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Research Article

A Stability Indicating RP-HPLC Method for Simultaneous Estimation of Solifenacin and Silodosin in Bulk and Formulation

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Abstract

A new RP-HPLC method was established for the concurrent measurement of Solifenacin and Silodosin in pharmaceutical products, characterized by its speed, precision, and sensitivity. To achieve effective separation, the researchers utilized a Waters Alliance e2695 system paired with a Hyperclone C18 column (250 × 4.6 mm, 5 µm). The process involved a mobile phase composed of acetonitrile and 0.1% formic acid (50:50 v/v), which was delivered at a constant flow rate of 1.0 mL/min. Analysis was performed at ambient temperature, with detection set at a wavelength of 272 nm using a PDA detector. The integrity of the system was confirmed through suitability parameters, which recorded theoretical plates exceeding 2000 and a tailing factor under 2.0 for both active ingredients. Additionally, the %RSD remained below 2.0, showcasing the method's high level of reproducibility and precision. This analytical approach was fully validated according to ICH guidelines, proving to be a robust, accurate, and budget-friendly option. Because it operates without interference from pharmaceutical excipients, it is highly recommended for routine laboratory analysis and stability testing of Solifenacin and Silodosin.

Keywords: RP-HPLC; Solifenacin and Silodosin; Method Validation; Stability Studies

Abbreviations

RP-HPLC: Reverse Phase High Performance Liquid Chromatography; HPLC: High Performance Liquid Chromatography; PDA: Photodiode Array; LOD: Limit of Detection; LOQ: Limit of Quantification; RSD: Relative Standard Deviation; BPH: Benign Prostatic Hyperplasia; LUTS: Lower Urinary Tract Symptoms.

Introduction

Benign prostatic hyperplasia is a prevalent urological condition primarily found in older males. It often manifests through lower urinary tract symptoms (LUTS), such as an increased frequency and urgency of urination, waking up at night to void (nocturia), and the sensation that the bladder has not fully emptied. Combination

therapy involving silodosin and solifenacin has emerged as an effective treatment strategy for managing both voiding and storage symptoms associated with BPH and overactive bladder syndrome. Silodosin is a highly selective α1A-adrenoceptor antagonist that improves urinary flow by relaxing smooth muscles in the prostate and bladder neck, whereas solifenacin succinate is a competitive muscarinic receptor antagonist used to reduce bladder overactivity and urinary frequency [1,2]. Several analytical methods have been reported individually for solifenacin and silodosin, including UV spectrophotometry, HPLC, LC-MS/MS, UPLC, RP-HPLC methods [3-19]. However, only limited studies are available for the simultaneous determination of both drugs in combined formulations includes RP-HPLC, HPTLC, HPLC(DAD) [20-22]. This research focuses on the creation and verification of a straightforward, quick, accurate, and durable RP-HPLC technique for concurrently measuring silodosin and solifenacin in drug products. Following ICH Q2(R2) protocols for validation, this approach is suitable for consistent quality assessment and monitoring the stability of medicinal blends involving these two components.

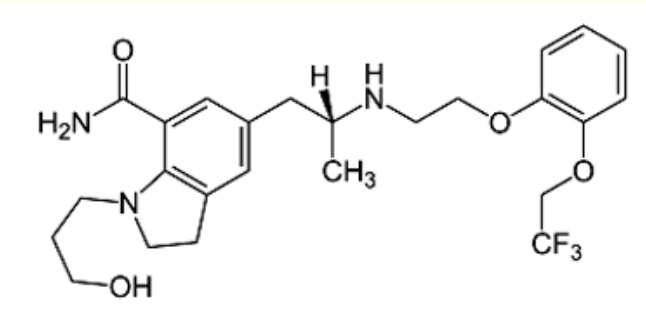

Figure 1: Molecular structure of Silodosin.

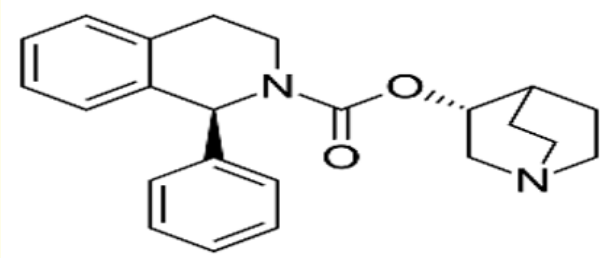

Figure 2: Molecular structure of Solifenacin.

Materials and Methods

Diluent: Acetonitrile is used as a diluent.

Standard solution protocol

To prepare the primary stock solution, precisely weigh 5 mg of Solifenacin and 8 mg of Silodosin working standards and transfer them into a clean, dry 10 mL volumetric flask. Add the specified diluent and sonicate the mixture until the components are entirely dissolved. Dilute the solution to the 10 mL mark with the same solvent.

To create the working standard**,** pipette 1 mL of the stock solution into a separate 10 mL volumetric flask. Dilute this to the mark with the diluent to reach final concentrations of 50 ppm for Solifenacin and 80 ppm for Silodosin**.**

Sample solution protocol

Begin by accurately weighing 172 mg of the Solifenacin and Silodosin sample and transferring it into a 10 mL volumetric flask. After adding the diluent, the mixture must be sonicated for 30 minutes**,** followed by 30 minutes of centrifugation to ensure the sample is fully dissolved. Once the volume is adjusted to the 10 mL mark with the diluent, the resulting stock solution should be passed through a 0.45-micron injection filter**.**

For the final analytical sample, transfer 1 mL of this filtered stock into a 10 mL volumetric flask and dilute it to the mark with the diluent. This procedure yields a solution containing 50 ppm of Solifenacin and 80 ppm of Silodosin.

System suitability

The system suitability criteria require that the tailing factor for Solifenacin and Silodosin peaks should not exceed 2.0, ensuring acceptable peak symmetry. Additionally, theoretical plates should be ≥2000 and resolution between the peaks should be ≥2, confirming adequate efficiency and separation of the method.

Optimized chromatographic conditions

Equipment

The HPLC system used is Waters Alliance e2695 with Empower 2.0 software for chromatographic analysis. Supporting instruments include pH meter (Eutech), analytical balance (Sartorius), UV-V is spectrophotometer (UV-1700), and glassware (Borosil). Sample

Parameters	Observation
Instrument used	Waters HPLC with auto sampler and PDA detector.
Injection volume	10µl
Mobile Phase	Acetonitrile: 0.1% Formic acid (50:50)
Column	Hyperclone 5**µ** BDS C18 130°A (250x 4.6 mm, 5**µ**)
Detection Wave Length	272nm
Flow Rate	1 mL/min
Runtime	8 min
Temperature	Ambient (25° C)
Mode of separation	Isocratic mode

Table 1: Optimized chromatographic conditions.

preparation and mobile phase handling were assisted by an ultrasonicator (UCA 701, Unichrome) and an isocratic pump system.

Reagents and chemicals

The HPLC method utilized acetonitrile and Milli-Q water of HPLC grade, along with formic acid and orthophosphoric acid of analytical reagent (AR) grade for mobile phase and pH adjustment. These chemicals were sourced from Merck and in-house production, ensuring suitable purity for chromatographic analysis and method reliability.

Method validation

Method specificity

The specificity of an analytical procedure is defined by its capacity to accurately quantify the target analyte in the presence of other components, such as known impurities or blanks. In this study, specificity was confirmed by comparing the chromatograms of the blank, standard, and sample solutions. Because the blank chromatogram exhibited no signal at the specific retention times for the drugs, the method's ability to specifically identify the analytes was verified.

Linearity assessment

To evaluate linearity, a stock solution was prepared by precisely weighing 5 mg of Solifenacin and 8 mg of Silodosin standards and dissolving them in a 10 mL volumetric flask using a diluent and sonication. This stock was used to create six different concentration levels:

- **Solifenacin:** 12.50 to 75.00 ppm
- **Silodosin:** 20.00 to 120.00 ppm

These levels were achieved by transferring between 0.25 and 1.50 mL of the stock into separate 10 mL flasks and diluting to the required volume. The linearity of the methodology was then determined by generating a calibration curve that plotted peak area against concentration, allowing for the calculation of the correlation coefficient.

Range

Range represents the span between the lowest and highest concentrations of an analyte including those specific limits where the method has successfully demonstrated accuracy, precision, and linearity.

Accuracy

Accuracy study solutions at 50%, 100%, and 150% levels were prepared by accurately weighing 86 mg, 172 mg, and 258 mg of Solifenacin and Silodosin samples, respectively, into separate 10 mL volumetric flasks containing diluent. The solutions were sonicated to dissolve completely and diluted up to the mark to obtain stock solutions. Further, 1 mL of each stock solution was transferred into separate 10 mL volumetric flasks and diluted with diluent to obtain final concentrations of 25/40 ppm, 50/80 ppm, and 75/120 ppm of Solifenacin and Silodosin, respectively. The prepared standard and accuracy level solutions were injected into the chromatographic system for recovery analysis.

Precision

Precision describes how repeatable an analytical technique is when used during standard operations. This concept is categorized into system, method, and intermediate precision. Testing these parameters involves different protocols:

- System precision is verified by performing six consecutive injections of a standard reference solution.
- Method precision is confirmed by conducting six separate trials on a consistent, uniform sample and then calculating the percentage relative standard deviation (%RSD).

As a specific example of instrument validation, precision can be tested by injecting six replicates of a solution containing 50 ppm Solifenacin and 80 ppm Silodosin.

Limit of detection (LOD) and limit of quantification (LOQ)

The LOD and LOQ for drug carry were determined using mathematical equations. These calculations adhered to the standardized guidelines established by the ICH.

$$LOD = 3.3 \times \sigma / S$$

$$LOQ = 10 \times \sigma / S$$

Robustness

Robustness of the method was evaluated by making deliberate variations in flow rate (0.9-1.1 mL/min) and mobile phase composition using standard solutions containing 50 ppm of Solifenacin and 80 ppm of Silodosin. The developed method is robust because minor changes in chromatographic conditions did not significantly impact its performance.

Degradation studies

Stock solution preparation

To prepare the initial stock, 172 mg of the Solifenacin and Silodosin sample is precisely weighed and transferred into a clean, dry 10 mL volumetric flask. A diluent is added, and the mixture undergoes sonication to ensure the sample is entirely dissolved. Finally, additional diluent is used to fill the flask to the 10 mL graduation mark.

Acidic degradation procedure

For the acid-induced stress test, 1 mL of the previously prepared stock solution is moved into a 10 mL flask and combined with 1 mL of 1N HCl. This mixture is incubated at 60°C for one hour. After heating, the solution is neutralized using 1N NaOH and then diluted to a final volume of 10 mL with the diluent. To prepare for storage, the solution is passed through 0.45-micron syringe filters and moved into collection bottles.

Alkaline degradation procedure

The process for basic degradation involves pipetting 1 mL of the stock solution into a 10 mL volumetric flask and adding 1 mL of 1N NaOH. The flask is maintained at a temperature of 60°C for one hour. Following this, the solution is neutralized with 1N HCl and diluted to the 10 mL mark using the diluent. The resulting liquid is then filtered through a 0.45-micron syringe filter and placed into vials.

Thermal stress testing

To assess how the samples react to heat, Solifenacin and Silodosin were placed in a hot air oven. The drugs were exposed to a temperature of 105°C for a duration of three hours. Following this thermal exposure, the samples were prepared using diluents and subsequently analyzed via HPLC.

Oxidative (Peroxide) degradation

For oxidative stress testing, 1 ml of the primary stock solution was transferred into a 10 ml vacuum flask. To this, 1 ml of 3% (w/v) hydrogen peroxide was added, and the flask was filled to the graduation mark with diluent. This mixture was heated to 60°C for 60 minutes before being allowed to settle at room temperature for an additional 15 minutes. Before analysis, the solution was passed through a 0.45-micron syringe filter and moved into storage bottles.

Reductive degradation

The reduction protocol involved mixing 1 ml of the stock solution with 1 ml of 10% sodium bisulfite within a 10 ml vacuum flask. After reaching the required volume with diluent, the flask was kept at 60°C for one hour. The preparation was then cooled at room temperature for 15 minutes. Finally, the liquid was processed through 0.45-micron syringe filters and transferred into bottles.

Photolytic stress testing

To determine the impact of light, Solifenacin and Silodosin samples were kept in a photostability chamber for three hours. Once the exposure period was complete, the samples were diluted accordingly and injected into the HPLC system for measurement.

Hydrolytic degradation

In this procedure, 1 ml of the stock solution and 1 ml of HPLC-grade water were combined in a 10 ml vacuum flask, which was then filled to capacity with diluent. The solution was subjected to a temperature of 60°C for one hour, followed by a 15-minute stabilization period at ambient temperature. The resulting mixture was filtered using 0.45-micron syringe filters and placed in bottles for further analysis.

Results and Discussion

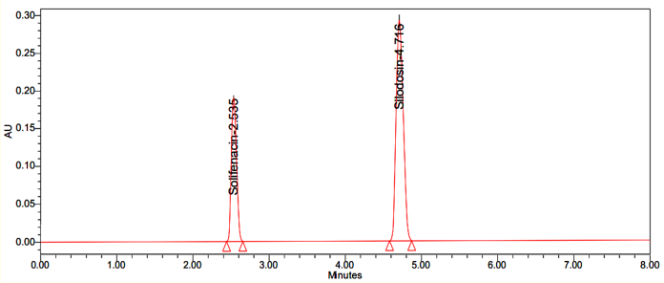

Figure 3: Optimized chromatogram.

Parameters	Solifenacin	Silodosin
RT	2.535	4.716
Area	224840	3581428
USP Plate Count	8523	10447
USP Tailing	1.07	1.15
USP Resolution	___	7.48

Table 2: Results of Optimized chromatogram.

System suitability

All the system suitability parameters were within the range and satisfactory as per ICH guidelines 4.

S. no	Parameter	Solifenacin	Silodosin
1	Retention time	2.535	4.716
2	Plate count	8523	10447
3	Tailing factor	1.07	1.15
4	Resolution	----	7.48
5	%RSD	0.36	0.34

Table 3: System suitability parameters for Solifenacin and Silodosin.

Analytical method validation (HPLC)

The method was validated for its linearity range, accuracy, precision and specificity. Method validation was carried out as per ICH guidelines.

Specificity

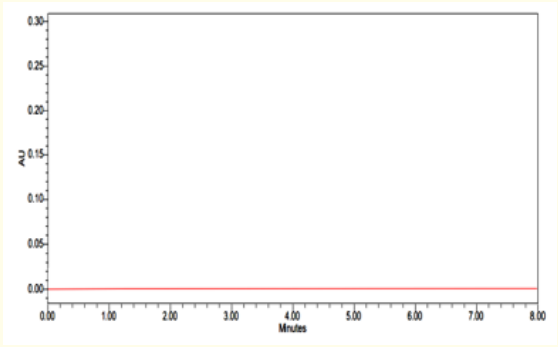

Figure 4: Chromatogram of blank.

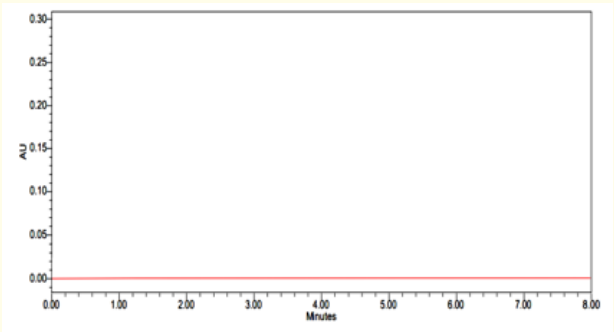

Figure 5: Chromatogram of placebo.

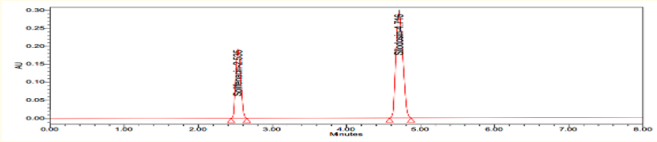

Figure 6: Optimized chromatogram.

Precision

S. No	Concentration Solifenacin (µg/ml)	Area of Solifenacin	Concentration of Silodosin (µg/ml)	Area of Silodosin
1.	50	2248402	80	3581428
2.	50	2229073	80	3596572
3.	50	2235956	80	3560654
4.	50	2229647	80	3582898
5.	50	2231617	80	3590947

6.	50	2244456	80	3578854
Mean	2236525		3581892	
S.D	8138.980		12320.750	
%RSD	0.36		0.34	

Table 4: System Precision.

Linearity

S. NO	Solifenacin		Silodosin	
	Conc.(µg/ml)	Peak area	Conc.(µg/ml)	Peak area
1	12.50	626937	20.00	846844
2	25.00	1145462	40.00	1781815
3	37.50	1743954	60.00	2713037
4	50.00	2262381	80.00	3576514
5	62.50	2829698	100.00	4387252
6	75.00	3381034	120.00	5198609
Regression equation	y =44758.69x +34329.82		y =43698.83x +21509.21	
Slope	44758.69		43698.83	
Intercept	34329.82		21509.21	
R^2	0.99980		0.99963	

Table 5: Linerity of Solifenacin and Silodosin.

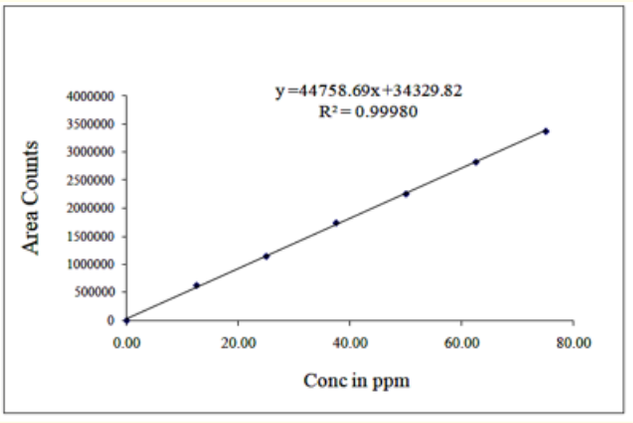

Figure 7: Calibration curve for Solifenacin.

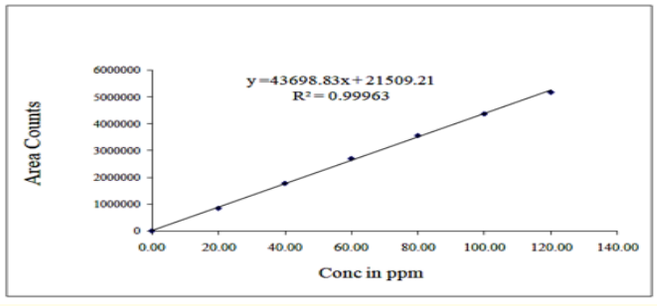

Figure 8: Calibration curve for Silodosin.

Assay

Brand	Drug	Sample area	Avg sample area (n = 2)	Std. Conc. (µg/ml)	Sample Conc. (µg/ml)	Label amount (mg)	Std purity	Amount found (µg/ml)	% assay
Silotag-SF	Solifenacin	2232547	2228352	50	50	5	99.9	4.98	99.6
		2224156							
	Silodosin	3574263	3582645	80	80	8	99.8	8.00	100.0
		3591027							

Table 6: Assay of Solifenacin and Silodosin

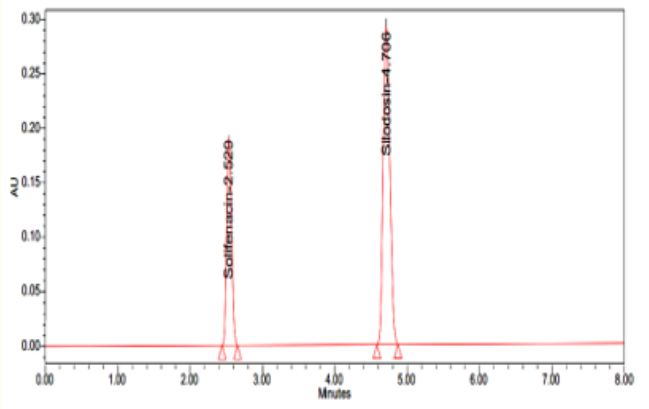

Figure 9: Chromatogram of Assay-1.

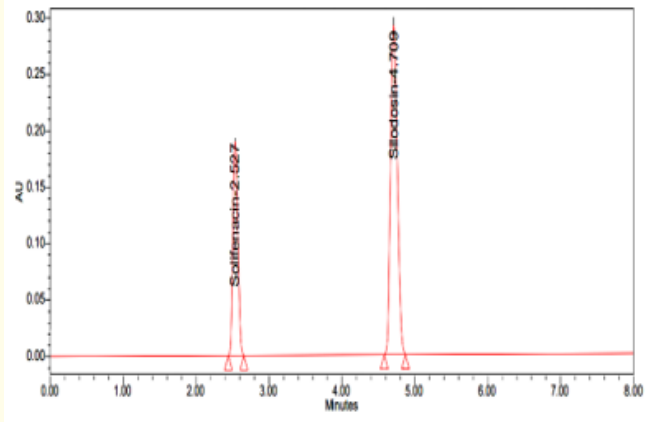

Figure 10: Chromatogram of Assay-2.

Repeatability

S. No.	Area for Solifenacin	Area for Silodosin
1	2242261	3521984
2	2254589	3595491
3	2225473	3560482
4	2233675	3533734
5	2210969	3605487
6	2245239	3577890
Average	2235368	3565845
Standard Deviation	15559.469	33403.955
%RSD	0.70	0.94

Table 7: Method Precision for Solifenacin and Silodosinby RP-HPLC method.

Intermediate precision (Day_ Day Precision)

S. No.	Area for Solifenacin		Area for Silodosin	
	Day-1	Day-2	Day-1	Day-2
1	2252261	2254647	3572415	3594215
2	2239950	2233108	3567881	3562418
3	2251334	2240356	3545612	3550231
4	2236891	2227950	3585206	3551724
5	2218068	2238687	3597823	3586210
6	2206522	2241233	3538679	3561203
Average	2234171	2239330	3567936	3567667
Standard Deviation	18365.107	9032.339	22653.402	18309.384
%RSD	0.82	0.40	0.63	0.51

Table 8: Intermediate Precision (Day variation) for Solifenacinand Silodosinby RP-HPLC method.

Accuracy

Concentration (at specification Level)	Area	Amount Added (mg)	Amount Found (mg)	% Recovery	Mean % Recovery
50%	1124857	2.5	2.51	100.4	99.9
	1109278	2.5	2.48	99.2	
	1118955	2.5	2.50	100.0	
100%	2231441	5.0	4.99	99.8	99.9
	2245598	5.0	5.02	100.4	
	2226891	5.0	4.98	99.6	
150%	3375608	7.5	7.55	100.7	100.2
	3361934	7.5	7.52	100.3	
	3344588	7.5	7.48	99.7	

Table 9: Accuracy results of Solifenacinby RP-HPLC method.

Concentration (at specification Level)	Area	Amount Added (mg)	Amount Found (mg)	% Recovery	Mean % Recovery
50%	1784840	4.0	3.99	99.8	99.8
	1806487	4.0	4.03	100.8	
	1774951	4.0	3.96	99.0	
100%	3561578	8.0	7.95	99.4	99.6
	3549854	8.0	7.93	99.1	
	3592602	8.0	8.02	100.3	
150%	5355895	12.0	11.96	99.7	99.4
	5293174	12.0	11.82	98.5	
	5377842	12.0	12.01	100.1	

Table 10: The Accuracy results for Silodosinby RP-HPLC method.

Robustness

Parameter	Solifenacin					
	Condition	Retention time (min)	Peak area	Tailing	Plate count	%RSD
Flow rate Change (mL/min)	Less flow (0.9 ml)	2.712	2191586	1.09	8457	1.02
	Actual (1.0 ml)	2.535	2248402	1.07	8523	0.36
	More flow (1.1ml)	2.203	2466390	1.02	8674	0.51
Organic Phase change	Less Org (45:55)	2.885	1909598	1.05	8361	0.80
	Actual (50:50)	2.530	2229073	1.01	8547	0.36
	More Org (55:45)	2.125	2536745	0.96	8758	0.30

Table 11: Robustness results of Solifenacinby RP-HPLC.

Parameter	Silodosin						
	Condition	Retention time (min)	Peak area	Resolution	Tailing	Plate count	%RSD
Flow rate Change (mL/min)	Less flow (0.9 ml)	4.804	3487854	6.82	1.19	10365	0.62
	Actual (1.0 ml)	4.716	3581428	7.48	1.15	10447	0.34
	More flow (1.1 ml)	4.536	3771852	8.54	1.12	10548	0.88
Organic Phase change	Less Org (45:55)	4.976	3280612	6.80	1.21	10312	0.35
	Actual (50:50)	4.718	3596572	7.42	1.17	10412	0.34
	More Org (55:45)	4.404	3860614	8.03	1.13	10609	0.71

Table 12: Robustness results of Silodosin by RP-HPLC.

Sensitivity

Name of drug	LOD (µg/ml)	s/n	LOQ (µg/ml)	s/n
Solifenacin	0.40	3	1.25	10
Silodosin	0.64	3	2.00	10

Table 13: Sensitivity parameters (LOD and LOQ) by RP-HPLC.

Degradation studies

Results: % Degradation results	Solifenacin					Silodosin				
	Area	% Assay	% Deg	Purity Angle	Purity Threshold	Area	% Assay	% Deg	Purity Angle	Purity Threshold
Control	2235672	100	0	3.987	8.466	3583672	100	0	2.435	6.214
Acid	1954263	87.4	12.6	3.932	8.435	3077241	85.9	14.1	2.486	6.269
Alkali	1986321	88.9	11.1	3.958	8.429	3032147	84.6	15.4	2.471	6.263
Peroxide	1882747	84.2	15.8	3.943	8.408	2987625	83.4	16.6	2.424	6.274
Reduction	2183848	97.7	2.3	3.907	8.471	3486214	97.3	2.7	2.451	6.206
Thermal	2012546	90.0	10.0	3.974	8.411	3551247	99.1	0.9	2.436	6.251
Photolytic	2155394	96.4	3.6	3.925	8.444	3495624	97.6	2.4	2.468	6.228
Hydrolysis	2221024	99.4	0.6	3.969	8.463	3557642	99.3	0.7	2.458	6.243

Table 14: Forced Degradation results for Solifenacin and Silodosin.

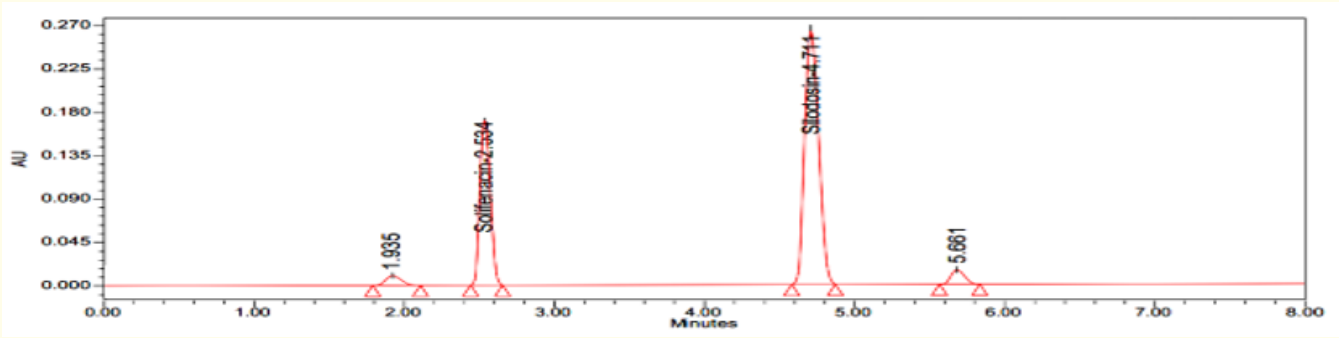

Figure 11: Chromatogram of Acid degradation.

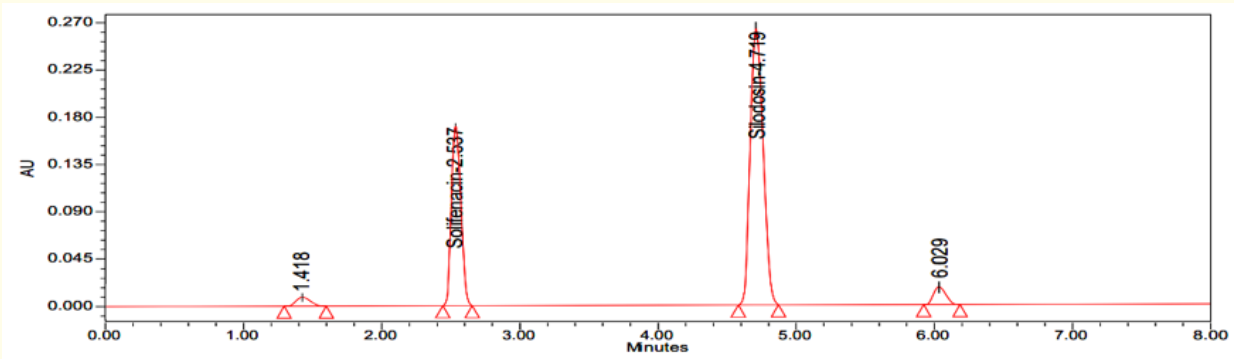

Figure 12: Chromatogram of Alkali degradation.

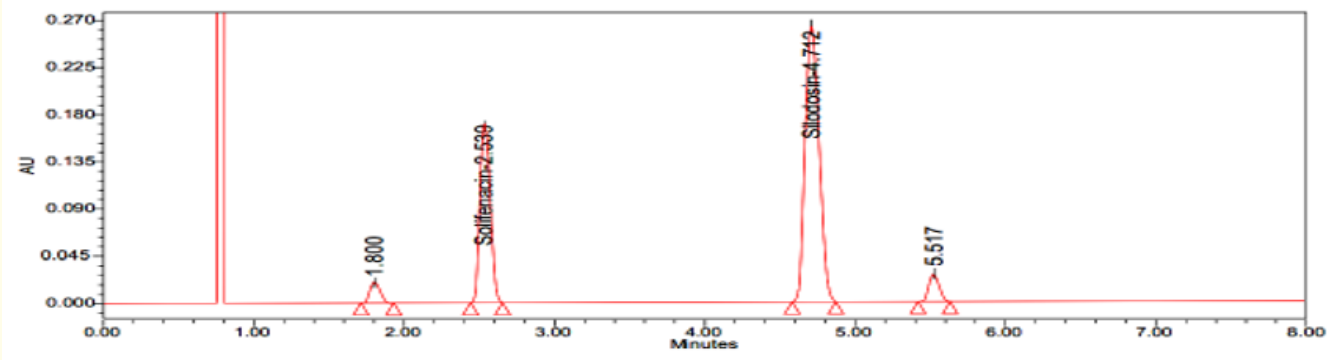

Figure 13: Chromatogram of Peroxide degradation.

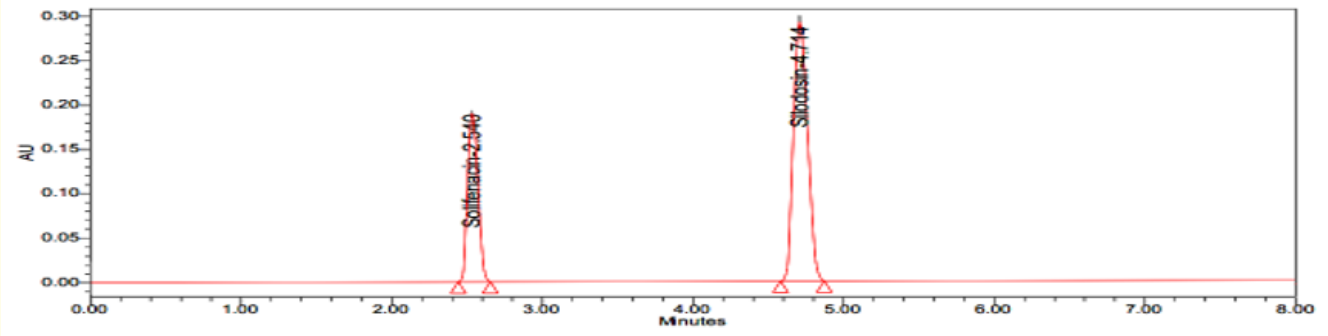

Figure 14: Chromatogram of Reduction degradation.

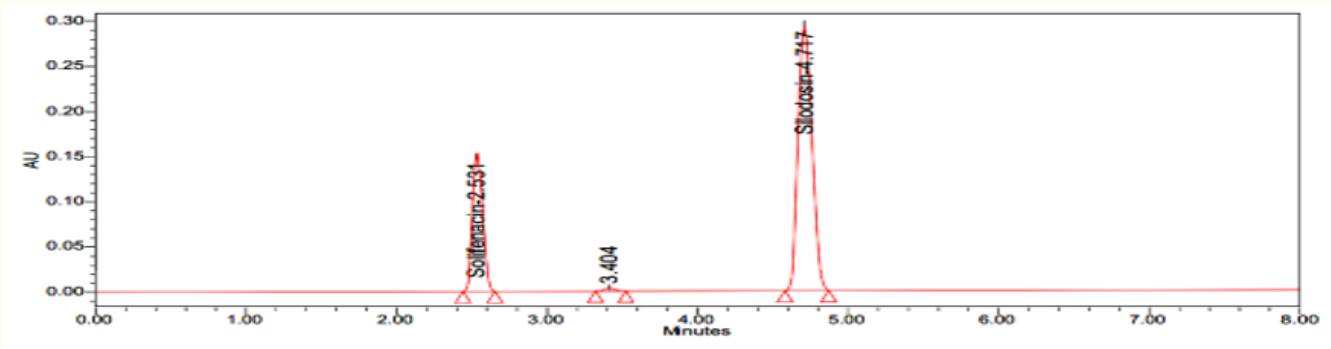

Figure 15: Chromatogram of Thermal degradation.

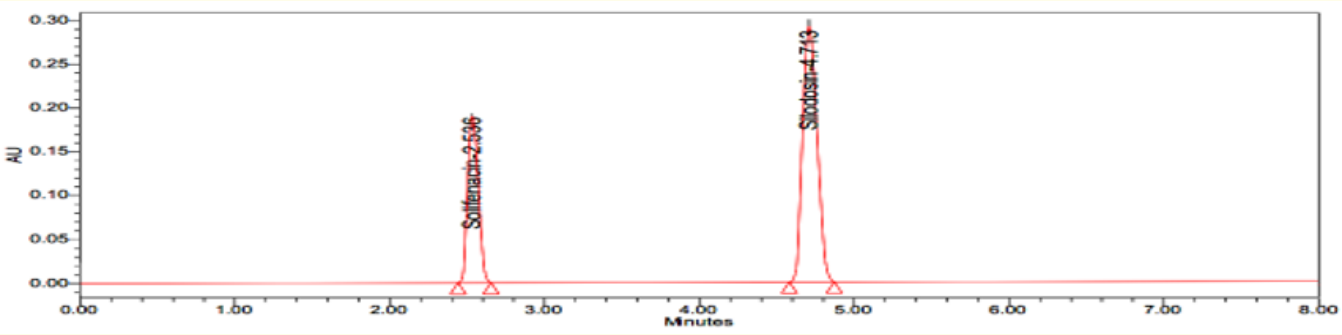

Figure 16: Chromatogram of Hydrolysis degradation.

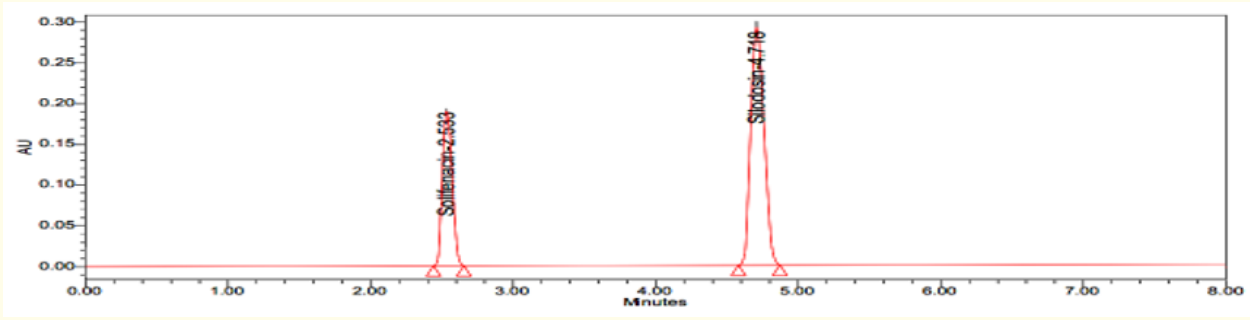

Figure 17: Chromatogram of Control degradation.

Discussion

The developed RP-HPLC method successfully achieved the simultaneous estimation of Solifenacin and Silodosin with excellent resolution (Rs = 7.48$) and short analysis time (8 minutes). System suitability parameters, including theoretical plates (>8000) and tailing factors (approx 1.1), surpassed ICH requirements, ensuring high column efficiency and peak symmetry. The method demonstrated strict linearity (R^2 > 0.999) and high accuracy, with recovery rates consistently near 100%. Notably, forced degradation studies revealed that both drugs are most susceptible to oxidative and alkaline conditions, yet the method remained stability-indicating as degradation products did not interfere with the primary peaks. This dependable and exact methodology is highly appropriate for the regular quality auditing of medical products. It also provides an effective means for assessing the shelf-life and stability of various drug formulations.

Conclusion

The developed RP-HPLC method for simultaneous estimation of Solifenacin and Silodosin was found to be simple, rapid, precise, and stability-indicating. chromatographic separation was achieved with retention times of 2.535 min (Solifenacin) and 4.716 min (Silodosin) with excellent resolution (7.48). The method showed high linearity over the range of 12.5-75 µg/mL and 20-120 µg/mL with correlation coefficients (R^2 = 0.99980 and 0.99963). Accuracy studies showed good recovery within 99.4-100.2% for both drugs, confirming method reliability. The validated method achieves high precision with relative standard deviations under 2% and maintains sensitivity at low detection and quantitation thresholds. Forced degradation experiments confirmed that the technique accurately monitors drug breakdown under stress, proving its effectiveness as a stability-indicating assay. Given these results, the procedure is appropriate for standard quality control and long-term stability analysis of combined pharmaceutical dosage forms.

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