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Original Article

Stability Indicating Method Development and Validation by Analytical Quality by Design Approach Using UV-Spectrophotometer for Alfuzosin Hydrochloride and Tadalafil in Bulk and Marketed Formulation

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ABSTRACT

Introduction: The combination of Alfuzosin and Tadalafil is used to treat both erectile dysfunction and lower urinary tract symptoms. The purpose of this work is to develop and evaluate a UV-spectrophotometric method for simultaneously estimating Alfuzosin hydrochloride and Tadalafil in bulk and marketed formulation, using a Analytical Quality by Design methodology to assure robustness and reliability. **Objectives:** The current work aims to develop a simple, precise and cost-effective UV-spectrophotometric technique for Alfuzosin Hydrochloride (ALF) and Tadalafil (TAD) and validating in accordance with ICH Q2 (R1) standards by applying Central Composite Design to achieve optimized conditions. **Materials and Methods:** The UV-spectrophotometric method as a part of green chromatographic approach which was established using 20% methanol as a solvent and both the drugs had maximum absorption at 272 nm (isobestic point). Design Expert software was used to create Design space. The new technique was validated using metrics such as specificity, linearity, precision, robustness, accuracy and ruggedness in accordance with ICH guidelines. Stress degradation experiments were carried out under various conditions, including acidic, basic, oxidative, thermal and photolytic degradation. **Results:** The technique was found to be linear across concentrations of 4-20 µg/mL, with a correlation value of 0.999. The newly devised approach was found to be specific, linear, precise, rugged and reproducible for estimating ALF and TAD, with %RSD values <2%. Forced degradation study outputs were under acceptable limits of <20%. **Conclusion:** The AQbD-driven approach develops a highly effective analytical procedure for the simultaneous identification of ALF and TAD without interference. This method provides a robust, efficient and cost-effective approach for routine analysis in quality control analysis.

Keywords: Alfuzosin hydrochloride, Tadalafil, UV-spectrophotometric, ICH guidelines, AQbD.

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INTRODUCTION

Many elderly men develop Benign Prostatic Hyperplasia (BPH), which causes lower urinary tract discomfort and erectile dysfunction. Combining an alpha-1 blocker like Alfuzosin hydrochloride (ALF), chemically, N-[3-[(4-amino-6,7-dimethoxyquinazolin-2-yl)-methylamino]propyl]oxolane-2-carboxacmide acid hydrochloride with a PDE5 inhibitor like Tadalafil (TAD), chemically, (2R,8R)-2-(2H-1,3-benzodioxol-5-yl)-6-methyl-3,6,17-triazatetracyclo[8.7.0.0{3,8}.0{11,16}heptadeca-1(10),11,13,15-tetraene-4,7-dione can considerably improve urinary symptoms and sexual function more than when given separately.[1-3] Structure of both the drugs are shown in Figures 1 (a, b).

Over the past five years, a limited analytical method have been reported for these drug analysis, including spectrophotometric techniques,[3,4] spectrofluorometric technique,[5,6] HPLC methods,[7] UPLC methods,[8] HPTLC methods[9] either individually or in combination. While previous studies employed absorbance subtraction and ratio difference methods, our method is the first to apply the AQbD framework-including Central Composite Design (CCD), Critical Method Attributes (CMAs), Critical Quality Attributes (CQAs), Method Operable Design Region (MODR), and ICH-compliant validation including forced degradation studies -for UV-spectrophotometric analysis of alfuzosin hydrochloride and tadalafil, optimized at the isobestic point using a cost-effective

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solvent system (20% methanol) compared to reported one using ethanol as a solvent.

As a result, the goal of this research was to develop a new, robust and cost-effective UV-spectrophotometric method based on the AQbD framework for analysing TAD and ALF simultaneously in both bulk and marketed formulation. This method ensures optimal performance and stability by using AQbD methodology, allowing for accurate estimation even under a variety of stress degradation scenarios. The proposed technique is cost-effective and reliable, allowing for faster and more accurate medication analysis, which benefits both pharmaceutical firms and patients.

MATERIALS AND METHODS

Instrumentation

The UV absorption spectra were recorded using a Shimadzu UV-visible spectrophotometer (model UV-1800, Shimadzu Corporation, Spectrophotometric Division, Kyoto, Japan) and 10 mm quartz cuvettes.[10-13]

Chemicals and reagents

Tadalafil and alfuzosin hydrochloride were obtained as free samples from Rakshit Drugs Pvt. Ltd., in Hyderabad and BalPharma Ltd., in Karnataka, respectively. The methanol used was analytical grade. Ultra-pure water was prepared using a Milli-Q water system. The design was optimised using the Design Expert software.

Preparation of standard stock solution

Tadalafil (TAD) and Alfuzosin Hydrochloride (ALF) of 10mg were accurately weighed and taken in a 10 mL volumetric flask. To prepare a standard stock solution with a concentration of 1000 µg/mL, methanol (20%) was added as a diluent and sonicated until thoroughly dissolved. The stock solution was diluted to a sub-stock solution with a concentration of 100 µg/mL. To produce a final concentration of 10 µg/mL (working solution), the TAD and ALF mixture was further diluted with 20% methanol.

Preparation of sample solution

To make a solution with a 1000 µg/mL concentration, a 10 mg powder quantity of TAD and ALF was added to a 10 mL volumetric flask diluted with 20% methanol (diluent). To achieve a final concentration of 10 µg/mL, the solution was further diluted with diluent.

Selection of wavelength

Working standard solution containing 10 µg/mL of ALF and TAD mixture was scanned in the range of 200-800 nm and the λ_{max} was found to be 272 nm.

AQbD approach for method development and optimization

Analytical Target Profile (ATP)

ATP outlines an analytical method's desirable performance goals, such as accuracy, precision, and sensitivity as well as the permissible limitations for these properties. It directs the methods' development and optimisation, ensuring that it meets regulatory standards. Critical Method Attributes (CMAs) are the specific factors that have direct impact on Critical Quality Attribute (CQAs) during method development. In UV spectrophotometry, CMAs include the solvent composition and scanning speed whereas CQAs includes the absorbance recorded. pH (neutral solvent system- 20% methanol) and temperature (~25°C) were held constant to reflect routine lab conditions and simplify the design, as solvent composition and scanning speed showed the most significant impact on absorbance in this AQbD-based method.

Design of Experiments (DoE)

Design-Expert® software was used to analyse the relationship between CMA and CQA. Key statistical measures, such as acceptable precision, F-value, *p*-value, and R^2 value, were derived by Analysis of Variance (ANOVA). In the current investigation, the Critical Material Attributes for the method were the percentage of methanol and scanning speed, while the dependent variables was the absorbance recorded for ALF and TAD. This framework permitted the building of a 2-factor, 1-level Central Composite Design (CCD), resulting in a total of nine runs and was evaluated based on several statistical criteria, with randomised optimisation of the system parameters carried out utilising working standard solution (10 µg/mL).

Establishing the Method Operable Design Region (MODR)

The MODR, derived from the DoE, defines the ideal operational range for dependent variables that consistently achieve the results defined in the ATP. After the instrument's nine predicted runs, we examined the data with regression analysis, two-way ANOVA, and three-dimensional response surface plots.

Method validation

The developed method was validated as per ICH Q2 (R1) guidelines[14] and the absorbance was recorded at 272 nm.

System suitability

The absorbance of ALF and TAD standard solution (16 µg/mL) was measured six times at optimized conditions.

Specificity

The solvent's spectrum was analysed and interference at the isobestic point (λ_{max}) of ALF and TAD standard solution (16 µg/mL) was assessed.

Linearity

Linearity was tested using ALF and TAD mixture at concentrations ranging from 2-10 µg/mL. A graph was created by plotting drug concentration against absorbance at 272 nm and the correlation coefficient was obtained.

Accuracy

Using the standard addition method, the accuracy experiment was repeated three times at concentrations of 80%, 100%, and 120%. The percentage recovery and percentage Relative Standard Deviation (%RSD) were then computed.

Precision

To measure intraday and interday precision, standard solutions with concentrations of 4, 12, and 20 µg/mL were scanned at 272 nm 6 times each. The findings of the repeatability assessment are reported as a percentage of RSD. This study demonstrates the method's reliability both in a single day and over numerous days.

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

LOD and LOQ were calculated by following formula.

LOD = 3.3 x SD of regression/Slope.

LOQ = 10 x SD of regression/Slope.

Robustness

Six duplicates of ALF and TAD standard solution (16 µg/mL) were analysed to ensure the method's robustness. The evaluation involved adjusting the wavelength (±2%). The method's stability under these changing settings was determined by calculating the %RSD.

Ruggedness

To assess ruggedness, six replicates of ALF and TAD mixture standard solution (16 µg/mL) were created. Each replicate's absorbance was evaluated by a different analyst and different instrument (Shimadzu UV-1900) and the %RSD was computed.

Stock solution stability

The working solution's stability was studied at a concentration of 16 µg/mL. Samples were kept at 2-8°C for one week. The stability was assessed by comparing the results obtained from fresh samples.

Forced degradation studies

Forced degradation studies were preliminary, aimed at assessing method sensitivity to degradation; detailed impurity profiling and full ICH Q1B photostability were beyond the scope of this UV-based method and are planned for future advanced studies.

Acid degradation

To perform UV analysis, 10 mL of 1N HCl was mixed with 5 mL of a 100 µg/mL stock solution in a round-bottom flask and refluxed at 80°C for 4 hr. After cooling, the sample was neutralised with the appropriate base.

Base degradation

To perform UV analysis, 10 mL of 0.1N NaOH was mixed with 5 mL of a 100 µg/mL stock solution in a round-bottom flask and refluxed at 80°C for 4 hr. After cooling, the sample was neutralised with the appropriate acid.

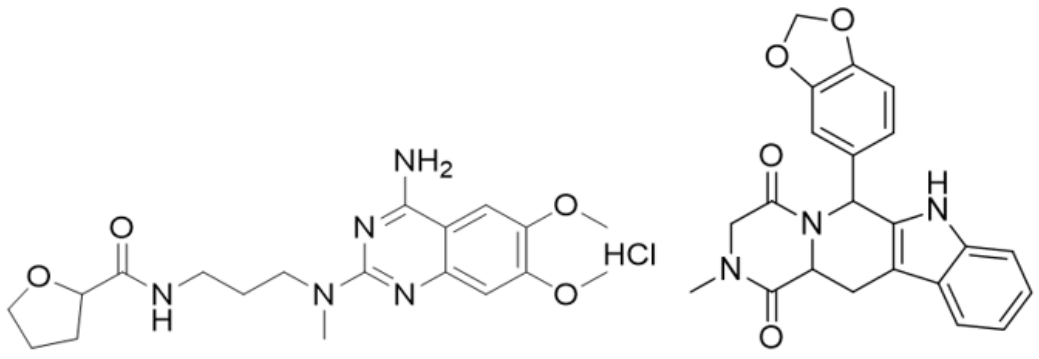

Figure 1: (a) Structure of Alfuzosin hydrochloride (b) Structure of Tadalafil.

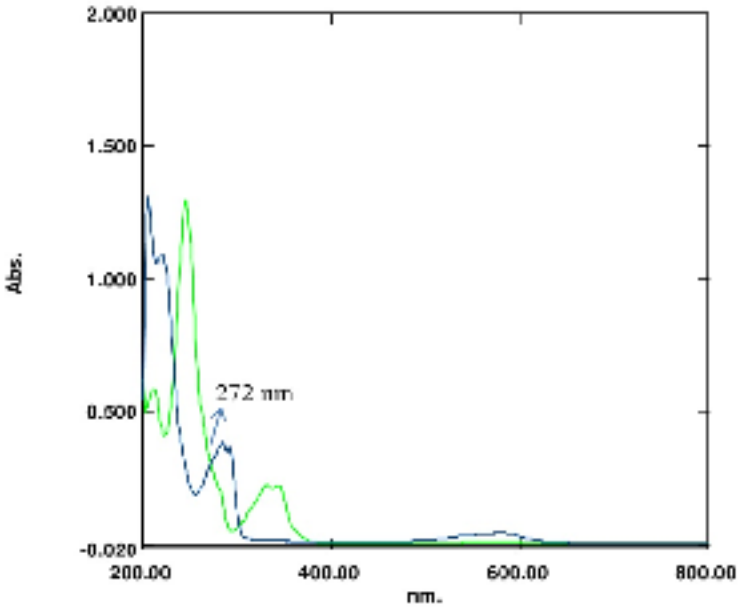

Figure 2: UV spectra of Alfuzosin HCl and Tadalafil at isobestic point (272 nm).

Oxidative degradation

To conduct UV analysis, a 5 mL sample of a 100 µg/mL stock solution was combined with 10 mL of 6% H_2O_2 and heated at 80°C for 4 hr. The mixture was then diluted at room temperature.

Thermal degradation

A 5 mL sample of a 100 µg/mL stock solution was refluxed at 100°C for 4 hr, cooled to room temperature, and diluted for UV analysis.

Photolytic degradation

The stock solution of 100 µg/mL was exposed to UV light for 24 hr. For analysis, the sample was further diluted.

RESULTS AND DISCUSSION

Wavelength determination

Both APIs were scanned in a UV-spectrophotometer and the maximum wavelength was recorded at 272 nm (isobestic point). Both drugs were examined simultaneously, and Figure 2 depicts the overlay spectra of both drugs, ALF and TAD, at the isobestic point.

Method optimization by Central Composite Design (CCD)

A central composite design was used to explore the impact of two independent variables, percent of solvent (methanol-X1: 10%, 20%, 30%) and scanning speed (X2: 1, 0, -1). Furthermore, nine combinations suggested by the DoE were examined to determine their impact on absorbance, so adding to the optimisation of the UV-spectrophotometric approach. Table 1 contains details on the results of these trials. A two-way ANOVA was carried out, yielding the statistical values shown in Table 2. The model's probability values, R^2, F-values, adequate precision, and percent Coefficients of Variance (C.V.%) are within acceptable ranges, indicating that it is significant for all responses, as evidenced by a *p*-value <0.05. The adequate precision assesses the signal-to-noise ratio, with a value over 4 being preferred, indicating that this model is suitable for exploring the design space as in Table 2. The Model F-value of 760.05 indicates that the model is significant. There is only a 2.79% chance that an F-value this large will occur owing to noise. *p*-values of less than 0.0500 suggest that model terms are significant. A and A^2 are significant model terms. Table 3 shows the measured and expected response values in optimized UV-spectrophotometric conditions of 20% methanol and medium scanning speed. It demonstrates a positive association between projected experimental values and observed outcomes, as seen in Figure 3 (a). The perturbation plot enables the study of the influence of all factors at a specific point in the design space.

Table 1: Central composite design using independent variables with their respective dependent variable responses at 272 nm.

Factor A % methanol	Factor B Scanning speed	Response Absorbance
10	1	0.721
10	0	0.711
30	1	0.864
10	-1	0.703
30	0	0.860
20	0	0.656
30	-1	0.854
20	1	0.657
20	-1	0.654

It depicts the response by altering one variable across its range while holding the other variables constant. These graphs showed how each factor correlated with the absorbance. Analysing the perturbation plots for the responses revealed that factors X1 and X2 had a substantial impact on the outcomes seen in Figure 3 (b). Figures 3 (c, d) also displays various plots generated during design, including Box-Cox and normal plots. All graphs demonstrate acceptable response criteria for comparing variables.

Evaluation of Contour Plots and Interaction Graphs

In addition, 2D contour plots [Figures 4 (a)] and 3D response surface plots [Figure 4 (b)] were constructed to show how each element influences the absorbance responses at 272 nm. The ideal conditions were identified using the combined findings of numerical optimisation, 3D surface plots and 2D contour plots: a solvent ratio of 20% methanol (80% water) and a medium scanning speed, resulting in a desirability score of 1.0. Figure 4(c) depicts the desirability contour plot. Graphical optimisation was used to study the design space or Method Operable Design Region (MODR), which revealed that modifications within the optimised conditions are acceptable and within operational quality parameters. This demonstrates the method's robustness for its intended use. The UV method's operating conditions were chosen based on criteria that were consistent with the analytical target profile and critical quality parameters. Figure 4 (d) depicts the MODR as an overlay plot, with the yellow region representing the optimised area. This region was defined using the ranges given to the independent variable restrictions to meet certain goals, as shown in Table 1. The design expert program suggested that the anticipated solution, represented by a flag within this zone, had a reasonable desirability value of 1.0. The examination of the plots indicated that an increase in variable X1 (the percentage of methanol) and variable X2 (scanning speed) resulted in increase in the absorbance (response).

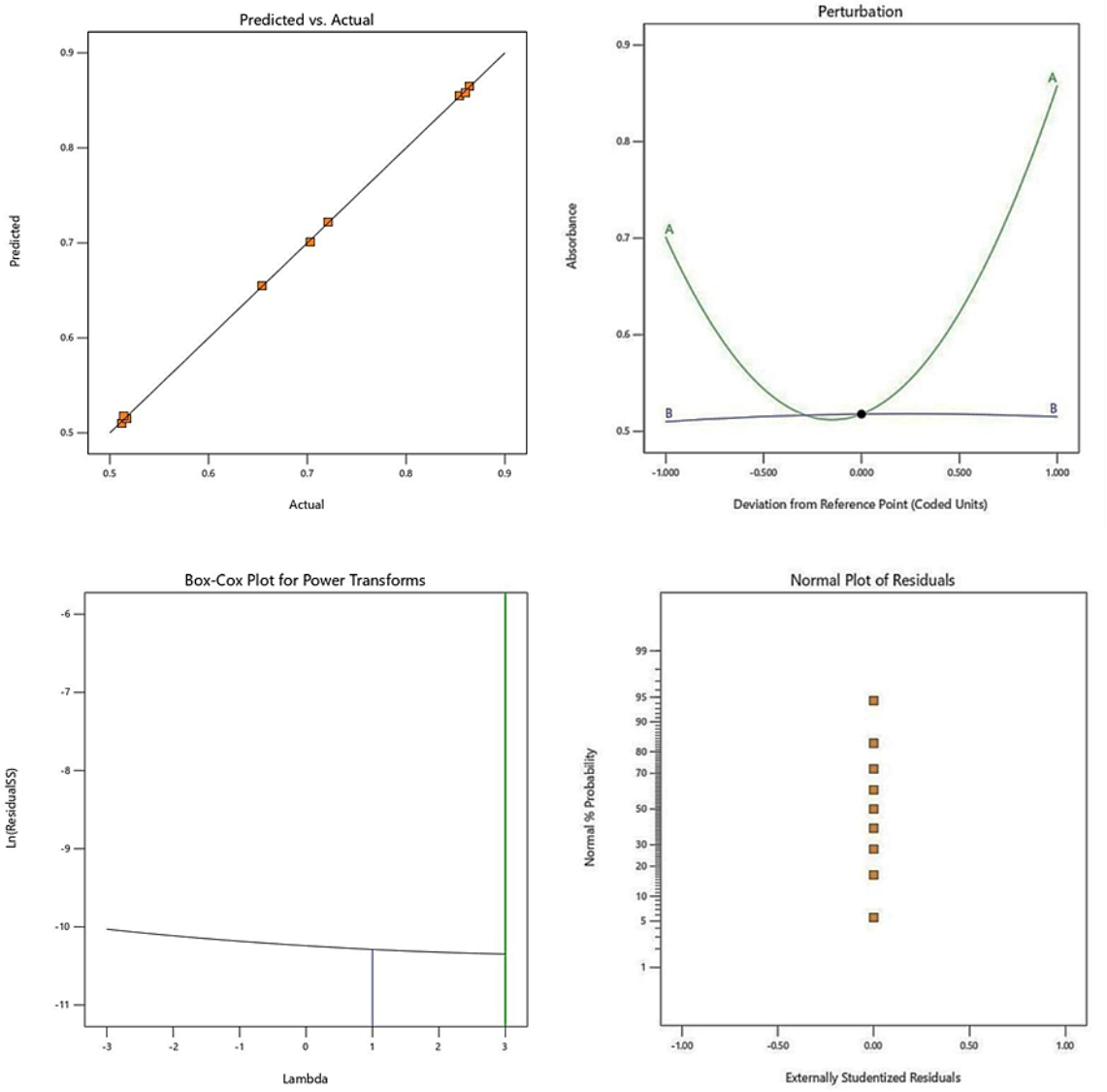

Figure 3: (a) Predicted v/s actual values plot for the response (b) Perturbation plot showing the effect of independent factors on absorbance (c) Box-Cox plot (d) Normal plot generated by Design-Expert® software.

Table 2: ANOVA results of factors and responses.

Source	F-value	*p*-value	Remarks
Model	760.05	0.0279	Significant
A- % Methanol	362.19	0.0334	
B- Scanning speed	0.3673	0.6531	
AB	23.87	0.1285	
A^2	4024.33	0.0100	
B^2	1.67	0.4191	
A^2B	10.99	0.1865	
AB^2	2.06	0.3874	
R- square	0.9998		
Predicted R-square	0.9658		
Standard deviation	0.0058		
C.V.%	0.8469		
Adequate precision	64.5336		

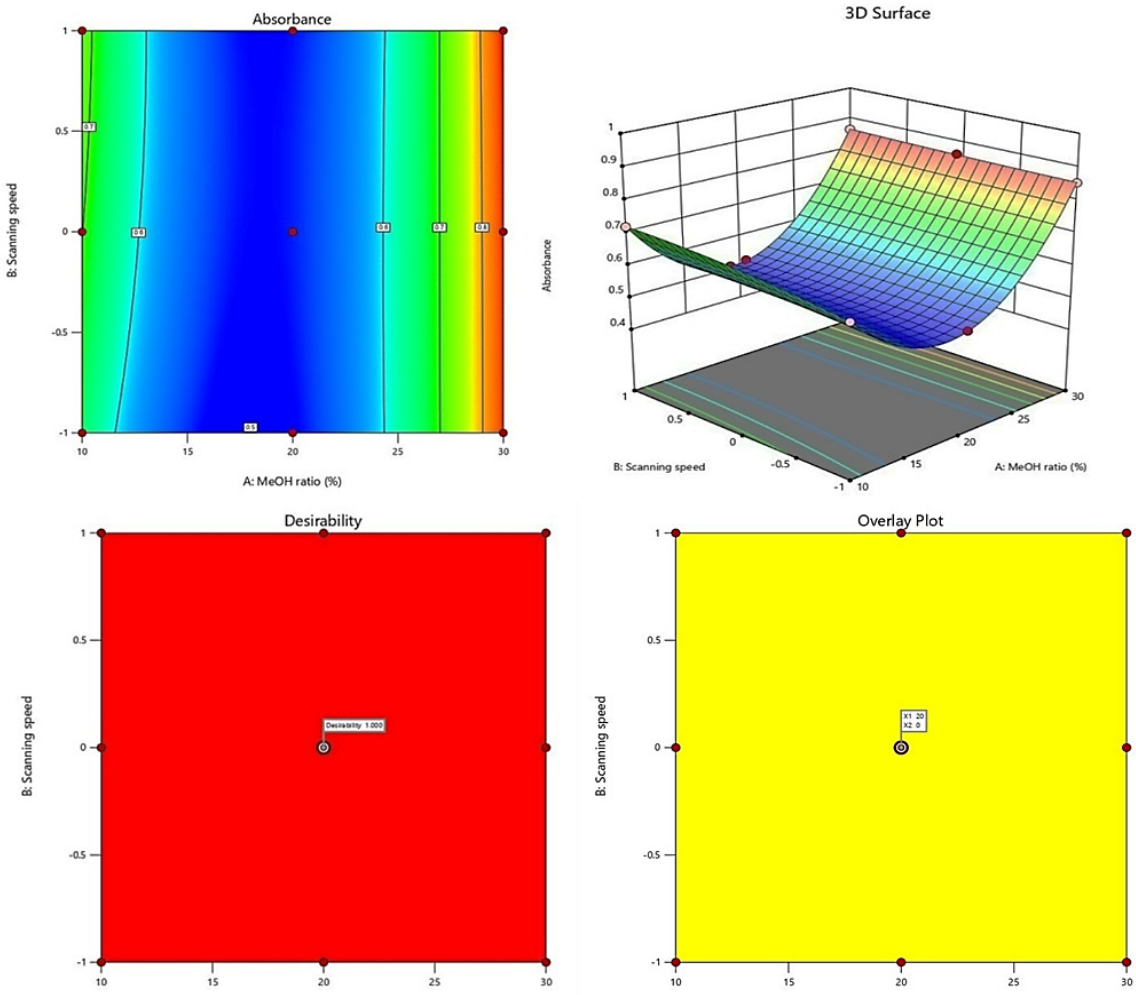

Figure 4: (a) 2D contour plot for % Methanol (%MeOH) and Scanning speed on Absorbance of ALF and TAD (b) 3D response surface plot for the effects of %MeOH and Scanning speed on Absorbance of ALF and TAD (c) Desirability contour plot showing optimum Method Operable Design Region (d) Design space for ALF and TAD optimization- Overlay contour plot depicting MODR.

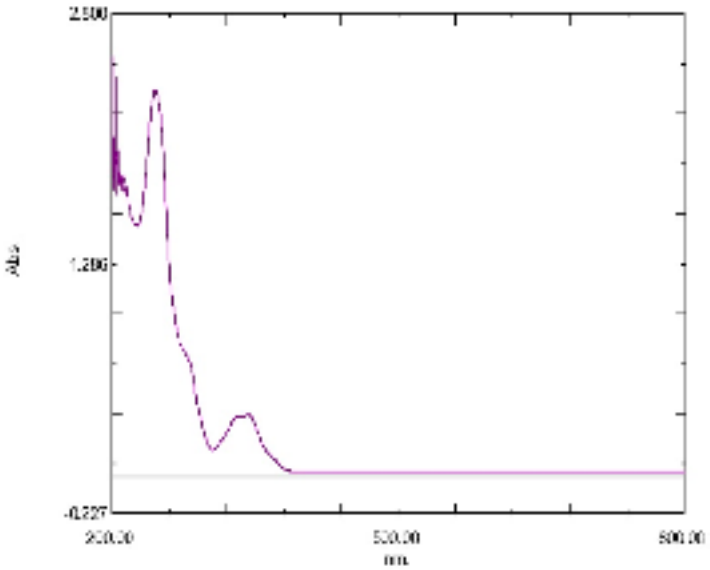

Figure 5: Overlay spectra of blank and standard solution of ALF and TAD.

Method validation

System suitability

The %RSD was determined to be less than 2.0% i.e., 0.218%. As a result, all parameters examined for system suitability were found to be satisfactory, showing that the system is suitable for simultaneous study of ALF and TAD.

Specificity

A 16 µg/mL concentration was subjected for specificity study where there was no interference of the blank (20% methanol) with the ALF and TAD peaks at 272 nm. The overlay spectra of the blank and the drugs are shown in Figure 5 demonstrating that the method is specific.

Linearity

The linearity of ALF and TAD (n=6) was validated within the concentration range of 4 µg/mL-20 µg/mL. The calibration curve mapping concentration (x-axis) against absorbance (y-axis) is displayed in Figure 6, revealing a linear relationship across the desired concentration range. Statistical analysis revealed the correlation coefficient and intercept, with the regression equation being, y = 0.082x+0.006. The correlation coefficient (R^2) was determined to be 0.999.

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

LOD and LOQ were calculated, which have yielded values of 0.98142 µg/mL and 2.974 µg/mL, respectively. Although the LOD (0.98 µg/mL) is higher than that of reported HPLC/UPLC methods, our UV method is a cost-effective, rapid, and robust alternative for routine quality control, especially in resource-limited environments. It offers acceptable accuracy, precision, and reliability under AQbD-optimized conditions, making it suitable for the routine estimation of ALF and TAD.

Table 3: Optimized conditions for simultaneous analysis of ALF and TAD at 272 nm.

Independent variables	X1: %Methanol	X2: Scanning interval
	20	0
Dependent variable (Absorbance)	Predicted value	Observed value
	0.650	0.656

Accuracy

The percentage recovery for accuracy was determined as 99.57-100.46% at 80%, 100% and 120% levels, which is regarded as satisfactory based on the accuracy data shown in Table 4.

Precision

Interday and intraday precision (n=6) are expressed in %RSD values, which were found to be less than 2%, showing that the approach performs satisfactorily. Table 4 presents the data for both measures.

Robustness

The method was found to be robust (n=6) even with wavelength fluctuations (±2%). The %RSD was found to be less than 2% (Table 4).

Ruggedness

Ruggedness (n=6) was assessed by changing the analyst and using a different instrument (Shimadzu UV-1900). The data showed that all of the results were within acceptable ranges, with a % RSD of less than 2% (Table 4).

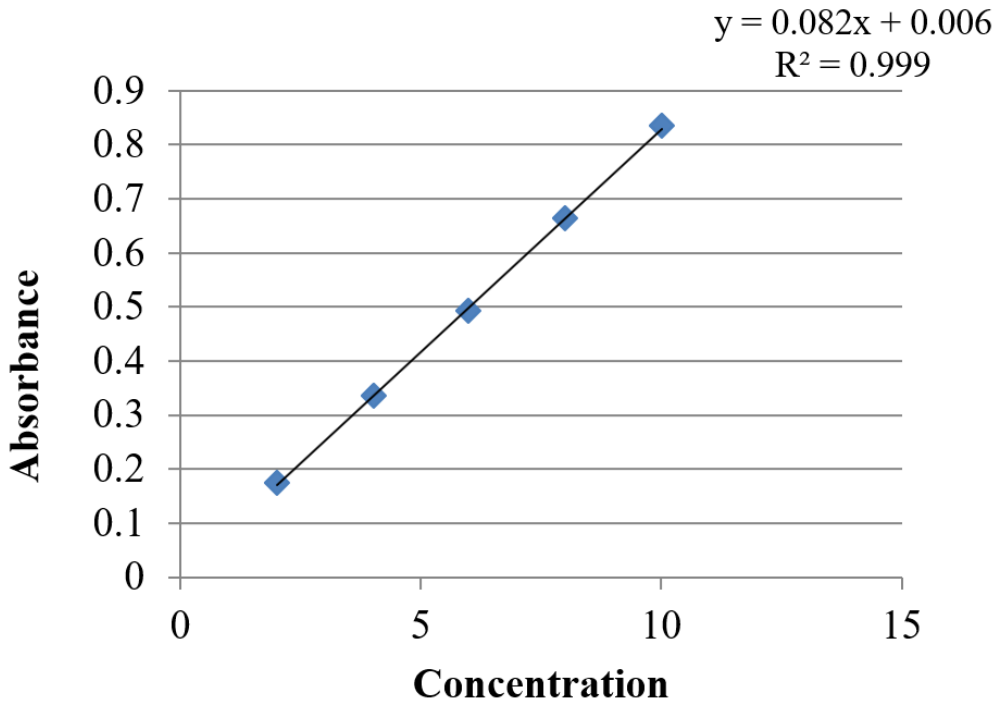

Figure 6: Calibration curve of ALF and TAD at 272 nm.

Stock solution stability

Stability (n=6) was determined by comparing the findings of six replicate injections of preserved solutions (2-8°C) with those of the fresh samples. The %RSD was determined to be 0.91%.

Assay of marketed formulation

The proposed spectroscopic method was utilised to measure Alfuzosin HCl and Tadalafil in the marketed formulation "Alfusin T". The percent recovery in the marketed formulation was calculated to be 99.71%. This shows that the approaches presented are appropriate for regular drug quality control. The proposed QbD-based UV method, though not cross-validated with pharmacopeial methods, was fully validated as per ICH Q2 (R1) guidelines, showing high accuracy (99.71% recovery), precision, and robustness. It offers a cost-effective, rapid alternative for routine analysis, especially in resource-limited environments, with future scope for cross-validation.

Forced degradation study

In this investigation, the ALF and TAD mixture's 10 µg/mL stock solution was subjected to forced degradation under various conditions to examine its stability profile, as shown in Figures 7 (a-e). Exposure to 1N HCl showed some degradation. Similarly, treating the solution with 0.1N NaOH revealed that the drug hydrolyses more quickly under strongly alkaline conditions than under acidic conditions. Furthermore, the stock solution degraded significantly in 6% H_2O_2, indicating its sensitivity to oxidative stress. In contrast, the drug's mixture showed low degradation when exposed to heat stress or UV light for 24 hr,

Table 4: Summary of validation parameters for simultaneous estimation of Alfuzosin HCl and Tadalafil.

Linearity	Range= 4-20 µg/mL	Correlation coefficient (r^2) = 0.999
Sensitivity	LOD= 0.98142 µg/mL	LOQ= 2.974 µg/mL
Accuracy (% recovery)	80% level	100.46%
	100% level	99.57%
	120% level	100.39%
Precision (%RSD)	Intraday precision	
	4 µg/mL	0.593%
	12 µg/mL	0.315%
	20 µg/mL	0.235%
	Interday precision	
	4 µg/mL	0.410%
	12 µg/mL	0.336%
	20 µg/mL	0.165%
Robustness (%RSD)	Change in wavelength (±2%)	
	274 nm	0.759%
	272 nm	0.318%
	270 nm	0.819%
Ruggedness (%RSD)	Change in analyst	0.272%
	Change in instrument (Shimadzu UV-1900)	0.988%

indicating strong stability under these conditions. These results indicate that the ALF and TAD mixture is more susceptible to breakdown in alkaline and oxidative stress than in acidic condition or UV-induced situations. Overall, the data show that these drugs combination is more sensitive to alkaline hydrolysis, followed by oxidative degradation, as opposed to thermal or photolytic degradation (Table 5).

Table 5: Forced degradation study results.

Degradation conditions	% degradation of ALF
Acidic degradation	6.8%
Basic degradation	16.54%
Oxidative degradation	10.65%
Thermal degradation	2.6%
Photolytic degradation	4.63%

CONCLUSION

The study simultaneously analyzed Alfuzosin HCl and Tadalafil using Design of Experiments for the development and validation (according to ICH Q2 R1 guidelines) by UV-spectrophotometric method for these drugs in bulk and marketed formulation. Using Quality by Design principles, this study presents an easy, reproducible, and cost-effective UV-spectrophotometric approach for determining Tadalafil and Alfuzosin HCl simultaneously. After determining ATP, CQAs, and CMAs, the chosen model was optimised using CCD as the optimisation approach. This

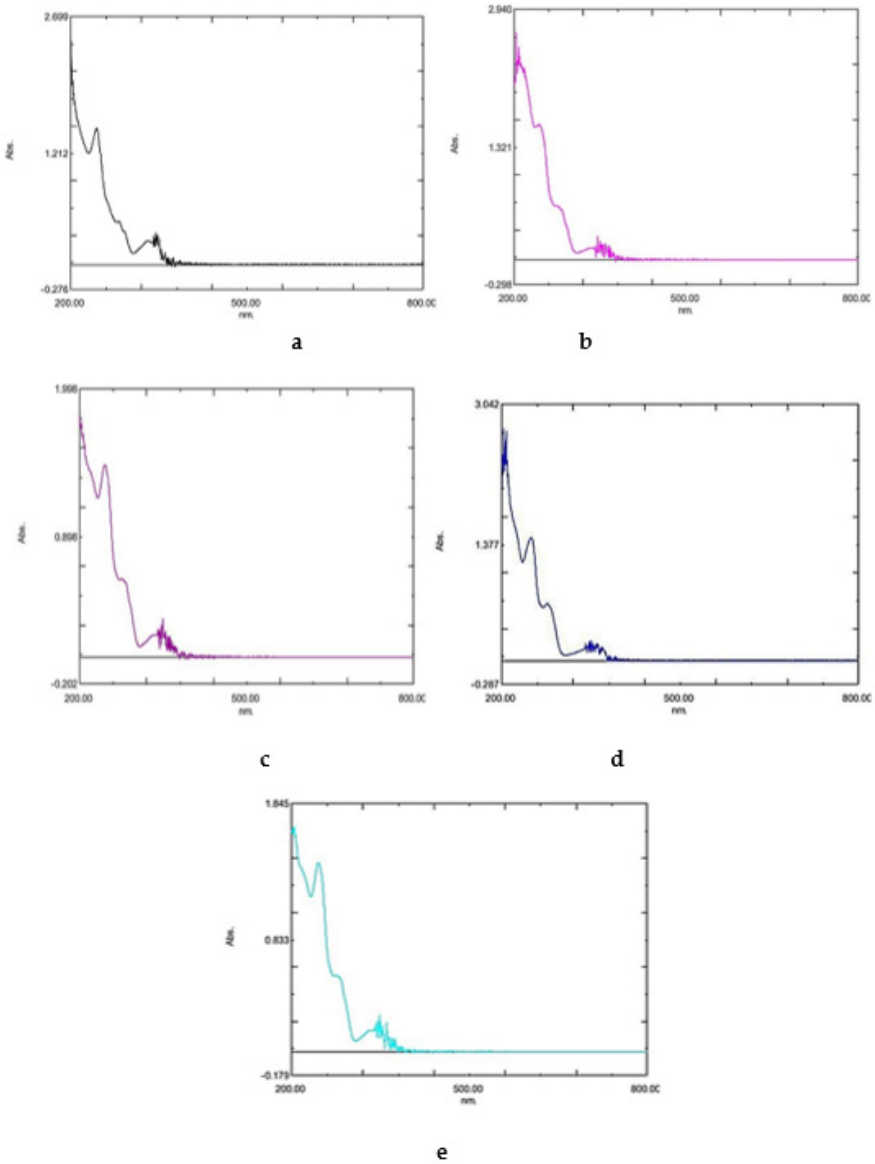

Figure 7: UV spectrum of Forced degradation study under different stress conditions (a) Acidic degradation (b) Basic degradation (c) Oxidative degradation (d) Thermal degradation (e) Photolytic degradation.

offered a thorough grasp of the relationship between response components and their interactions.

The analytical method was verified in accordance with ICH Q2 (R1) principles such as linearity, accuracy, precision, robustness, ruggedness, limit of detection, and limit of quantification. The ruggedness test was performed using a separate instrument, the Shimadzu UV-1900, which produced satisfactory results with %RSD values of less than 2%. Furthermore, the approach proved to be robust, with the standard solution subjected to stress testing that resulted in drug degradation up to specified limitations, demonstrating its stability and reliability under difficult conditions. The assay findings validated the method's simplicity, economical and precise making it ideal for regular Quality Control analysis.

Its future plans include extending to new medicine combinations, improving stability testing, and carrying out drug analysis across many formulations. This method's simplicity and precision could considerably help pharmaceutical quality testing, improving drugs development and quality assurance operations.

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ABBREVIATIONS

RSD: Relative Standard Deviation; **ANOVA:** Analysis Of Variance; **ATP:** Analytical Target Profile; **CCD:** Central Composite Design; **CMA:** Critical Method Attributes; **CQA:** Critical Quality Attribute; **DOE:** Design of Experiments; **ICH:** International Conference on Harmonization; **LOD:** Limit of Detection; **LOQ:** Limit of Quantification**; AQbD:** Analytical Quality by Design; **QC:** Quality Control**; R^2:** Correlation coefficient; **RP-HPLC:** Reverse Phase- High Performance Liquid Chromatography; **SD:** Standard Deviation; **UV:** Ultra-Violet; **v/v:** Volume by volume; **µg/mL:** Microgram per Milliliter.

CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

SUMMARY

This study presents a validated, economical UV-spectrophotometric method for the simultaneous quantification of Alfuzosin Hydrochloride and Tadalafil in both bulk and marketed formulations, developed using the Analytical Quality by Design (AQbD) framework. Method optimization was achieved through Central Composite Design (CCD), and validation adhered to ICH Q2(R1) guidelines. The method exhibited good linearity, precision, and robustness, with %RSD values below 2%, and successfully withstood stress degradation testing. Its simplicity, reliability, and cost-efficiency make it highly suitable for routine quality control and future applications to other drug combinations.

REFERENCES

1. PubChem. Alfuzosin Hydrochloride. pubchem.ncbi.nlm.nih.gov. Available from: https://pubchem.ncbi.nlm.nih.gov/compound/Alfuzosin-Hydrochloride. Accessed on April 13, 2024.
2. PubChem. Tadalafil. pubchem.ncbi.nlm.nih.gov. Available from: https://pubchem.ncbi.nlm.nih.gov/compound/Tadalafil. Accessed on April 13, 2024.
3. Alqahtani A, Alqahtani T, Ramzy S. Utilization of absorbance subtraction and ratio difference green spectrophotometric methods for the quantification of alfuzosin hydrochloride and tadalafil in their binary mixture. BMC chemistry. 2024; 18(1): 96.
4. Tantawy MA, Weshahy SA, Wadie M, Rezk MR. Eco-friendly spectrophotometric methods for assessment of alfuzosin and solifenacin in their new pharmaceutical formulation; green profile evaluation via eco-scale and GAPI tools. Current Pharmaceutical Analysis. 2021; 17(8): 1093-103.
5. Elama HS, Shalan SM, El-Shabrawy Y, Eid MI, Zeid AM. A synchronous spectrofluorometric technique for simultaneous detection of alfuzosin and tadalafil: applied to tablets and spiked biological samples. Royal Society Open Science. 2022; 9(7): 220330.
6. Sayed RA, Mohamed AR, Shalaby A, Ibrahim H. Micellar-enhanced and green-assessed first-derivative synchronous spectrofluorimetric approach for concurrent determination of alfuzosin hydrochloride and solifenacin succinate in different matrices: Docking simulation. SpectrochimicaActa Part A: Molecular and Biomolecular Spectroscopy. 2023; 293: 122442.
7. Gaonkar SG, Dinnimath BM. Quantitative estimation of drugs for erectile dysfunction and benign prostatic hyperplasia by high performance liquid chromatography: a review. Drug Analytical Research. 2024; 8(2): 7-24.
8. Balaji TS, Gavaskar D, Somanathan T. Analytical method validation of alfuzosin hydrochloride and its organic impurities by using ultra performance liquid chromatography. Materials Today: Proceedings. 2022; 69: 939-43.
9. Derayea SM, Zaafan AA, Nagy DM, Oraby M, Amir A, Zaafan S. Novel eco-friendly HPTLC method using dual-wavelength detection for simultaneous quantification of duloxetine and tadalafil with greenness evaluation and application in human plasma. Scientific Reports. 2024; 14(1): 23907.
10. Sharma S, Naman S, Goyal K, Baldi A. Simultaneous Estimation of Atovaquone and Mefloquine Hydrochloride: QbD based Method Development and Validation. Indian Journal Of Pharmaceutical Education and Research. 2023; 57(1): 250-63.
11. Shetti P, Jalalpure SS. Optimization of a validated UV-spectrophotometric methodology for assessment of apigenin in bulk powder. IJPER. 2022; 56(1): 281-6.
12. Agrawal YP, Agrawal MY, Jadhav SB, Shinde RJ. Development and validation of novel UV spectrophotometric method for the determination of evogliptintartarate in pharmaceutical dosage form. Indian Journal of Pharmaceutical Education and Research. 2020; 54(4): 1174-9.
13. Patil PH, Gurupadayya B, Hamrapurkar P. Integrated Quality by Design (QbD) Approach for Stability Indicating RPHPLC Method for the Estimation of Tadalafil Hydrochloride in Bulk Drug and Pharmaceutical Formulations. Current Pharmaceutical Analysis. 2021; 17(7): 932-44.
14. ICH Harmonized Tripartite Guidelines (2005). Q2 (R1) Validation of Analytical Procedures: Text and Methodology.

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