient mode pumping mobile phase consisting of acetonitrile and a 0.03 M buffer (Potassium dihydrogen orthophosphate in water with pH corrected to 3.2 with orthophosphoric acid) at a flow rate of 1 mL/min on a C-18 matrix Inertsil ODS-3V column with dimensions 250x4.6 mm and a 5-micron particle size. **Results:** At 6.052 and 7.986 minutes, respectively, the UV detector set at 245 nm was able to capture the peaks of MGB and SLD. The approach demonstrated linearity for MGB from 5 to 60 µg/mL and for SLD from 0.8 to 9.6 µg/mL, with matching r^2 values of 1 and 0.9999, respectively. A %RSD below 2 indicates that the procedure is both accurate and precise. **Conclusion:** It was concluded that the approach that was developed could be utilized for routine analysis of the pharmaceuticals in question in quality control laboratories, and that it was successfully applied to simultaneously estimate MGB and SLD in pure and its commercial medicinal dosage forms.

Keywords: Gradient, HPLC, Mirabegron, Silodosin, Simultaneous.

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INTRODUCTION

Mirabegron (MBG) is an innovative, first-in-class, powerful β3-AR agonist that operates orally once daily and is composed of 2-(2-Amino-1,3-thiazol-4-yl)-N-[4-[2-[((2R)-2-hydroxy-2-phenylethyl)amino]ethyl]phenyl]acetamide (Figure 1A) (Aditya *et al*., 2015). When a person has Overactive Bladder (OAB), they may have a number of unpleasant symptoms, including an overwhelming need to urinate at inappropriate times (such as during the night), leakage of urine following a strong urge, and a generalized lack of control over their bladder (Nandy and Ranganathan, 2024). A selective β3-adrenoceptor agonist, MBG is a relatively new component of OAB treatment (O'Kane *et al*., 2022). Because of the effect it has on the concentration of cyclic adenosine monophosphate in the bladder tissue, it can relax the bladder (Basu, 2020). As far as women experiencing symptoms of OAB are concerned, it is the first commercially available beta 3 adrenoreceptor agonist to have been approved for this purpose (Warren *et al*., 2016).

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A substantial decrease in incontinence events, micturition frequency, and urgency episodes was shown to be related with MBG (Coleman and Cox, 2012; Rossi and Roumeguère, 2010). In contrast, Silodosin (SLD) 1-(3-hydroxypropyl)-5-[(2R)-2-[2-[2-(2,2,2 trifluoromethoxy) phenoxy]ethylamino]propyl]-2,3-dihydroindole7-carboxamide (Figure 1B) is a selective α1 antagonist that inhibits receptors on prostate smooth muscle, resulting in relaxation of both the bladder neck and prostate smooth muscles (Bylund, 2016; Jindan *et al*., 2022). This, in turn, improves urine flow and reduces problems associated with Benign Prostatic Hyperplasia (BPH). For storage symptoms that are moderate to severe, SLD is not enough on its own; further treatment is necessary. Considering this, research examining the efficacy of combination therapy involving SLD and MBG found that it was much more effective than either drug alone or a placebo, had far fewer side effects, improved quality of life, and alleviated persistent storage symptoms in BPH patients. Consequently, it is crucial to design an efficient analytical method to enable the widespread deployment of the combination of MBG and Sildosin as an effective treatment.

Separately (Suryawanshi *et al*., 2020; RP-HPLC, 2018; Sankar *et al*., 2016; Godse and Sawant, 2024; Meijer *et al*., 2019) or in conjunction with other drugs (UHPLC, 2023; Patel *et al*., 2022;

Patil *et al.*, 2024; Andhale *et al.*, 2022; RP-HPLC, 2023; Rao and Meghana, 2023) MBG has been determined using a few different analytical methods. There is a plethora of analytical approaches that have been documented for the detection of SLD, either on its own (Harischandran *et al.*, 2012; Er and Erk, 2016; Tanuja *et al.*, 2021; Aneesh and Rajasekaran, 2012; Hasan *et al.*, 2024; Shaik *et al.*, 2014; Sayana *et al.*, 2012; Jahan and Malipatil, 2014; Rani and Venkateswarlu, 2016; Zhao *et al.*, 2009) or in conjunction with other medications (Nataraj *et al.*, 2020; Paljashuva and Ramarao, 2019; Gupta and Mishra, 2021; Kurmi and Asati, 2022; Dhiman *et al.*, 2022). However, HPLC techniques were found for the detection of MBG and Sildosin in a synthetic combination (Mishra *et al.*, 2024; Dudhrejiya *et al.*, 2024; Trivedi *et al.*, 2023). The development of analytical methods for the simultaneous detection and quantification has been further complicated by the development of numerous dosage form combinations in recent years. In response to the growing need for RP-HPLC methods that are sensitive, selective, accurate, precise, and robust enough to detect MGB and SLD simultaneously, the authors present a novel strategy based on acetonitrile as the organic solvent.

MATERIALS AND METHODS

Reagents and chemicals

Sigma-Aldrich Chemicals, Mumbai, India, supplied pharmaceutical grade (>99%) substances (I) MGB and SLD. Water and acetonitrile (HPLC grade) were procured from Ranbaxy Fine Chemical Limited, New Delhi, India. Qualigen-Fine chemicals supplied the remaining reagents, including phosphoric acid.

Chromatographic conditions and instrumentation

An HPLC system (2996) was employed for the analysis, which included an auto sampler and a PDA detector. Empower 2 software was employed to capture the data. Chromatographic separation was conducted on a C-18 matrix Inertsil ODS-3V, 250x4.6 mm, 5 microns, which was paired with a defense column of the same material. The mobile phase consisted of 0.03 M buffer (Potassium dihydrogen orthophosphate in water with pH corrected to 3.2 with orthophosphoric acid) and acetonitrile, which was pumped in a gradient mode at a flow rate of 1.0 mL/min. The UV detector was configured to operate at 245 nm to monitor the column effluent. A 50:50 (v/v) combination of water with acetonitrile was employed as a diluent. Prior to injection into the HPLC system, the mobile phase as well as standard solutions have been passed through a 0.45 µm nylon filter. The study was conducted at ambient temperature. The gradient program was executed in the following manner (Table 1).

Standard Stock Preparation

Transfer 50 mg of MGB and 8 mg of SLD working standards into 100 mL clean, dry volumetric flasks. Add 50 mL of diluent and sonicate for 20 min to dissolve the working standards completely. Make up to the mark with the same diluent. This results in a stock solution of 500 µg/mL of MGB and 80 µg/mL of SLD. 5.0 mL of the stock solution was pipetted into a 50 mL volumetric flask, and the final volume was added with diluent. This resulted in a 50 µg/mL MBG and 8 µg/mL SLD operating standard solution.

Sample Preparation

In a mortar and pestle, 20 tablets (Silodol-M 50) were precisely weighed, pulverized, and combined. Accurately weigh a portion of powder equivalent to 650 mg and transfer it to a 100 mL volumetric flask. Add 50 mL of diluent and sonicate for 30 min to dissolve the powder completely. Make up to the mark with the same diluent. The solution was filtered through a 0.45 µm membrane filter. The 5.0 mL of the filtered solution was pipetted into a 50 mL volumetric flask and subsequently diluted to the final volume. For HPLC analysis, 20 µL of this solution was injected.

Method Validation

Specificity Assessment

To evaluate the specificity of the novel technique, it is essential to ensure that the analyte response remains unaffected by any potential interferences, such as placebos or other naturally occurring compounds. This investigation involves bringing the system to equilibrium by optimizing chromatographic conditions beforehand. After a stable baseline is achieved, responses are recorded initially with a blank solution, followed by sample and standard preparations containing 50 µg/mL of MGB and 8 µg/mL of SLD.

Precision

To test the method's precision, the chromatographic conditions were set to stabilize the system before proceeding. Both a standard and drug solution was tested for precision at 100% concentration (50 µg/mL for MGB and 8 µg/mL for SLD). Six samples of these concentrations were examined on the same day to determine intra-day variability, and six were tested across three days to investigate inter-day variability.

Accuracy

Accuracy of the method was established through recovery studies, where a sample solution with known quantities was spiked at three standard concentration levels (approximately 80%, 100%, and 120%). Each concentration level was injected in triplicate, and the mean percentage recovery for each level was calculated to confirm the method's accuracy

Linearity

To evaluate linearity, working standards were formulated at six intensity levels: 20%, 40%, 60%, 80%, 100%, and 120%, resulting in final concentrations of 5 to 60 µg/mL for MGB and 0.8 to 9.6 µg/mL for SLD. Each standard solution was subjected to filtration via a 0.45 µm renewable cellulose filter before to injection. The

differing percentages of MGB and SLD in these standard working solutions have been introduced in triplicate to determine linearity and range. Peak sizes matching to each concentration were documented, and a curve for calibration was generated by graphing concentration against peak area for MGB and SLD. The data were examined employing the least-squares method to ascertain the calibration equations.

Limit of Detection (LOD) and Limit of Quantification (LOQ)

The Limits of Detection (LOD) and Quantification (LOQ) limits for MGB and SLD were established by examining many diluted specimens at levels of 20%, 10%, 5%, 2%, 1%, 0.5%, 0.2%, 0.1%, 0.05%, 0.02%, 0.01%, and 0.005% using this approach. Signal-to-noise ratios were documented to evaluate sensitivity. The Limit of Detection (LOD) was established as the concentration at which the signal-to-noise ratio of roughly 3:1, while the Limit of Quantification (LOQ) was determined at a ratio of around 10:1, accompanied by a Relative Standard Deviation (%RSD) of less than 10% (n=3).

Robustness

To assess robustness, slight modifications were implemented in method parameters; specifically (i) the utilization of alternative columns and (ii) a flow rate variation of±0.1 mL/min. Specimen and standard solutions were examined for each adjustment to assess any effects on the procedure. The percentage Relative Standard Deviation (RSD) was computed for each instance to evaluate consistency.

System appropriateness

Injecting standards of MGB and SLD into an HPLC system allowed us to verify that the established method's precision as well as accuracy were within the appropriate limits. Several metrics were assessed, including the Relative Standard Deviation (RSD), hypothetical plates as well, resolution, and USP tailing component.

RESULTS AND DISCUSSION

Optimization of chromatographic conditions

The chromatographic settings have been tuned to elute the compounds of interest simultaneously, a challenging task that involves regulating the pH of the mobile phase, which governs the ionization of the drug and thus speeds up elution. Various experiments were conducted in an isocratic mode using phosphate buffer at varying pH in conjunction with methanol and acetonitrile; however, the separation of pharmaceuticals was not sufficiently effective. Good retention was observed when the fluid was circulated in a gradient manner. The pH was further adjusted to 3.2 using orthophosphoric acid to enhance the resolution between the peaks and the morphology of the peaks. This was successful. The mobile phase is initially composed of 80% phosphate buffer (A) and 20% acetonitrile (B), which results in a more polar operating environment. MBG and SLD both associate with the stationary phase; however, the elution is slowed by the higher polarity of phase A, which enables them to engage with the column and retain them for an extended period. The proportion of acetonitrile (B) increases considerably to 80% over the first 5 min, while the phosphate buffer (A) decreases to 20%. The mobile phase is generally less polar than the phosphate buffer due to the fact that acetonitrile is less polar. The interaction between the stationary phase and MBG and SLD is disrupted by this alteration, resulting in an increase in their elution rate. For the subsequent five minutes, the ratio remains constant at 20% A and 80% B. The low-polarity environment that is maintained by the high concentration of acetonitrile facilitates the elution of both compounds from the column, if they have not already done so, in accordance with their respective affinities. Compounds such as SLD and MBG, which elute at varying rates based on their molecular size or polarity, can be successfully separated during this period. The mobile phase reverts to the initial conditions of 80% phosphate buffer and 20% acetonitrile after 10 minutes. By reestablishing a polar environment, this reconstitution conditions the column for the subsequent cycle. The UV absorption spectrum of MGB and SLD were combined, and they intersected at 245 nm. This proved that it is feasible to detect many signals at once using just one wavelength.

Table 1: Programming for mobile phase pumping in gradient manner.

Time	Mobile phase A	Mobile phase B
0.01	80.0	20.0
5.0	20.0	80.0
10.0	20.0	80.0
10.1	80.0	20.0
13.0	80.0	20.0

Validation

Specificity assessment

The chromatograms of the blank, standard, and test samples, as illustrated in Figure 2, verify the analyte's distinct evaluation, thereby proving the specificity of the approach that was created.

Precision

The precision of the method is indicated by % RSD values, which are calculated, based on the peak response areas from six injections each of MGB and SLD sample and standard solutions. For intraday precision, data was collected within a single day, while interday precision data were gathered across three separate days. In both cases, % RSD values were below 2%, confirming the method's reliability, as summarized in Table 2.

Table 2: **Report of precision study results of MGB and SLD.**

Intraday Precision				
	Standard		Sample	
	MGB	SLD	MGB	SLD
Mean RT±SD	6.033±0.016	7.996±0.011	6.025±0.005	8.011±0.005
%RSD	0.258	0.142	0.088	0.063
Mean Area±SD	6254898.3±1800.3	1883241.8±1544.7	6241884.0±1763.2	1881521.3±1988.4
%RSD	0.2	0.1	0.3	0.1
Interday Precision				
	Standard		Sample	
	MGB	SLD	MGB	SLD
Mean RT±SD	6.013±0.018	7.786 ±0.015	6.017±0.047	0.078
%RSD	0.258	0.168	0.078	0.058
Mean Area±SD	6254898.3±1800.3	1891541.8±1426.9	6252762.0±1812.2	1887528.4±1876.4
%RSD	0.2	0.2	0.4	0.2

*Mean *n*=6 determinations.

Table 3: **Results for MGB and SLD Accuracy**

	MGB			SLD		
	120%	100%	80%	120%	100%	80%
Unspiked standard Area	7436241.± 956.6	6216462.7± 1648.7	4955698.7± 2056.7	2287307.7± 1692.0	1885230.0± 1866.1	1504217.7± 1416.0
Spiked standard Area	8113602.± 1062.8	6810144.0± 859.7	5685089.7± 1932.5	2507352.0± 1724.7	2096484.0± 1993.5	1697878.7 ± 2543.9
Average % recovery	109.1	109.6	114.7	109.6	111.2	112.9
%RSD	1.8	0.2	0.5	1.4	0.9	2.0
SEM	3.12	0.35	0.87	2.42	1.56	3.46

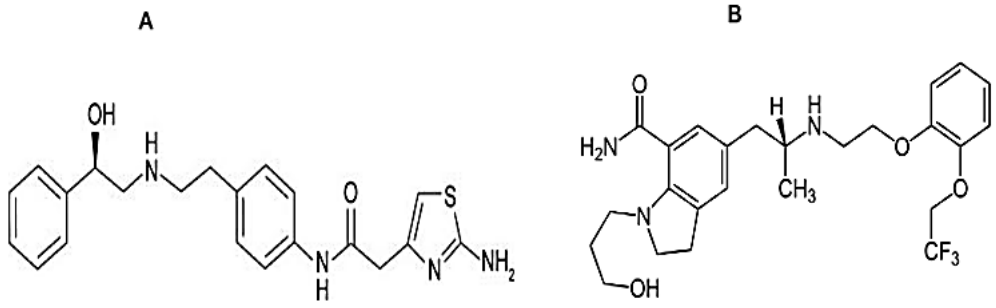

Figure 1: (A) Chemical structure of MGB and (B) Chemical structure of SLD.

Accuracy

The percentage mean recovery of MGB and SLD at 3 different concentration levels demonstrated the method's compliance with acceptance criteria. These results confirm the method's reliability and are presented in Table 3.

Linearity

The regression analysis of mean peak areas vs concentrations established a linear correlation within the defined concentration ranges: 5 µg/mL to 60 µg/mL for MGB and 0.8 µg/mL to 9.6 µg/mL for SLD. The determination Coefficients (R^2) derived from the linear regression study were 1 for MGB and 0.9999 for SLD, signifying exceptional linearity. Figure 3 illustrates the linear correlation between MGB and SLD. The corresponding chromatograms depicting linearity are shown in Figure 4.

Limit of Detection (LOD) and Limit of Quantification (LOQ)

This approach demonstrated significant sensitivity, producing LOD levels of 0.05% for MGB and 0.2% for SLD. The LOQ values were determined to be 0.15% for MGB and 0.60% for SLD.

Robustness

The approach exhibited considerable robustness, as variations in mobile phase flow velocity and the application of various columns had no major impact, as indicated by consistent % RSD results in Table 4.

System appropriateness

The results showed that MGB and SLD separated at a resolution of 9.08 and a retention duration of 6.052 and 7.986 min, respectively. With a tailing factor of 1.55 for MGB and 0.95 for SLD, the theoretical plate count was determined to be 32285.08 and 13,275.44, respectively.

Applications of the developed analytical method in the assay of formulations

The test of existing tablets in the market was used to assess the suggested procedure. There was a comparison of the tablet dosage forms' responses to their respective standard solutions. All the drugs were found to be within the specified limits (i.e., 95-105%), as stated in Table 5.

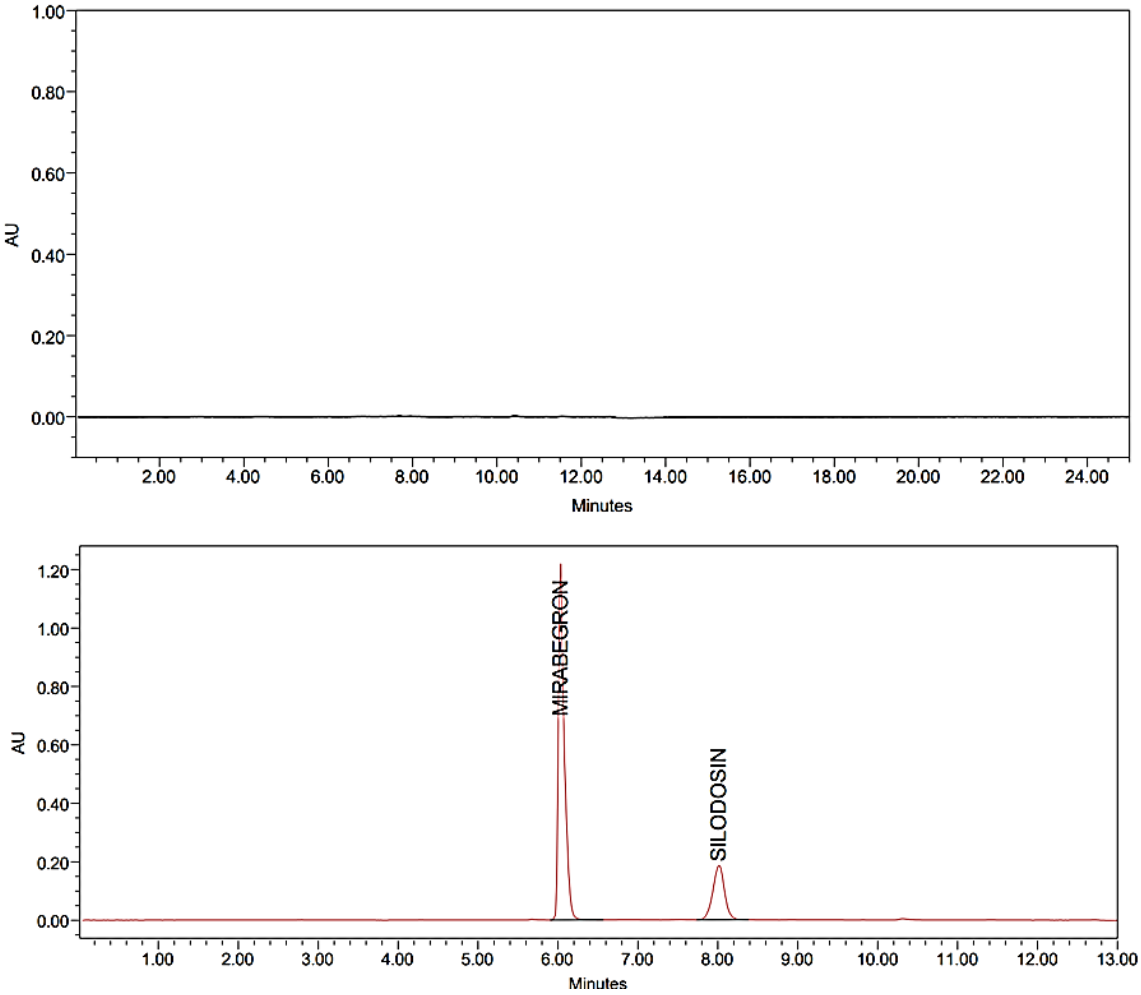

Figure 2: Chromatograms that show how the blank, he sample, and the standard layer compared to each other.

Table 4: Results of assessments of method robustness.

	MGB				SLD			
Parameter	Mean area ±SD	%RSD	RT ±SD	%RSD	Mean area ±SD	%RSD	RT ±SD	%RSD
Different column								
Sample	6343669.7±1966.0	0.1	7.928±0.01	0.015	1941994±1936.5	0.1	5.972±0.01	0.02
STD	6330477.7±2305.2	0.2	7.941±0.009	0.107	1926133.7±980.2	0.1	5.978±0.007	0.111
Flow decrease								
Sample	2141419.0±1563.4	0.1	8.38±0.005	0.055	7069205.7±1888.2	0.1	6.382±0.006	0.08
STD	2178750±1255.2	0.1	8.391±0.010	0.7	7077793.0±1479.0	0.01	6.384±0.009	0.13
Flow Increase								
SAMPLE	1753226.7±1423.0	0.1	7.525±0.004	0.058	5781497.7±2703.8	0.01	5.624±0.003	0.051
STD	1753662±1669.4	0.1	7.524±0.011	0.151	5829478.7±1705.5	0.02	5.627±0.011	0.188

Mean*n=3 Determinations.

Table 5: HPLC assay results for tablet formulations.

	Peak Area of STD	Peak Area of Sample	Label claim (mg)	Amount found (mg)	%Assay
MGB	6254898.3	6241884.0	50	49.65	99.3%
SLD	1883241.8	1881521.3	8	7.98	99.81%

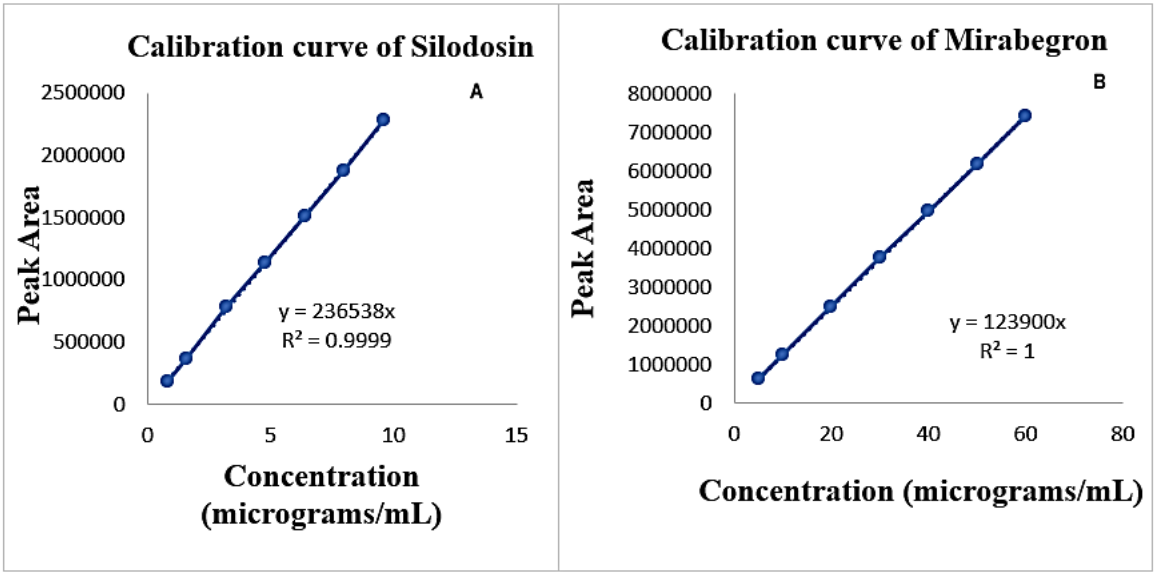

Figure 3: Calibration curve of HPLC method showing linearity of A. Silodosin B. Mirabegron.

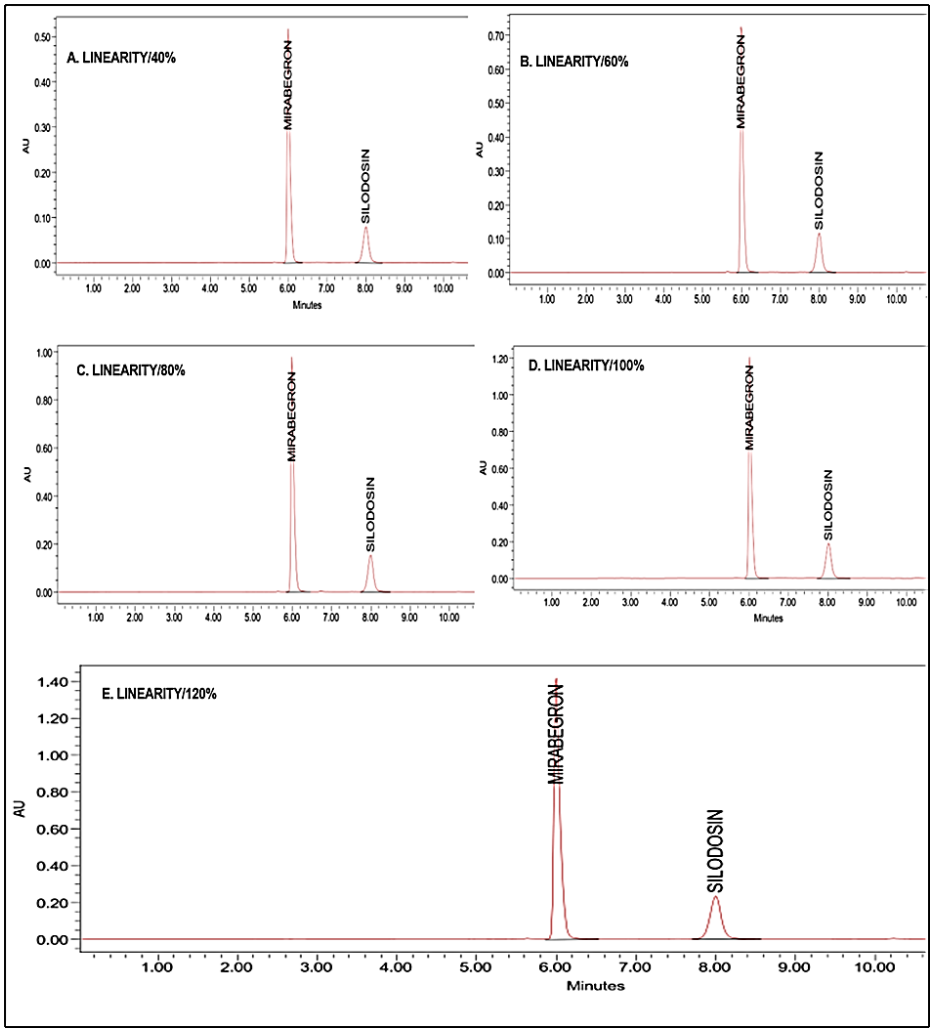

Figure 4: Chromatograms illustrating linearity at A. 40%, B. 60%, C. 80%, D. 100%, and E. 120%.

CONCLUSION

The successful development of a simultaneous HPLC method allowed for the successful optimization, validation, and development of its separation and detection of MGB and SLD in their mixed dosage form in a singular mixture. Selective, precise, accurate, and robust are the characteristics of the method as demonstrated by the experiments conducted in accordance with the ICH guidelines. The proposed approach is suitable for the quality monitoring of dosage forms due to its simplicity and effectiveness in identifying the proposed drugs. The gradient elution achieves effective separation by exploiting both the polarities of MBG and SLD in relation to the mobile phase. The relationship of each substance with the stationary state is manipulated by altering the mobile phase constitution over time, resulting in a differential separation that facilitates their efficient separation.

CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

ABBREVIATIONS

MBG/MGB: Mirabegron; **SLD:** Silodosin; **OAB:** Overactive Bladder; **BPH:** Benign Prostatic Hyperplasia; **RP-HPLC:** Reverse-Phase High Performance Liquid Chromatography; **HPLC:** High Performance Liquid Chromatography; **UV:** Ultraviolet; **PDA:** Photodiode Array; **RT:** Retention Time; **SD:** Standard Deviation; **SEM:** Standard Error of the Mean; **LOD:** Limit of Detection; **LOQ:** Limit of Quantification; **RSD:** Relative Standard Deviation; **ICH:** International Council for Harmonisation; **AR:** Adrenoreceptor; **β3-AR:** Beta-3 Adrenoreceptor; **mg:** Milligram; **mL:** Milliliter; **µg/mL:** Microgram per Milliliter; **nm:** Nanometer; **M:** Molar; **pH:** Potential of Hydrogen; **v/v:** Volume/Volume; **%RSD:** Percentage Relative Standard Deviation; **R^2:** Coefficient of Determination; **STD:** Standard; **USP:** United States Pharmacopeia; **HPTLC:** High-Performance Thin Layer Chromatography; **LC-MS/MS:** Liquid Chromatography-Tandem Mass Spectrometry; **ESI-MS:** Electrospray Ionization-Mass Spectrometry; **UHPLC:** Ultra-High Performance Liquid Chromatography.

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