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ORIGINAL ARTICLE **OPEN ACCESS**

RP-HPLC Method Development and Validation for The Estimation of Luliconazole in Semisolid Dosage Form

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ABSTRACT
An innovative imidazole antibacterial option for the treatment of fungal skin infections is liconazole (LCZ). The problem can only now be treated with long-term, recurrent doses due to the exceedingly slow and poor skin absorption. A stability-indicating analytical method is needed to separate the active pharmaceutical ingredient (API) peak from the peaks of all potential degradation products, process related impurities, potential packaging leachable, excipients, and also separate these compounds from one another in order to perform batch release testing and stability studies of liconazole in pharmaceutical semisolid products. The stationary phase in the already proposed approach was Inertsil ODS -3V (150 mm × 4.6 mm, 5 µm). While the 0.1% Perchloric acid buffer mixture and acetonitrile were used as the mobile phase A and the 0.1% Perchloric acid buffer mixture and methanol were used as the mobile phase B in a gradient mode. 1.5 ml per minute is used to pump it through the chromatographic apparatus. At 210 nm, the UV detector is in operation. The validation study is conducted in accordance with ICH guidelines Q2 (R1) to demonstrate that the new analytical method satisfies the reliability characteristics, which demonstrate an analytical method's capacity to maintain the fundamental validation criteria over time, including selectivity, linearity, precision, accuracy, and specificity. During the working day, the stability indicating method is used for commercial Luliconazole semisolid dosage form quality control to quantify the drug and its degradation products and to verify the Tube uniformity test.
Keywords: *Luliconazole, Assay, HPLC, Validation, Accuracy*

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INTRODUCTION

Fungi in the environment are frequently one of the primary causes of skin problems. Fungi-caused diseases are responsible for the deaths of around 150 million people worldwide each year. The underdeveloped world and the third world have the highest prevalence of these illnesses. Despite the fact that they do not cause death, fungal pathogens are the most prevalent cause of illness and significant medical care expenditures. Twenty to twenty-five percent of the world's population suffers from opportunistic fungal infections, which are connected to common factors such as dirty environments and insufficient medical care. [1-2]. The optically active version of Lanoconazole is Luliconazole, also known as the R-enantiomer. In the course of ongoing clinical research for more effective topical treatments for fungal infections, it was discovered that a novel imidazole molecule has improved patient compliance, increased efficacy, and improved tolerability. [3, 4]. The antifungal medicine Luliconazole has been shown to effectively cure tinea pedis, as well as cruris and corporis. [5, 6]. According to laboratory study, it has been proven efficient against both dermatophytes and Candida. In 2005, luconazole derived from licorice was introduced as a topical antifungal therapy in Japan. Dermatophytosis, candidiasis, and Pityriasis Versicolor can be treated with Iraconazole. 1% creams and solutions are now permitted for use [6-8].

A stability-indicating analytical method for pharmaceutical cream and ointment products must separate the API peak from the peaks of all potential degradation products, process-related impurities, potential packaging leachables, and excipients, as well as the separation of these peaks from one another. Additionally, the peaks of these compounds are separated from one another. In the product release specifications, approval criteria and limitations for the quantity of luconazole in the formulation should be specified [9, 10]. Product Stability Guideline Q1A (R2) of the International Conference on Harmonization (ICH drug) recommends performing stress tests on a drug in order to determine its inherent stability features. This will make it possible to identify degradation byproducts and evaluate the applicability of the specified analytical methodologies. Through the process of analytical method

validation, we are able to ensure the reliability and accuracy of the results from our numerous HPLC analytical methods. During this approach, the restrictions of accuracy, linearity, precision, detection, and quantitation are revealed, making it a crucial step in the process of generating new dosage forms. In accordance with the ICH guideline, validation is required prior to establishing that an analytical technique is suitable for the purpose for which it was intended. As part of the process for producing a new drug, it is now required to send validation data to the relevant authorities. Not always was this the case. ICH and USP publications [11–14] contain a description of technique validation.

Throughout the course of scientific history, a range of measuring instruments, such as the UV spectrophotometer, high performance liquid chromatography, HPLC-MS, and UPLC [15-17], have been used to determine the quantity of luconazole present, either simultaneously or singularly. On the other hand, it was discovered that the currently existing technology for detecting luconazole in dosage forms, which was developed using RP-HPLC, was user-friendly, accurate, rapid, and cost-effective. Several RP-HPLC approaches for determining LCZ concentrations have been published in a variety of books; however, each of these procedures was found to be overly difficult and time-consuming. The objective of this study was to develop a novel RP-HPLC method for determining LCZ in pharmaceutical dosage forms. This technique had to be dependable, sensitive, cost-effective, stable, and involve a minimum of potentially harmful substances. These initiatives contribute to the advancement of eco-friendly chemistry. On this newly designed LCZ, RP-HPLC technology, validation was performed in compliance with ICH Q2 specifications (R1). The method for LCZ [18-20] was developed after comprehensive testing of its precision, accuracy, linearity, specificity, limit of detection (LOD), and limit of quantification (LOQ), as well as its capacity to measure LCZ in the semisolid dosage form recommended. After extensive testing of its precision, accuracy, linearity, and specificity, the method was devised.

MATERIAL AND METHODS

Chemical and reagents

Dr. Reddy's Laboratories provided a gift sample of Luliconazole (99.73 percent pure) (Hyderabad, India). The HPLC-grade solvents used in this study were obtained from Merck Ltd. in Bangalore, India, including acetonitrile, methanol, Perchloric acid and water. All of the chemicals used were of the highest quality for HPLC.

Instruments and chromatography condition

The HPLC was carried out on a Waters 2695 Alliance system equipped with a 2996 photodiode array detector (Waters) (PDA). The standards were resolved on a reverse-phase Inertsil ODS -3V (150 mm× 4.6 mm, 5 μm). Whereas Mixture of 0.1% Perchloric acid buffer and acetonitrile in the ratio 80:20 as Mobile phase A and Mixture of 0.1% Perchloric acid buffer, acetonitrile and methanol in the ratio 20:70:10 as Mobile phase B in a gradient mode used as mobile phase. The selected diluent is mixture of water and acetonitrile in the ratio of 20:80. Before the first injection, the column was saturated for 30 min with the initial mobile phase. The temperature was maintained at 40°C. Injection volume was decided to maintain at 10 μL. The PDA was set by optimizing wavelength to give the best response for two peaks at 210 nm to acquire the chromatogram. A software system called Water Empower 3 was used to collect the chromatographic data for this study. The standard Luliconazole were identified by comparing the retention time and spectra obtained from the sample and standard solutions [20-22].

Selection of lambda max

An ultraviolet (UV) spectrophotometer is used to calculate Lambda's maximum value. You must choose this option considering how crucial sensitivity is to the RP-HPLC procedure. When measuring the absorbance of a drug, finding the wavelength that produces the most precise reading enables pinpoint accuracy. High-performance liquid chromatography was employed in this work to scan between 200 and 400 nm. The findings demonstrated that CC concentrations could reach 100 ppm of purity (Waters 2695 Alliance system).

Gradient Program

Preparation of Luliconazole Standard Stock Solution:

From a scale that measures mass, precisely 40 mg of the working standard for luconazole should be transferred to a volumetric flask that has a capacity of 50 mL. Utilizing a sonicator, dissolve the substance in 35 mL of diluent, and after that, add more diluent until the volume is the same. (The concentration of Luliconazole in its theoretical form is 800 parts per million.)

Preparation of Standard Solution:

Pipette out 5.0mL of Luliconazole Standard Stock Solution transfer it into 50 mL volumetric flask and dilute to volume with diluent and mix well. (Theoretical Concentration: 80ppm of Luliconazole)

Preparation of Sample solution:
Weigh and transfer accurately about 2000 mg of sample to a 250mL volumetric flask, add about 150mL of diluent and vortex for 2 minutes. Sonicate for 15 minutes with intermittent shaking. Allow the Sample solution to equilibrate to room temperature. Make up to volume with diluent and mix well. Pipette out 5.0mL of above solution to 25mL volumetric flask and dilute to volume with diluent and mix well. Filter the solution through 0.45µm Teflon filter with discarding first five mL.

Method of analysis

The baseline stabilisation procedure took 30 minutes under the same chromatographic conditions as before. After stabilizing each peak region, the repeatability of the Blank and the produced concentration solution of the standard drug was assessed. The concentration of the material was determined by an injection of its solution. The ratio of the standard peak to the sample peak served as our basis for estimating the response factor. To make sure the novel method could be repeated, it was tested six times using the same procedure [23–25].

Validation of RP-HPLC method

Accuracy

The precision of a measurement refers to how closely the measured value matches the real value. Each of the three LCZ standards and samples contained a concentration ranging from 80 to 120 milligramme. To make sure the plan we established worked, these solutions were administered to the volunteers serving as testing. The discrepancies that appeared between the sample solutions of all three concentrations were then analyzed. This section provides a detailed explanation of the formula used to calculate the proportion of successful recoveries. The recommended range for recovery rates is between 98 and 102 percent.

Precision

The numerical difference that exists between the various outcomes for the same quantity or range of amounts is what we refer to as accuracy. In order to determine whether or not there were substantial differences on a daily or weekly basis, six replicates of a solution with a concentration of 100 ppm were analyzed on the same day and on three additional days. Following is the formula that was used in the calculation of the percent relative standard deviation (RSD): In most circumstances, the barrier for the admission of RSD is set at a percentage of the entire that is lower than 2%.

Linearity

To ascertain the linearity of the LCZ solution, several different LCZ solutions with concentrations ranging from 50 mg/ml to 120 mg/ml were introduced to a test tube. Each concentration solution was injected into the column six times, and each time it was tested under the same circumstances. By matching the peak area in the chromatogram to the amount of LCZ solution used in the experiment, a linearity calibration curve was created. Because the slope and intercept values were already known, regression analysis was used to determine the coefficient of correlation (R2). Regression analysis' significance level should be set to more than 0.999.

System suitability

In order to evaluate the practicability of the approach, the United States Pharmacopeia was analyzed (USP). It took six injections of the LCZ concentration solution in order to obtain values for things like peak symmetry factor, column efficiency, resolution, and percentage coefficient in peak area or height. The relative standard deviation (RSD), theoretical plate value (TPV), tailing factor (TF), and system correctness were all calculated utilizing its observed value [26-28].

Specificity and selectivity

The excipients that were making it difficult to detect the LCZ needed to be discovered, and since assessing the specificity and selectivity of the new approach was essential, this testing had to take place as soon as possible. To serve as a control, a "blank solution" that did not include LCZ was prepared and given. The chromatograms that were obtained from the standard, the sample, and the blank chromatogram were all compared to one another, and the results showed that there was no discernible difference between any of them. Comparing the three let us determine whether or not the excipients made the dosing process more difficult.

Robustness and ruggedness

To demonstrate the resilience and reliability of the LCZ RP-HPLC method, we made only minimal modifications to the chromatographic conditions used in the initial development of the technique. In order to determine the effect of changing parameters, we adjusted the temperature, flow rate, and mobile phase concentration of the column's operating conditions. Here, we have taken into account changes in chromatographic parameters.

The following modifications to the Chromatographic conditions will be evaluated:

- Change in column Temperature (±5°C)

- Change in wavelength (±5 nm)
- Change in Flow rate (± 0.1 ml\min) 10% change [29-30].

RESULTS AND DISCUSSION:

Development of RP-HPLC method

Completed is an RP-HPLC method for the quantification of LCZ in medicines. Mobile phase A was 0.1% Perchloric acid buffer and acetonitrile (80:20), whereas Mobile phase B was 0.1% Perchloric acid buffer, acetonitrile (20:70:10), and methanol (10:1). Various chromatographic settings, including flow rate, column temperature, and the ratio of mobile phase components, were investigated in order to create a sharp, symmetric peak with the proper retention time. We used the Inertsil ODS -3V column to improve the peak (150 mm × 4.6 mm, 5 µm). To customize the chromatographic parameters to meet particular needs, researchers may vary the mobile phase to modify the retention time, theoretical plate number (N), retention factor, and selectivity. We utilised a Waters 2695 Alliance system outfitted with a 2996 photodiode array detector to determine the wavelength. This was undertaken to assure the sensitivity of the LCZ technique (PDA). Between 200 and 400 nm, the LCZ standard solution was analyzed to determine its peak wavelength. The best peak was found at 210 nautical miles **(Figure 1).**

Validation of RP-HPLC method

Accuracy

Placebo of Luliconazole gel was spiked with Luliconazole drug Substance at three different levels: 80%, 100% and 120% of the label claim in triplicate (in total nine determinations) and then proceeded with Sample solution as described under. As demonstrated in **Table 2,** the information received was deemed to be accurate. According to the findings, the percentage recovery of standard and sample LCZ was 101.2 percent, respectively. It was determined that the acquired result is within the range of typical recovery values (98.0 percent to 102.0 percent).

Precision

This study looked at the system, technique, and intermediate degrees of accuracy. Six replicates of the same standard were injected from the same vial to test the system's accuracy. The findings were recorded in terms of percent relative standard deviation (% RSD), tailing, plate count, and resolution. The material was processed six times using the aforementioned steps. To depict the % assay for each analyte, standard deviation percentages were used (percent RSD). The data were reported as a percentage relative standard deviation after two independent analysts examined six different extract samples on two different systems, one using a Waters e2695 Alliance system with a 2996 PDA and the other using a 2489 ultraviolet (UV) detector. The results of this investigation showed a better way to locate LCZ in its dose form **(Table 3).**

Linearity and range

The linearity calibration curves were found to have an R2 value of 1.0000. The calibration curve that was drawn in the concentration range of 40–120 ppm was found to be linear in nature **(Table 4).** The equation and regression coefficient (R2) are presented in Fig. 2. According to the results, the relative standard deviation was in the range of 1.0 to 1. A higher correlation value was discovered between the observation derived from peak value and the concentration of the drug solution than had previously been seen. A series of Standard preparations of Luliconazole were prepared over a range of 50% to 150% of the working concentration of Luliconazole. (Minimum Five points in the range 80-120% of standard / sample concentration for Assay). Since the working concentration is 80 µg per ml of Luliconazole, the range proposed is about 40 µg per ml to 120 µg per ml of Luliconazole.

System suitability

During the testing to determine whether or not the system was suitable, a standard LNZ solution containing 100 ppm of concentration was utilised, and the findings were analyzed. It was determined that 9.9 minutes were required in order to properly separate the components using chromatographic conditions. The tailing factor, retention length, theoretical plate number (N), and system accuracy were found to be within the permissible limits of 2 percent in a variety of frameworks. The results of the tests showed that the substance fell within the parameters established by the United States Pharmacopeia for what was considered to be acceptable at the time. Table 5, which was displayed right here, had a great deal of informative data.

Specificity and selectivity

When comparing the results of the current study to those of past research studies on the same medication, it was discovered that the retention period with readily accessible mobile phase was superior. The approach was quantified accurately and with high resolution. It was not possible to draw any conclusions from the blank sample. A cost-effective mobile phase consisting of Mixture of 0.1%

Perchloric acid buffer and acetonitrile in the ratio 80:20 as Mobile phase A and Mixture of 0.1% Perchloric acid buffer, acetonitrile and methanol in the ratio 20:70:10 as Mobile phase B is utilised in this procedure. **Figure 3** shows the retention time for standard and sample LCZ concentrations. The retention time for standard and sample LCZ concentrations was 9.9 minutes. When compared to other approaches that have been developed, the retention time attained was found to be shorter.

Robustness

In order to determine the robustness of the currently developed luliconazole RP-HPLC method, minor variations in chromatographic parameters, such as the rate of flow of mobile phase (1.4 ml/min and 1.6 ml/min), different wavelengths (205 and 215), and temperature of the column (35 degrees Celsius and 45 degrees Celsius), were applied. The collected results did not reveal any statistically significant differences in peak area or retention duration. The percentage recovery of LCZ for the standard solution was almost identical to 99.0 percent, whereas the percentage recovery of LCZ for the sample solution was nearly identical to 99.2 percent. According to the findings, the percent RSD was less than 2.0 percent under various situations, indicating that the current approach is robust and tough. The values of % RSD as shown in **Table 6** indicate better robustness of the method [28-30].

Table 1: Details of Gradient program

Time (Minutes)	Mobile Phase A (% v/v)	Mobile Phase B (%v/v)
0	80	20
10	65	35
15	32	68
17	80	20
20	80	20

Table 2: Accuracy studies of developed method

Sample No.	Amount added (mg)	Amount recovered (mg)	% Recovery
Acc. 80% -1	80.40	81.00	100.7
Acc. 80% -2	80.08	80.98	101.1
Acc. 80% -3	80.44	81.12	100.8
Acc. 100% -1	99.86	101.81	102.0
Acc. 100% -2	100.19	101.27	101.1
Acc. 100% -3	99.64	101.33	101.7
Acc. 120% -1	119.51	120.95	101.2
Acc. 120% -2	119.35	121.27	101.6
Acc. 120% -3	119.94	121.13	101.0
Mean			**101.2**
SD			**0.433**
% RSD			**0.43**

Table 3: Method Precision and Intermediate precision Results

Sample	Method Precision % Assay	Intermediate Precision % Assay
1	102.2	103.0
2	101.4	100.4
3	101.7	99.9
4	101.2	100.7
5	101.3	100.8
6	101.5	100.5
Mean	**101.6**	**100.9**
SD	**0.362**	**1.083**
%RSD	**0.36**	**1.07**
Overall Mean	**101.2**	
Overall SD	**0.845**	
Overall %RSD	**0.83**	

Table 4: Linearity of Luliconazole

% Concentration	Concentration (µg per ml)	Response (Area)	Statistical analysis	
50%	40.077	1217552	**Slope**	**30570.24206**
80%	64.124	1949310		
90%	72.139	2196004	**Intercept**	**-8617.79594**
100%	80.155	2440345		
110%	88.170	2686431		
120%	96.186	2932388	**Correlation Coefficient**	**1.0000**
150%	120.232	3665931		

Table 5: System suitability of Luliconazole

Sr.No.	Solution Name	Retention Time	USP Tailing	USP Plate Count
1	Standard	9.946	1.3	75214
2	Sample	4,256	1.3	73113

Table 6: Robustness for Luliconazole

Robustness parameter		% RSD Luliconazole	Remark
Wavelength (nm)	205	1.88	Pass
	210	0.36	Pass
	215	1,27	Pass
Temperature (°C)	35	1,25	Pass
	40	0.36	Pass
	45	1.06	Pass
Flow (mL/min)	1.4	0.84	Pass
	1.5	0.36	Pass
	1.6	0.84	Pass

Figure 1: HPLC spectra of LCZ

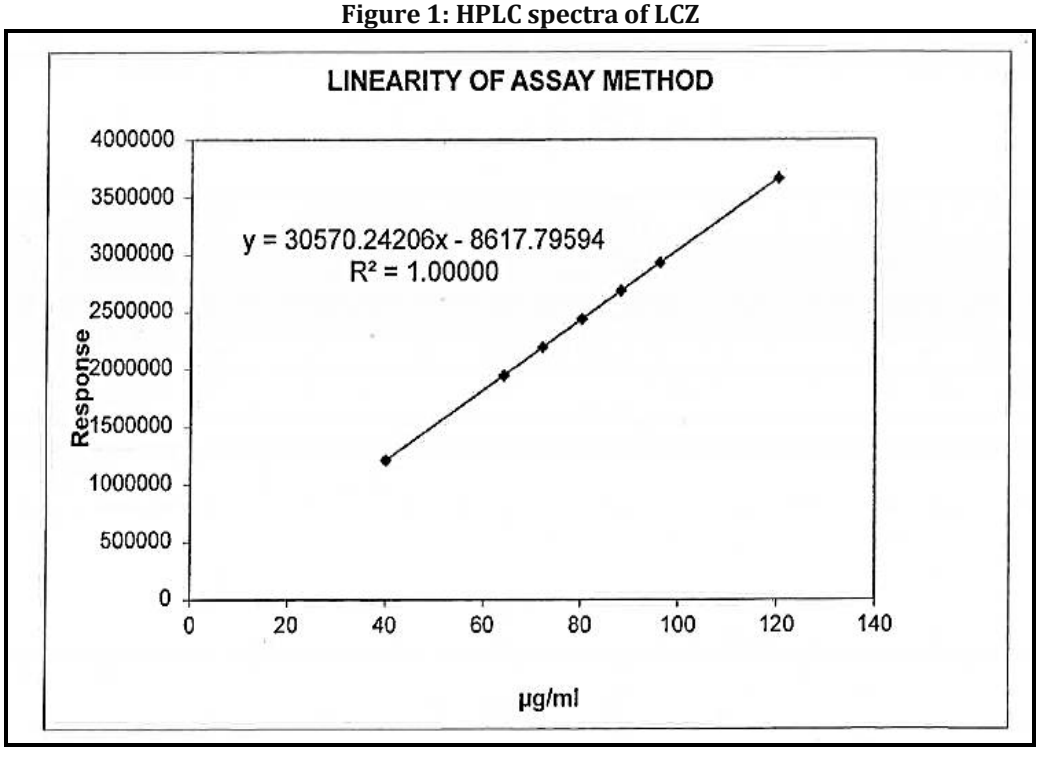

Figure 2: Linearity Graph for Luliconazole

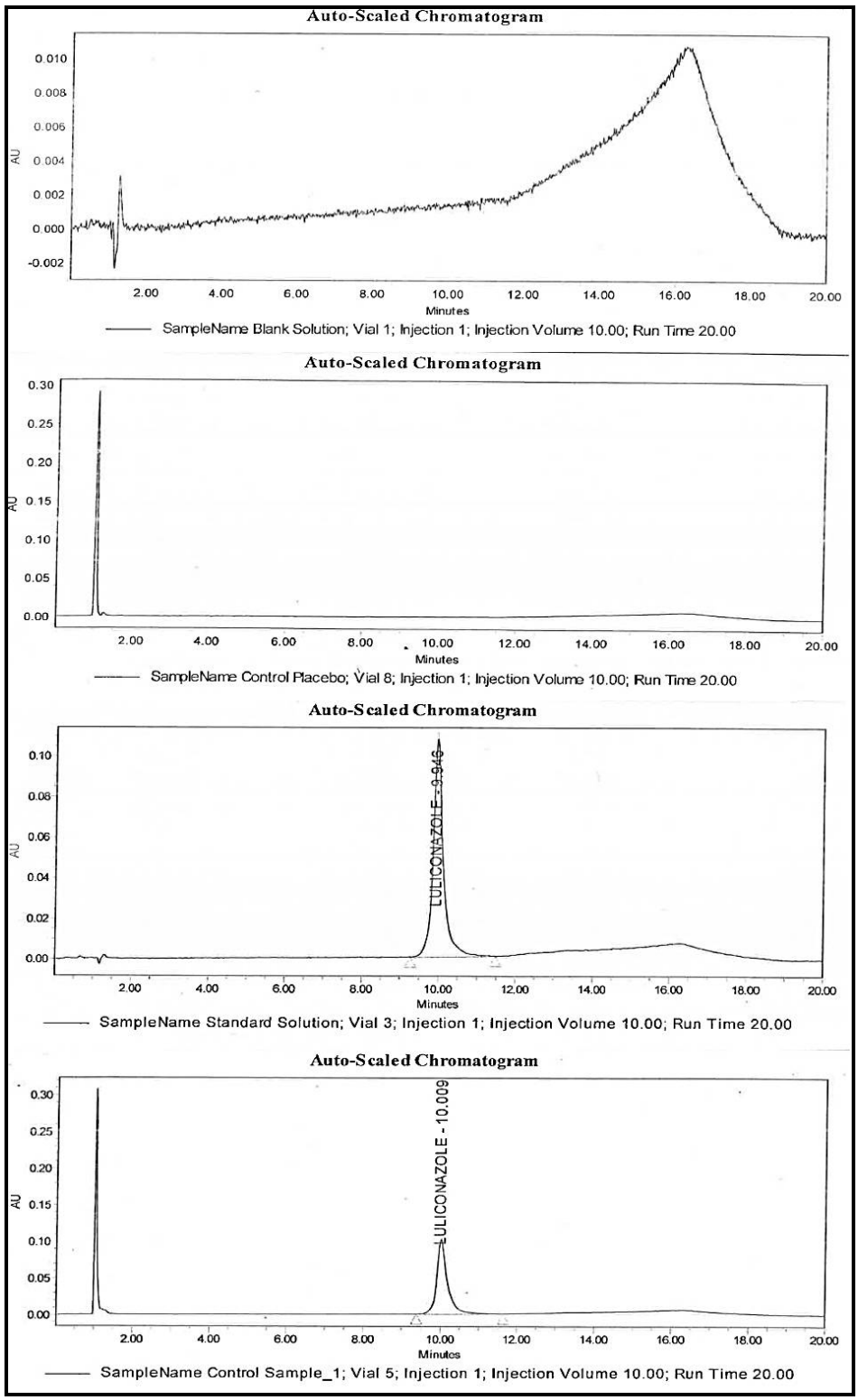

Figure 3: System suitability of Luliconazole

CONCLUSION

The amount of LCZ in dosage form may now be measured with accuracy, precision, strength, dependability, and repeatability thanks to the RP-HPLC method. The mobile phase utilised had a very high resolution rate while requiring a shorter retention period. The method was carried out in accordance with ICH and FDA regulations, and the provided report complied with all requirements. The

correctness, precision, and straightness of the operation were all evaluated in order to determine how effective the medicine was. It is possible to measure LCZ repeatedly using the RP-HPLC technique described in this article. The proposed strategy might be a useful addition to how we often solve problems, according to the statistics. According to the specificity report, the excipient had no impact on the outcomes. The pace of reactions might then be investigated using plasma and biological fluids as a potential next step. A crucial discovery was the fact that this novel method outperformed earlier trials in terms of cost-effectiveness ratio.

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Conflicts of interest
No conflicts of interest are declared by the authors.

Authors' contribution
Vibhavari M. Chatur & Shashikant N. Dhole were involved in the sample selection, the planning and execution of lab research, the interpretation of data, and the writing of the report. Shashikant N. Dhole's efforts include data analysis and chemical identification. The final document was interpreted and approved by each author.

REFERENCES

1 Baby AR, Maciel CP, Kaneko TM, Velasco MV. UV spectrophotometric determination of bioflavonoids from a semisolid pharmaceutical dosage form containing Trichilia catigua Adr. Juss and Ptychopetalum olacoides Bentham standardized extract: analytical method validation and statistical procedures. Journal of AOAC International. 2006 Nov 1; 89(6):1532-7.
2 Bongomin F, Gago S, Oladele RO, Denning DW. Global and multi-national prevalence of fungal diseases estimate precision. Journal of fungi. 2017 Dec; 3(4):57.
3 Chaudhari MJ, Chaudhari SR, Chalikwar SS, Shirkhedkar AA. Application of area under curve technique for UV-Spectrophotometric determination of Luliconazole in bulk and pharmaceutical formulation. Asian Journal of Pharmaceutical Analysis. 2018 Mar 1; 8(1).
4 Cheng J, Weijun K, Yun L, et al. Development and validation of UPLC method for quality control of Curcuma longa Linn. Fast simultaneous quantitation of three curcuminoids. J Pharm Biomed Anal. 2010; 53:43–49.
5 Daneshgar P, Norouzi P, Moosavi-Movahedi AA, et al. Fabrication of carbon nanotube and dysprosium nanowire modified electrodes as a sensor for determination of curcumin. J Appl Electrochem. 2009; 39:1983–1992.
6 Dave HN, Mashru RC, Thakkar AR. Simultaneous determination of salbutamol sulphate, bromhexine hydrochloride and etofylline in pharmaceutical formulations with the use of four rapid derivative spectrophotometric methods. Anal Chim Acta. 2007; 597:113–120.
7 Desai NJ, Maheshwari DG (2014) UV Spectrophotometric Method for the Estimation of Luliconazole in Marketed Formulation (Lotion). IJPSR 5(2): 48-54.
8 Desai NJ, Maheshwari DG. UV spectrophotometric method for the estimation of Luliconazole in marketed formulation (lotion). Pharma Science Monitor. 2014 Apr 2; 5.
9 Dewani AP, Dabhade SM, Bakal RL, Gadewar CK, Chandewar AV, Patra S. Development and validation of a novel RP-HPLC method for simultaneous determination of paracetamol, phenylephrine hydrochloride, caffeine, cetirizine and nimesulide in tablet formulation. Arabian journal of chemistry. 2015 Jul 1; 8(4):591-8.
10 Erpina E, Rafi M, Darusman LK, et al. Simultaneous quantification of curcuminoids and xanthorrhizol in *Curcuma xanthorrhiza* by high-performance liquid chromatography. *J Liq Chromatogr Relat Technol.* 2017; 40:635–639.
11 Gupta AK, Daigle D. A critical appraisal of once-daily topical Luliconazole for the treatment of superficial fungal infections. Infection and drug resistance. 2016; 9:1.
12 Jadhav BK, Mahadik KR, Paradkar AR. Development and validation of improved reversed phase-HPLC method for simultaneous determination of curcumin, demethoxycurcumin and bis-demethoxycurcumin. Chromatographia. 2007 Apr; 65(7):483-8.
13 Jahan MS, Islam MJ, Begum R, Kayesh R, Rahman A. A study of method development, validation, and forced degradation for simultaneous quantification of paracetamol and ibuprofen in pharmaceutical dosage form by RP-HPLC method. Analytical chemistry insights. 2014; 9:75.
14 Kadam PV, Bhingare CL, Nikam RY, Pawar SA. Development and validation of UV spectrophotometric method for the estimation of curcumin in cream formulation. Pharmaceutical methods. 2013 Nov 1; 4(2):43-5.
15 Kaul S, Yadav S, Dogra S. Treatment of dermatophytosis in elderly, children, and pregnant women. Indian dermatology online journal. 2017 Sep; 8(5):310.
16 Kaur M, Singh K, Jain SK. Luliconazole vesicular-based gel formulations for its enhanced topical delivery. Journal of liposome research. 2020 Oct 1; 30(4):388-406.

17 Khanna D, Bharti S. Luliconazole for the treatment of fungal infections: an evidence-based review. Core evidence. 2014; 9:113.
18 Koga H, Nanjoh Y, Makimura K, Tsuboi R. In vitro antifungal activities of Luliconazole, a new topical imidazole. Medical mycology. 2009 Sep 1; 47(6):640-7.
19 Konduru N, Kethe VB, Gundla R, Katari NK, Mallavarapu R. Determination of progesterone (steroid drug) in the semi-solid dosage form (vaginal gel) using a stability-indicating method by RP-HPLC/PDA detector. Biomedical Chromatography. 2022 Jan; 36(1):e5246.
20 Li J, Jiang Y, Wen J, Fan G, Wu Y, Zhang C. A rapid and simple HPLC method for the determination of curcumin in rat plasma: assay development, validation and application to a pharmacokinetic study of curcumin liposome. Biomedical chromatography. 2009 Nov; 23(11):1201-7.
21 Malasiya A, Goyal A. Method development and validation of RP HPLC method for assay and related substances of Luliconazole in topical dosage form. International Journal of Pharmaceutical Chemistry and Analysis. 2017; 4(2):46-50.
22 Malasiya Aditi, Goyal Aditi (2017) Method Development and Validation of RP HPLC Method for Assay and related Substances of Luliconazole in Topical Dosage form. IJPCA 4(2): 46-50.
23 Shah Y, Iqbal Z, Ahmad L, Khan A, Khan MI, Nazir S, Nasir F. Simultaneous determination of rosuvastatin and atorvastatin in human serum using RP-HPLC/UV detection: Method development, validation and optimization of various experimental parameters. Journal of Chromatography B. 2011 Mar 15; 879(9-10):557-63.
24 Shaikh MS, Kale MA, Mahaparle PR, Rajput H, Karkhele SM. Development and validation of UV spectrophotometric method for the estimation of Luliconazole in bulk, marketed formulations. Journal of Current Pharma Research. 2020 Apr 1; 10(3):3759-70.
25 Soman A, Qiu Y, Chan Li Q. HPLC-UV method development and validation for the determination of low level formaldehyde in a drug substance. Journal of chromatographic science. 2008 Jul 1; 46(6):461-5.
26 Sonawane S, Gide P (2016) Application of experimental design for the optimization of forced degradation and development of a validated stability- indicating LC method for Luliconazole in bulk and cream formulation. Arabian Journal of Chemistry 9(2): S1428-S1434.
27 Sowjanya G, Mohana K. Quantification and stability aspects of Luliconazole in bulk and pharmaceutical dosage forms by UV spectroscopy. Journal of Drug Delivery and Therapeutics. 2019 Apr 15; 9(2-s):300-6.
28 Watanabe S, Takahashi H, Nishikawa T, Takiuchi I, Higashi N, Nishimoto K, Kagawa S, Yamaguchi H, Ogawa H. Dose-finding comparative study of 2 weeks of Luliconazole cream treatment for tinea pedis–comparison between three groups (1%, 0.5%, 0.1%) by a multi-center randomized, double-blind study. Mycoses. 2007 Jan; 50(1):35-40.
29 Watanabe S, Takahashi H, Nishikawa T, Takiuchi I, Higashi N, Nishimoto K, Kagawa S, Yamaguchi H, Ogawa H. A comparative clinical study between 2 weeks of Luliconazole 1% cream treatment and 4 weeks of bifonazole 1% cream treatment for tinea pedis. Mycoses. 2006 May; 49(3):236-41.
30 Yang J, Liang Z, Lu P, Song F, Zhang Z, Xia H, He J, Zhou T, Zhang J. A sensitive and rapid bio analytical method for the quantitative determination of Luliconazole in rabbit eye tissues using UPLC-MS/MS assay. Journal of Chromatography B. 2022 Apr 1; 1194:123173.

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