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Original Article

Development and Validation of Stability Indicating Liquid Chromatographic Method for Simultaneous Estimation of Silodosin and Dutasteride in API and Combined Dosage Form

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ABSTRACT

Background: The proposed work was done with a view to develop a RP-HPLC approach for the concurrent quantification of Dutasteride and Silodosin in API and capsule formulation and validate it. **Materials and Methods:** A C_{18} Thermo BDS column (150×4.6 mM, 5 µM) was utilized, which also used buffer and acetonitrile as mobile phase (70:30 v/v) eluent A and (30:70 v/v) eluent B at flow rate of 1 mL/min. The samples were quantified at 250 nm employing a PDA detector. In compliance with ICH recommendations, the methodology was validated. **Results:** For DUT and SIL, linear response was obtained in the range of 5-15 µg/mL and 40-120 µg/mL, individually. The LOD and LOQ values of DUT and SIL were respectively observed 0.302 µg/mL, 1.859 µg/mL and 0.909 µg/mL, 5.634 µg/mL. Both drugs had assay results that ranged from 99.13 to 99.79%. Stress testing using acid, base, peroxide, light and heat were carried out. After adequate treatment, these mixtures were injected in HPLC and it was revealed that products generated from the stress studies were resolved from the peaks of analyte. **Conclusion:** The current approach was considered accurate, robust, linear, specific and precise and it can be utilized for the concurrent investigation of the drugs stated in its capsule.

Keywords: Dutasteride, Forced Degradation, Simultaneous estimation, Stability Indicating RP-HPLC Method Silodosin.

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INTRODUCTION

As people get older, the chances to develop Benign Prostatic Hyperplasia (BPH) increases. It is also referred to as an enlarged prostate. The majority of adult males with urologic conditions are more prone to it. BPH is commonly found in elderly men, which is also the main cause of symptoms involving the lower urinary system.[1,2]

Alpha blockers such as Silodosin (SIL; Figure 1a), is used to improve urination in men with benign prostatic hyperplasia.[3] Dutasteride (DUT; Figure 1b), inhibitor of 5-alpha reductase is also indicated for treatment of BPH. The urine flow can be increased with DUT.[4] The combined dosage form is utilized to treat the symptoms of BPH in adults.

A stability-indicating assay method must be used to evaluate all pharmaceuticals in accordance with Current Good Manufacturing Practices prior to their release. Forced Degradation (FD) demonstrates the accuracy of stability procedures in identifying possible impurities in drug material and drug components. Stress studies, stress testing, forced decomposition investigation, stress decomposition studies and other terms are also used to refer forced degradation studies.[5-7] As a result, degradation products are produced that may be examined to find out how stable a molecule is. This methodology is a crucial component of the drug development process.[8-10] The purpose of the research involving stability studies is to give information on how the consistency of the material changes over time under the influence of several environmental variables, including temperature, light and humidity. This information enables the suggested storage settings,

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intervals for reanalysis and shelf life (expiry).[11-13] The ICH recommendation states that stress investigations are intended to find the expected degradation components, which helps in figuring out the molecule's fundamental stability, establishing the degradation pathways and validating the stability indicating approaches used.[14-16]

Different Chromatographic methods[17,18] is available for the concurrent quantification of SIL and DUT but, till now, there is no stability indicating Chromatographic approach available for the cited combination. All the reported chromatographic methods were able to separate the drugs in bulk and dosage form, but the current method helps to investigate the degradation behavior of SIL and DUT in various environments and can resolve drugs from its degradation products. A critical factor in predicting the impact of degradants on the analyte peak is the stability indicating technique. Thus, an effort was undertaken to develop a repeatable, accurate, selective and reliable stability indicating liquid chromatographic technique for simultaneous quantitation of SIL and DUT in formulation. ICH Q2 (R1)[13] was referred for the validation. ICH Q1A (R2)[12] was referred to perform stability studies.

MATERIALS AND METHODS

Chemicals and Materials

SIL (99.75% purity) and DUT (99.89% purity) was gifted by Stermone chemicals and Metrochem API Pvt. Ltd., correspondingly. Methanol (Finar, Ahmedabad HPLC grade), Acetonitrile (Merck life science limited, Mumbai, HPLC grade) and Potassium dihydrogen phosphate (S D Fine-Chem limited, Mumbai) were utilized as chemicals in the research. The capsule (Silodosia 4D) comprising 4 mg SIL and 0.5 mg DUT was purchased from local pharmacy. Milli Q water was used throughout the research.

Chromatographic conditions and instruments

The HPLC instrument utilised in this approach was an Agilent technologies 1200 Infinity series with a PDA detector and EZChrom software. C_{18} Thermo BDS Hypersil (150×4.6 mM, 5 µm) column was utilized and the column temperature was set at 25°C. Eluent A; Buffer: Acetonitrile (70:30% v/v) and Eluent B; Buffer: Acetonitrile (30:70% v/v) were utilized for the separation. The proposed technique had used 20 µL injection volumes, 1 mL/min as the rate of eluent, 254 nm as detection wavelength. The run time was 15 min.

Buffer Preparation

Potassium dihydrogen phosphate (6.8 g) was added to 1 L of water and potassium hydroxide solution was utilized for pH adjustment. pH of the final solution was adjusted to 5.

Preparation of Diluent

Methanol was utilized as diluent.

Standard Stock Solution preparation

Preparation involved weighing of 100 mg SIL and 12.5 mg DUT in 100 mL volumetric flask separately and diluting it with diluent.

Sample preparation

The contents of 20 capsules were emptied. Weigh powder equivalent to 4 mg SIL in a 50 mL volumetric flask. Diluent was utilised to make up to the mark. After a 20 min sonication, the mixture was filtered. The final solution represents SIL (80 µg/mL) and DUT (10 µg/mL).

Method Validation

The proposed approach was validated for its linearity, accuracy, intermediate precision, specificity, robustness, LOQ, selectivity, repeatability, LOD.

System Suitability Parameters

To assess the applicability of the HPLC system, mixed standard solution comprising SIL (80 µg/mL) and DUT (10 µg/mL) was introduced to HPLC in six replicas. From the resultant chromatogram, variables such as Asymmetry factor, Resolution, Theoretical Plates (NTP) and Retention Time (R_t) were documented.

Specificity and Selectivity

The response (chromatogram) of blank, sample solution and standard solution of SIL (80 µg/mL) and DUT (10 µg/mL) to assess the specificity. The responses of blank, standard and test were evaluated for R_t and resolution. The selectivity was further observed by employing a peak purity test. It was estimated employing a PDA detector.

Linearity

It was evaluated by creating a calibration curve at five different concentration levels from 40 to 120 µg/mL SIL and 5 to 15 µg/mL DUT. Different aliquots (2, 3, 4, 5 and 6 mL) of the solution (standard) were added in 50 mL volumetric flasks and diluted. Diluent was utilized for further dilution. The parameter was assessed in a triplicate. The peak area was plotted against concentration and equation was computed.

Precision

Method Precision

The standard solution of 80 µg/mL SIL and 10 µg/mL DUT was injected to the system six times and the data were then analysed. The % RSD was calculated.

Intermediate Precision

Three standard drug concentrations were employed to accomplish intermediate precision (intraday and inter-day), which were then examined thrice on same day and on 3 successive days, individually. The standard solution comprising 3 concentrations of SIL (60, 80, 100 µg/mL) and DUT (7.5, 10, 12.5 µg/mL) were utilized for the study. The percent RSD were computed.

Recovery Study

Standard addition approach was employed. Standard solution comprising SIL (40, 80, 120 µg/mL) and DUT (5, 10, 15 µg/mL) were spiked to the pre analysed sample solution at 3 levels 50%, 100% and 150% correspondingly. Suitable dilutions were done to get the concentration within linearity range. The outcomes (% recovery) were documented.

LOQ and LOD

They were evaluated by replacing the respective values in the equation mentioned in ICH guidelines.[13]

Robustness

It was evaluated using solution comprising 80 µg/mL SIL and 10 µg/mL DUT. The modifications in the parameters, like wavelength (±1 nm), column temperature (±1°C), pH of mobile phase (±0.1) and flow rate (±0.1 mL/min) were done. The outcomes were presented as a percentage RSD.

Solution Stability

The stability of test solution (80 µg/mL SIL, 10 µg/mL DUT) was investigated for 24 hr at different time intervals. Stability samples were analysed and compared with freshly prepared solution comprising 80 µg/mL SIL and 10 µg/mL DUT.

Forced Degradation

Preparation of Test solution

Weigh accurately 1000 mg SIL and 125 mg DUT in 50 mL volumetric flask. Dilute it using diluent. Aliqout 5 mL from the above solution and dilute to 100 mL with diluent. This solution was further utilized for degradation studies.

Acidic and Alkaline Degradation

Each mL of the test solution was transferred to two 10 mL volumetric flask. Same quantity of 0.1 N Hydrochloric acid and 0.1 N Sodium hydroxide was added to the flask separately. Heat both the flasks at 40°C for 1 hr. Equal amount of 0.1 N Sodium hydroxide and 0.1 N Hydrochloric acid was employed for neutralization, respectively.

Oxidative Degradation

One mL of the test solution and 3% Hydrogen peroxide was mixed in 10 mL volumetric flask and store at room temperature for 2 hr.

Thermal Degradation

80 mg SIL and 10 mg DUT were put in a petri dish and kept at 80°C in hot air oven for 2 hr. Volume was made up with diluent. Take a mL of the aforesaid mixture in 10 mL volumetric flask and dilution was done.

Photolytic degradation

80 mg SIL and 10 mg DUT were kept in a petri dish and exposed to sunlight for 2 hr. Dilute with diluent. Take 1 mL of the aforesaid mixture in 10 mL volumetric flask. Make up to mark using diluent.

RESULTS

Method Development and Optimization

SIL and DUT separation using stability indicating liquid chromatographic method in dosage form or in blend powder has not been reported till date, so in order to distinguish the analyte peaks from the impurities that arise during the forced degradation investigation, the current approach was developed. To increase the effectiveness of the chromatographic system, chromatographic parameters comprising flow rate, detection wavelength, mobile phase composition, analytical column and column temperature were taken into consideration while developing the method.

During the development process, two HPLC analytical columns, C_{18} ODS (250×4.6 mM, 5 µM) and C_{18} Thermo BDS Hypersil (150×4.6 mM, 5 µM), were examined. Retention time, Theoretical plates, Tailing factor and Resolution were considered for system appropriateness parameter. Gradient elution (Table 1) was utilised since isocratic elution did not yield adequate results (a broad peak for the DUT was seen). Thermo BDS Hypersil C_{18} (150×4.6 mM, 5 µM) column was finalised. Different mobile phases including Water, Methanol, Phosphate buffer, O-Phosphoric Acid (OPA)

Table 1: Gradient Programming.

Time (min)	Mobile phase-A* (% v/v)	Mobile phase-B# (% v/v)
0	100	0
1	100	0
7	0	100
10	0	100
12	100	0
15	100	0

*Mobile phase-A: Buffer (Potassium dihydrogen phosphate): Acetonitrile (70:30).#Mobile phase-B: Buffer (Potassium dihydrogen phosphate): Acetonitrile (30:70).

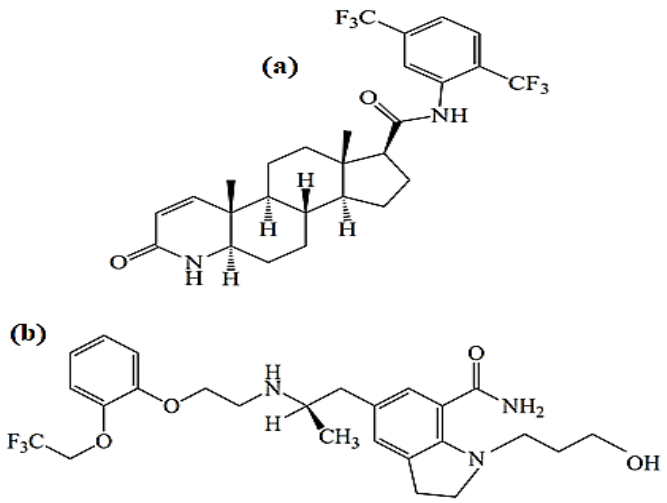

Figure 1: Structures of a) DUT b) SIL.

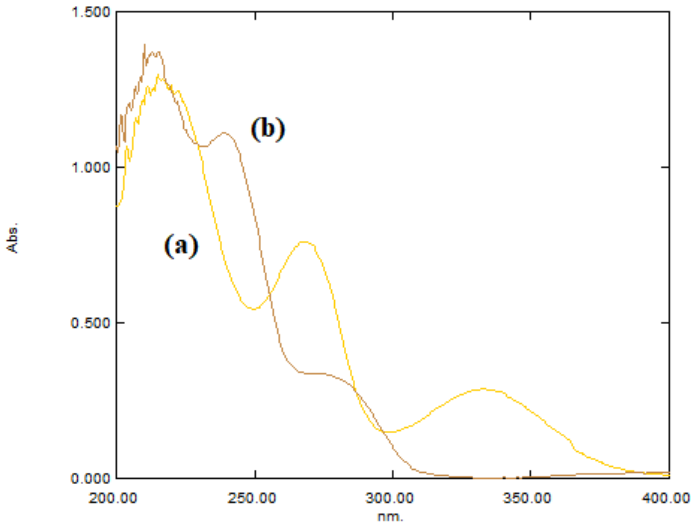

Figure 2: Overlain Spectra of (a) DUT and (b) SIL.

and Acetonitrile in various ratios were tried. But, sharp peak, good separation and resolution of DUT and SIL, maximum NTP with minimum tailing factor and short analysis time was achieved by the combination of eluent A; Acetonitrile: Buffer (Potassium dihydrogen phosphate) (30:70% v/v) and eluent B; Acetonitrile: Buffer (Potassium dihydrogen phosphate) (70:30% v/v). It was clear from the overlapped spectra of the two drugs, DUT and SIL, that both exhibit an iso-absorptive point at 254 nm (Figure 2).

System Suitability Parameters

The system suitability tests were carried out and the parameters were within acceptable limits (Table 2).

Method Validation

Specificity

It was determined that there was no excipient interference in the chromatogram obtained from blank, standard and sample solution and depicted in Figure 3. Therefore, it was determined that the approach was specific for the analysis of marketed formulation.

Selectivity

Since there were no excipients co-eluting with the analytes and DUT and SIL with peak purity values of 0.99948 and 0.99927 correspondingly, it was assumed that the approach demonstrates selectivity.

Linearity

By scanning five solutions (standard) of the SIL and DUT in triplicate, linearity was assessed. The approach depicted linearity over 40-120 µg/mL for SIL and 5-15 µg/mL for DUT. The slope, intercept, correlation coefficient for SIL and DUT were found to be 3457.9, 69004, 0.9997 and 2963.2, 5911.6, 0.9998 correspondingly.

Precision

Method Precision

The % RSD of SIL and DUT were discovered to be 0.88 and 0.75, correspondingly. It may be said that the developed approach was repeatable because the percent RSD value was found less than 2.

Intermediate Precision

The findings showed % RSD ranging from 0.46-0.89% for intraday and 0.38-0.65% for interday determinations for SIL. The studies showed% RSD in the range of 0.56-0.83% for intraday and 0.28-0.63% for interday investigations for DUT.

Accuracy

By employing the standard addition technique to estimate SIL and DUT recoveries, the accuracy of the methodology was evaluated. The results of the recovery were ranged from 99.65 to 100.02% for SIL and 99.20 to 100.06% for DUT.

LOD and LOQ

For SIL and DUT, the LOD values were 1.859 µg/mL and 0.302 µg/mL individually. For SIL and DUT, the LOQ values were 5.634 µg/mL and 0.909 µg/mL individually.

Robustness

Variations in wavelength, rate of flow, column temperature and pH of mobile phase were done to assess the robustness. The outcomes were represented in Table 3. It was determined that the responses (peak areas, R_t or NTP) had not undergone any significant changes as a result of the variations made.

Solution Stability

Less than 2% of variation in assay results was found (99.16% for SIL and 99.08% for DUT at 24 hr) and no significant changes in drug solution content were found over the course of solution

stability for both drugs. Therefore, it suggests that the test solution remained unchanged for a day (24 hr).

Assay of dosage form

The results revealed that the mean % purity for DUT and SIL were 99.47±0.30 and 99.57±0.19 correspondingly. DUT and SIL were found to have percentage RSD of 0.30% and 0.19%, correspondingly.

Study of Forced Degradation

The chromatogram of both drugs under various stressful environment is depicted in the Figures 4 and 5. Peak purity examinations on the degraded samples revealed that the parent peaks obtained in the optimized approach were spectrally pure. Table 4 represents the outcomes of the study.

DISCUSSION

A novel, simple, specific and selective stability demonstrating liquid chromatographic method was designed for the concurrent quantitation of SIL and DUT in bulk and formulation by utilizing BDS Hypersil C_{18} column, combination of eluent A; Acetonitrile: Buffer (Potassium dihydrogen phosphate) (30:70% v/v) and eluent B; Acetonitrile: Buffer (Potassium dihydrogen phosphate) (70:30% v/v) as mobile phase and detection at 254 nm. The retention time of SIL and DUT was found at 3.5 and 9.2 min correspondingly. The approach depicted linearity over 40-120 µg/mL for SIL and 5-15 µg/mL for DUT. Intraday and interday precision studies showed % RSD values less than 2. The results of the recovery trials showed that all of the established techniques were accurate, as they ranged between 98 to 102%. The

Table 2: System Suitability Parameters.

Parameters (*n*=6)	DUT (Mean±SD, % RSD)	SIL (Mean±SD, % RSD)
Retention time (R_t)	9.2±0.021, 0.22	3.5±0.015, 0.43
Theoretical Plates (NTP)	5421±10.536, 0.19	3179±8.145, 0.21
Tailing Factor (T_f)	0.98±0.006, 0.58	0.96±0.006, 0.59
Resolution (R_s)	9.15±0.021, 0.13	0.00, 0.00

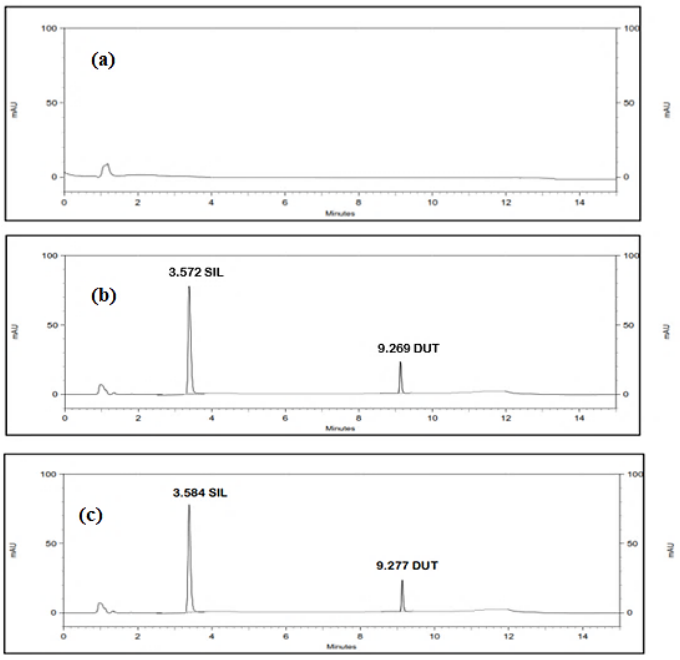

Figure 3: Specificity chromatogram of a) Blank b) Standard c) Sample.

Table 3: Results of Robustness Study.

Parameter	Variation	Mean Peak Area±% RSD (*n*=3)		Mean R_t±% RSD (*n*=3)	
		DUT (10 µg/mL)	SIL (80 µg/mL)	DUT (10 µg/mL)	SIL (80 µg/mL)
Flow rate (1 mL/min) (±0.2 mL/min).	0.8	23254±0.11	202485±0.28	3.759±0.05	9.469±0.09
	1.0	23271±0.17	203852±0.27	3.535±0.08	9.281±0.07
	1.2	23274±0.10	205816±0.28	3.310±0.33	9.096±0.06
Wavelength (250 nm) (±2 nm).	252	23269±0.48	204843±0.22	3.529±0.11	9.276±0.08
	254	23394±0.49	206811±0.20	3.538±0.18	9.282±0.05
	256	23459±0.53	208868±0.25	3.531±0.23	9.279±0.06
Column Temperature (±1°C).	24	23293±0.45	204169±0.17	3.475±0.32	9.395±0.12
	25	23348±0.38	205279±0.11	3.537±0.24	9.285±0.38
	26	23572±0.31	206426±0.41	3.496±0.43	9.124±0.20
pH (±0.2).	4.8	23293±0.45	204169±0.17	3.539±0.14	9.285±0.18
	5.0	23482±0.22	208239±0.28	3.532±0.19	9.281±0.24
	5.2	23572±0.31	206426±0.41	3.542±0.31	9.291±0.16

Table 4: **Results of Forced Degradation Study.**

Degradation Condition	Drug	% Degradation	R_t of observed Peak	Peak Purity
Acid/0.1 N Hydrochloric acid (40°C, 1 hr).	DUT	13.78	9.253	0.9997
	SIL	11.28	3.548	0.9992
Alkali/0.1 Sodium hydroxide (40°C, 1 hr).	DUT	6.39	9.236	0.9995
	SIL	5.84	3.562	0.9991
Oxidative 3% Hydrogen peroxide (Room Temperature, 2 hr).	DUT	12.01	9.212	0.9996
	SIL	7.67	3.510	0.9998
Photolytic/Direct Sunlight (2 hr).	DUT	7.01	9.265	0.9997
	SIL	7.50	3.559	0.9993
Thermal (80°C, 2 hr).	DUT	8.72	9.278	0.9995
	SIL	10.93	3.544	0.9999

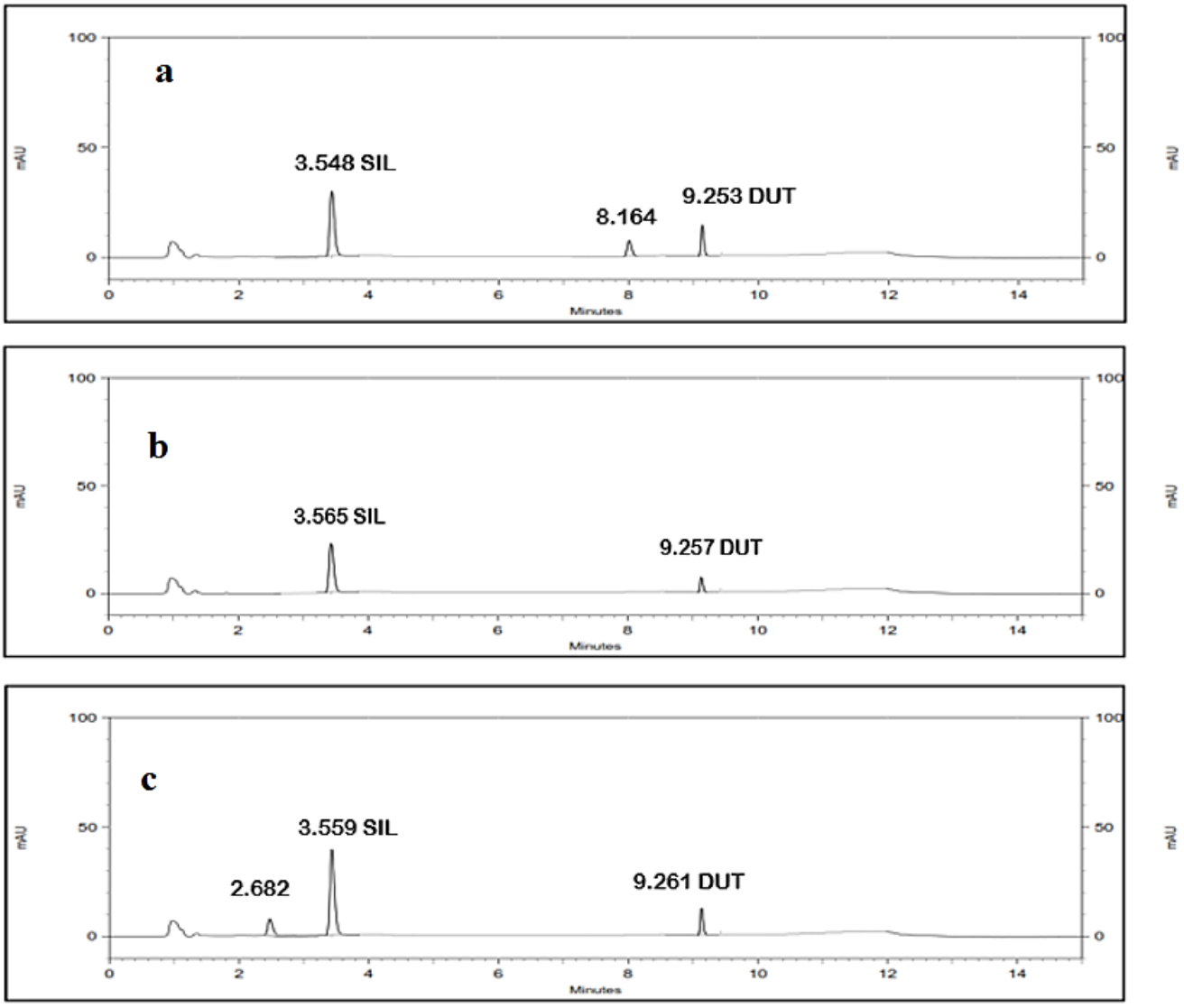

Figure 4: HPLC chromatogram of (a) Acid degradation of SIL and DUT (b) Alkali degradation of SIL and DUT (c) Oxidative degradation of SIL and DUT.

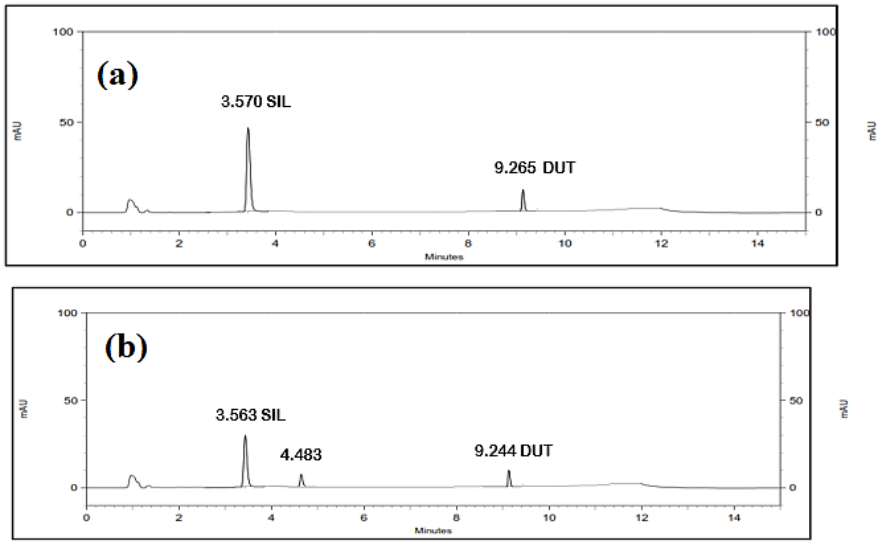

Figure 5: HPLC chromatogram of (a) Photolytic degradation of SIL and DUT (b) Thermal degradation of SIL and DUT.

proposed approach was found to be robust as per the findings, no appreciable changes in peak area and R_t were observed.

To evaluate the suggested RP HPLC technique's capacity to separate the drug from its degradants, a variety of stress conditions were employed, comprising of acid hydrolysis, alkaline hydrolysis, oxidative degradation, heat degradation and photolytic degradation. In comparison to the other conditions utilized for the degradation investigation, SIL showed more deterioration in acid and thermal environments. DUT was more susceptible to degrade under acidic and oxidative environment. In case of alkaline and photolytic conditions, both drugs showed less than 10% degradation.

CONCLUSION

A stability indicating RP-HPLC method that is precise, selective and accurate has been proposed. Since analytes were subjected to a variety of ICH recommended stress conditions, the outcomes showed that the degradants were separated from the drug. The methodology has been validated in compliance with ICH guidelines. When compared to other exposures, both drugs exhibited degradation in oxidative and acidic environments. The results conclude that developed approach is specific, reliable, efficient and reproducible by using RP-HPLC. The current technique has worked well for separating the drug from its degradants and can be utilized for quantitation of drug in bulk and capsule.

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ABBREVIATIONS

DUT: Dutasteride; **SIL:** Silodosin; **RP:** Reverse Phase; **HPLC:** High Performance Liquid Chromatography; **BDS:** Base Deactivated Silica; **RSD:** Relative Standard Deviation; **BPH:** Benign Prostate Hyperplasia; **LOD:** Limit of Detection; **Conc.:** Concentration; **ODS:** Octadecyl silane; **LOQ:** Limit of Quantitation; **PDA:** Photodiode array; **ICH:** International Conference on Harmonization; **R_t:** Retention Time; **NTP:** Theoretical Plates; **SD:** Standard Deviation; **OPA:** Ortho phosphoric acid; **API:** Active Pharmaceutical Ingredient.

CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

SUMMARY

The proposed approach presents the novel stability indicating liquid chromatographic method for the simultaneous quantification of Silodosin and Dutasteride in API and dosage form. The eluent A; Acetonitrile: Buffer (Potassium dihydrogen phosphate) (30:70% v/v) and eluent B; Acetonitrile: Buffer (Potassium dihydrogen phosphate) (70:30% v/v) were optimised. pH was adjusted to 5 utilising potassium hydroxide solution. The retention time of SIL and DUT was found 3.5 and 9.2 min correspondingly. Linear response was observed for SIL and DUT in the range of 40-120 µg/mL and 5-15 µg/mL correspondingly. The approach was validated as per ICH recommendations. Forced Degradation Studies included all the exposure parameters as per ICH. Stress studies revealed that both drugs were degraded in acidic and oxidative environments.

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