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Development and Validation of a Stability-Indicating RP-HPLC Method for Quantitative Estimation of Lasmiditan in Bulk Drug and Pharmaceutical Dosage Forms

Sajid Jahangir Sayyad[1], Allabaksha Shaikh[2]
[1]Pharmaceutical Quality Assurance Department, Savitribai Phule Pune University, Pune, Maharashtra, 411001
[2]Pharmacology Department, Savitribai Phule Pune University, Pune, Maharashtra, 411001

***Abstract*—Background**: *Lasmiditan is a novel, highly selective 5-hydroxytryptamine 1F (5-HT$_1$F) receptor agonist approved for the acute treatment of migraine with or without aura. Owing to its unique non-vasoconstrictive mechanism of action, it represents an important therapeutic alternative for patients with cardiovascular contraindications to triptans. The increasing pharmaceutical application of lasmiditan necessitates reliable analytical methods for routine quality control, formulation development, and stability assessment. Although a few chromatographic methods have been reported, there remains a need for a rapid, economical, and stability-indicating RP-HPLC method validated according to International Council for Harmonisation (ICH) guidelines.[17,21–33]* **Objective**: *The present study aimed to develop and validate a simple, rapid, precise, accurate, and stability-indicating reverse-phase high-performance liquid chromatographic (RP-HPLC) method for the quantitative estimation of lasmiditan in bulk drug and pharmaceutical dosage forms following ICH Q2(R1) recommendations.[21]* **Methods**: *Chromatographic separation was achieved using a Phenomenex Kinetex XB-C18 column (150 × 4.6 mm, 5 µm) with a mobile phase consisting of 0.1% perchloric acid and acetonitrile (58:42, v/v) at a flow rate of 1.0 mL/min. Detection was performed at 228 nm using a diode array detector. The developed method was validated for system suitability, specificity, linearity, accuracy, precision, robustness, sensitivity, assay, and forced degradation studies in accordance with ICH guidelines.[21]* **Results**: *The optimized chromatographic conditions produced a sharp and symmetrical lasmiditan peak with a retention time of approximately 2.59 min. The method exhibited excellent linearity over the concentration range evaluated, with a correlation coefficient (R^2) of 1.000. Accuracy studies demonstrated recoveries within acceptable limits, while precision studies showed percentage relative standard deviation values below 2%, confirming excellent reproducibility. The developed method successfully resolved lasmiditan from its degradation products under acidic, alkaline, oxidative, thermal, and photolytic stress conditions, confirming its stability-indicating capability.* **Conclusion**: *The proposed RP-HPLC method is simple, rapid, economical, accurate, precise, robust, and stability-indicating. It complies with ICH Q2(R1) validation requirements and is suitable for routine quality control, assay determination, and stability evaluation of lasmiditan in bulk drug and pharmaceutical dosage forms.*

***Keywords*—** *Lasmiditan; RP-HPLC; Stability-indicating method; Method validation; ICH Q2(R1); Pharmaceutical analysis; Quality control; Migraine.*

I. INTRODUCTION

1.1 Background of Migraine

Migraine is a chronic and disabling neurological disorder characterized by recurrent episodes of moderate to severe headache that are frequently associated with nausea, vomiting, photophobia, and phonophobia. It affects approximately one billion people worldwide and remains one of the leading causes of disability among individuals under 50 years of age. The recurrent nature of migraine substantially impairs patients' quality of life, work productivity, and social functioning while imposing a considerable economic burden on healthcare systems. Despite continuous advances in therapeutic interventions, effective migraine management remains challenging because of interindividual variability in disease presentation and treatment response.[47–50]

1.2 Lasmiditan as a Novel Antimigraine Drug

Recent advances in migraine pharmacotherapy have led to the development of selective serotonin receptor agonists with improved safety profiles. Lasmiditan is the first clinically approved, highly selective 5-hydroxytryptamine 1F (5-HT$_1$F) receptor agonist indicated for the acute treatment of migraine with or without aura in adults. Unlike triptans, which exert their pharmacological activity through 5-HT$_1$B/1D receptors and produce cerebral vasoconstriction, lasmiditan selectively activates neuronal 5-HT$_1$F receptors without causing clinically significant vasoconstriction. This unique mechanism provides an important therapeutic advantage, particularly for patients with cardiovascular or cerebrovascular disorders in whom conventional triptan therapy is contraindicated. Clinical studies have demonstrated that lasmiditan provides effective pain relief while maintaining an acceptable safety profile, thereby expanding therapeutic options for acute migraine management.[47–50]

1.3 Need for Reliable Analytical Methods

The increasing clinical utilization of lasmiditan has generated a growing demand for validated analytical methods capable of ensuring the quality, safety, and efficacy of pharmaceutical formulations. Analytical procedures are fundamental throughout the pharmaceutical product life cycle, including raw material testing, formulation development, in-process quality control, finished product evaluation, stability

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assessment, and regulatory submissions. Consequently, analytical methods employed for routine pharmaceutical analysis must consistently provide accurate, precise, selective, and reproducible results under diverse laboratory conditions.[1–21]

1.4 Importance of RP-HPLC in Pharmaceutical Analysis

Reverse-phase high-performance liquid chromatography (RP-HPLC) remains one of the most extensively employed analytical techniques for pharmaceutical quality assessment owing to its excellent sensitivity, selectivity, reproducibility, and operational simplicity. The technique offers efficient separation of pharmaceutical compounds from impurities, degradation products, and formulation excipients while providing high analytical precision and relatively short analysis times. Because of these advantages, RP-HPLC has become the preferred analytical tool for assay determination, impurity profiling, dissolution studies, content uniformity testing, and stability evaluation of pharmaceutical products.[1–20]

1.5 Regulatory Perspective

International regulatory authorities, including the International Council for Harmonisation (ICH), emphasize the importance of validating analytical procedures before their routine implementation in pharmaceutical quality control. According to ICH Q2(R1), analytical methods should be evaluated for parameters such as specificity, system suitability, linearity, accuracy, precision, robustness, limit of detection, limit of quantification, and analytical range to ensure reliable performance. Furthermore, ICH Q1A(R2) recommends the use of forced degradation studies under acidic, alkaline, oxidative, thermal, and photolytic stress conditions to establish the stability-indicating capability of chromatographic methods and to support stability studies during product development.[17,21]

1.6 Literature Review and Research Gap

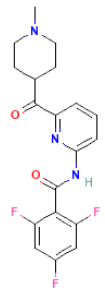
Several chromatographic methods have been reported for the quantitative estimation of lasmiditan in bulk drug substances and pharmaceutical formulations. Published studies have demonstrated the applicability of RP-HPLC, LC–MS/MS, and other analytical techniques for drug estimation. However, many of these methods primarily focus on assay determination or bioanalytical applications, while comparatively fewer studies comprehensively evaluate stability-indicating characteristics in accordance with current ICH validation requirements. In addition, some reported procedures employ longer chromatographic run times, complex mobile-phase compositions, or analytical conditions that may not be readily adaptable to routine pharmaceutical quality control laboratories.[22–33,41]

Therefore, there remains a need for a simple, rapid, economical, and stability-indicating RP-HPLC method that combines excellent chromatographic performance with comprehensive validation and practical applicability for routine pharmaceutical analysis.

1.7 Aim of the Present Study

The present investigation was undertaken to develop and validate a simple, rapid, accurate, precise, robust, and stability-indicating RP-HPLC method for the quantitative estimation of lasmiditan in bulk drug substances and pharmaceutical dosage forms. The developed method was validated according to the recommendations of ICH Q2(R1) by evaluating system suitability, specificity, linearity, accuracy, precision, sensitivity, robustness, assay performance, and forced degradation behavior. The proposed analytical method is expected to provide a reliable, economical, and regulatory-compliant analytical tool for routine quality control and stability assessment of lasmiditan pharmaceutical formulations.

Figure 1. Chemical structure of lasmiditan illustrating the molecular framework responsible for its selective 5-HT$_1$F receptor agonistic activity.



II. MATERIALS AND METHODS

2.1 Chemicals and Reagents

Lasmiditan reference standard (purity ≥99.0%) was obtained as a gift sample from a reputed pharmaceutical manufacturer and used without further purification. The commercially available tablet formulation containing lasmiditan was procured from the local market for assay analysis. HPLC-grade acetonitrile and methanol were purchased from Merck (Mumbai, India). Perchloric acid, hydrochloric acid, sodium hydroxide, and hydrogen peroxide of analytical reagent grade were used for the preparation of mobile phase and forced degradation studies. Ultrapure water was obtained using a Milli-Q water purification system and was employed throughout the investigation. All chemicals and reagents used during method development and validation were of analytical or HPLC grade to minimize analytical variability and ensure reproducibility.[1–5,21]

2.2 Instrumentation

Chromatographic analysis was performed using an Agilent 1260 Infinity II High-Performance Liquid Chromatography system equipped with a quaternary solvent delivery pump, autosampler, thermostatically controlled column compartment, and diode array detector (DAD). Data acquisition and chromatographic processing were carried out using OpenLab EZChrom software. Separation was achieved using a Phenomenex Kinetex XB-C18 column (150 mm × 4.6 mm, 5 µm particle size). A calibrated analytical balance (Shimadzu), ultrasonic bath, digital pH meter, membrane filtration

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assembly, and hot air oven were used during sample preparation and validation studies.

2.3 Selection of Detection Wavelength

A standard solution of lasmiditan was scanned between 200 and 400 nm using the diode array detector to determine the wavelength corresponding to maximum absorbance (λmax). The drug exhibited maximum absorbance at 228 nm, providing excellent detector response with minimal baseline noise. Therefore, 228 nm was selected as the optimum wavelength for subsequent chromatographic analysis.

2.4 Chromatographic Method Development and Optimization

Several chromatographic trials were carried out to optimize the analytical conditions for achieving satisfactory peak symmetry, adequate theoretical plates, minimum tailing factor, acceptable retention time, and efficient separation of lasmiditan from potential degradation products. Different mobile-phase compositions comprising aqueous acidic buffers and organic solvents in varying proportions were evaluated using C18 stationary phases.

TABLE 1. Instruments and analytical equipment used during method development and validation.

Instrument	Model/Specification	Manufacturer
HPLC System	Agilent 1260 Infinity II	Agilent Technologies
Detector	Diode Array Detector (DAD)	Agilent Technologies
Column	Phenomenex Kinetex XB-C18 (150 × 4.6 mm, 5 µm)	Phenomenex
Analytical Balance	AU Series	Shimadzu
Ultrasonic Bath	Digital Sonicator	Generic/As per thesis
pH Meter	Digital pH Meter	Eutech/Equivalent
Membrane Filter	0.45 µm Nylon Filter	Millipore

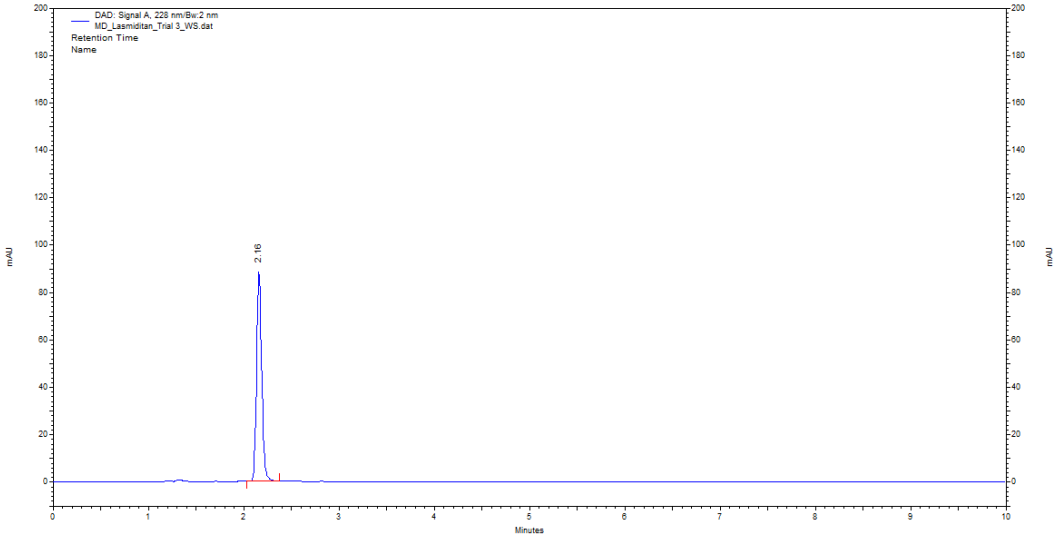

Figure 2. UV absorption spectrum of Lasmiditan showing λmax at 228 nm.

TABLE 2. Optimized chromatographic conditions for RP-HPLC analysis of Lasmiditan.

Parameter	Optimized Condition
Column	Phenomenex Kinetex XB-C18 (150 × 4.6 mm, 5 µm)
Mobile Phase	0.1% Perchloric Acid : Acetonitrile (58:42, v/v)
Flow Rate	1.0 mL/min
Detection Wavelength	228 nm
Injection Volume	10 µL
Column Temperature	30°C
Diluent	Water : Acetonitrile (50:50)
Run Time	10 min
Retention Time	2.59 min

Optimization of chromatographic variables included the composition of the mobile phase, flow rate, column temperature, detection wavelength, injection volume, and run time. Among the various experimental conditions investigated, the combination of 0.1% perchloric acid and acetonitrile (58:42, v/v) provided a sharp, symmetrical peak with excellent chromatographic performance and minimal interference from excipients or degradation products.

2.5 Preparation of Mobile Phase

The mobile phase consisted of 0.1% perchloric acid and acetonitrile in the ratio of 58:42 (v/v). Both components were mixed thoroughly, filtered through a 0.45 µm membrane filter, and degassed by ultrasonication for 15 minutes prior to chromatographic analysis.

2.6 Preparation of Standard Solution

An accurately weighed quantity of 10 mg of lasmiditan reference standard was transferred into a 100 mL volumetric flask. Approximately 70 mL of diluent was added, and the solution was sonicated until complete dissolution. The final volume was adjusted with the same diluent to obtain the stock solution. Appropriate serial dilutions were prepared to obtain

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the required working concentration for chromatographic analysis.

2.7 Preparation of Sample Solution

Twenty tablets were accurately weighed, and the average tablet weight was calculated. The tablets were finely powdered, and a quantity equivalent to 10 mg of lasmiditan was transferred into a 100 mL volumetric flask. Approximately 70 mL of diluent was added, and the mixture was sonicated for complete extraction of the active pharmaceutical ingredient. After cooling, the volume was made up to the mark with diluent and filtered through a 0.45 µm membrane filter. Suitable dilution of the filtrate was performed to obtain the working concentration for HPLC analysis.

2.8 Method Validation

The developed RP-HPLC method was validated in accordance with the recommendations of the International Council for Harmonisation (ICH) Q2(R1) guideline for analytical procedure validation. Validation parameters included system suitability, specificity, linearity, accuracy, precision, sensitivity (LOD and LOQ), robustness, assay of marketed formulation, and forced degradation studies.[21]

The acceptance criteria for each validation parameter were established according to ICH recommendations before initiating the validation experiments.

2.9 Forced Degradation Studies

To evaluate the stability-indicating capability of the developed RP-HPLC method, lasmiditan was subjected to forced degradation under stress conditions recommended by ICH Q1A(R2). Acidic degradation was performed using hydrochloric acid, alkaline degradation using sodium hydroxide, oxidative degradation using hydrogen peroxide, thermal degradation by exposing the drug to elevated temperature in a hot air oven, and photolytic degradation by exposure to ultraviolet light. After completion of the stress studies, the samples were neutralized where appropriate, diluted with the mobile phase, filtered through a 0.45 µm membrane filter, and analyzed under the optimized chromatographic conditions. The percentage degradation was calculated by comparing the stressed samples with the unstressed standard solution.[17],[21]

2.10 Statistical Analysis

All analytical experiments were carried out in triplicate unless otherwise specified. The results were expressed as mean ± standard deviation (SD). Linearity was evaluated by least-squares linear regression analysis, and precision was assessed using the percentage relative standard deviation (%RSD). Statistical evaluation was performed using the chromatographic software integrated with the HPLC system.

III. Results And Discussion

The primary objective of this investigation was to develop a rapid, sensitive, economical, and stability-indicating RP-HPLC method for the quantitative estimation of lasmiditan in bulk drug and pharmaceutical dosage forms. Various chromatographic variables, including stationary phase, mobile phase composition, flow rate, column temperature, and detection wavelength, were systematically optimized to achieve satisfactory chromatographic performance. The optimized analytical conditions produced a well-resolved, symmetrical peak with excellent reproducibility and adequate separation from degradation products, confirming the suitability of the developed method for routine pharmaceutical analysis. The validation results obtained according to ICH Q2(R1) demonstrated that the proposed analytical procedure fulfilled all predefined acceptance criteria for pharmaceutical quality-control applications.[17],[21]

3.1 Method Development and Optimization

Different chromatographic conditions were investigated to obtain optimum separation of lasmiditan with satisfactory peak symmetry, acceptable retention time, and high column efficiency. Various combinations of aqueous and organic mobile phases were evaluated using different chromatographic parameters. Among the investigated conditions, a mobile phase consisting of 0.1% perchloric acid and acetonitrile (58:42, v/v) provided the most satisfactory chromatographic performance.

The optimized method produced a sharp, symmetrical, and well-resolved lasmiditan peak with a retention time of approximately 2.59 min. The selected chromatographic conditions also resulted in excellent peak shape, adequate theoretical plates, and minimal baseline interference, indicating suitability for routine pharmaceutical analysis.

3.2 System Suitability

System suitability testing was performed by six replicate injections of the standard solution under optimized chromatographic conditions.

The developed chromatographic method exhibited a mean retention time of 2.59 min with a mean peak area of 698326. The percentage relative standard deviation (%RSD) of peak area was 0.04%, demonstrating excellent injection repeatability. The theoretical plate count ranged from 8524 to 8557, while the asymmetry factor varied between 1.14 and 1.18. Peak purity analysis indicated a value of 1.00, confirming chromatographic homogeneity of the analyte peak. These results satisfied the predefined system suitability acceptance criteria.

TABLE 3: System Suitability of Lasmiditan

Parameter	Result
Retention time (min)	2.59
Mean peak area	698326
%RSD	0.04
Theoretical plates	8524–8557
Asymmetry factor	1.14–1.18
Peak purity	1.00

3.3 Specificity

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Specificity was evaluated by injecting blank, placebo, standard, and sample solutions under optimized chromatographic conditions.

No interfering peaks were observed at the retention time corresponding to lasmiditan in the blank or placebo chromatograms. The standard and sample chromatograms produced identical retention times without evidence of co-eluting peaks. Peak purity analysis further confirmed the absence of chromatographic interference, demonstrating that the developed RP-HPLC method was specific for quantitative estimation of lasmiditan.

3.4 Linearity

Linearity of the developed RP-HPLC method was evaluated over the concentration range of 8–12 µg/mL. A linear relationship was observed between peak area and analyte concentration throughout the investigated range.

The calibration curve demonstrated excellent linearity with the regression equation:

$y = 70354.7x – 471.2$

and a correlation coefficient (R^2) of 0.99997, indicating excellent proportionality between concentration and detector response.

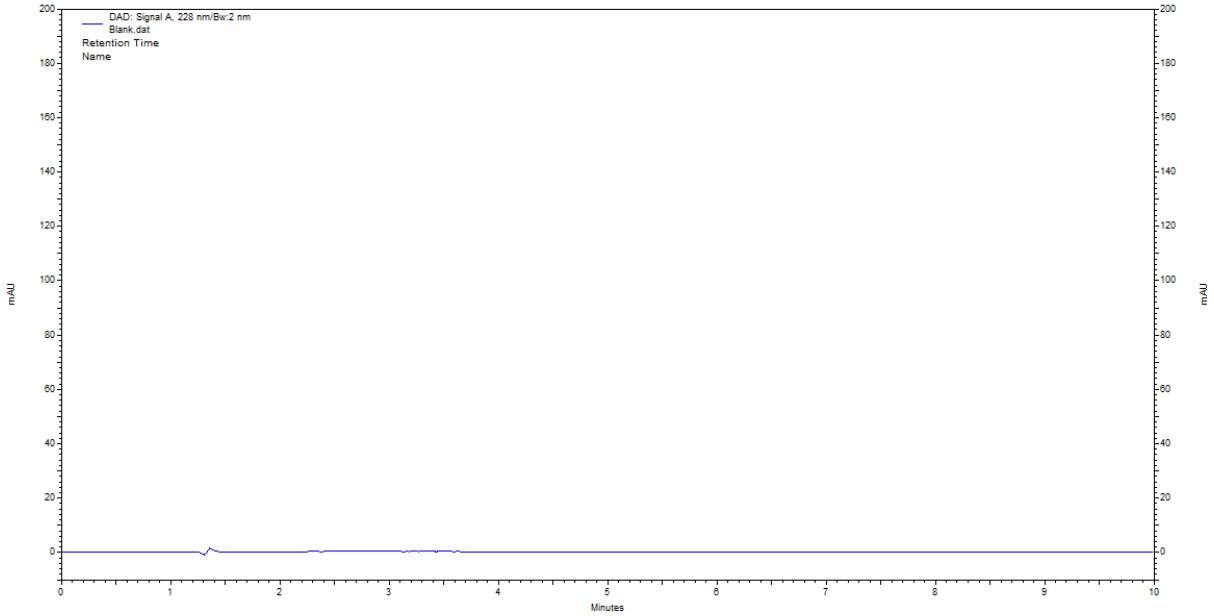

Figure 3: Diluent Chromatogram

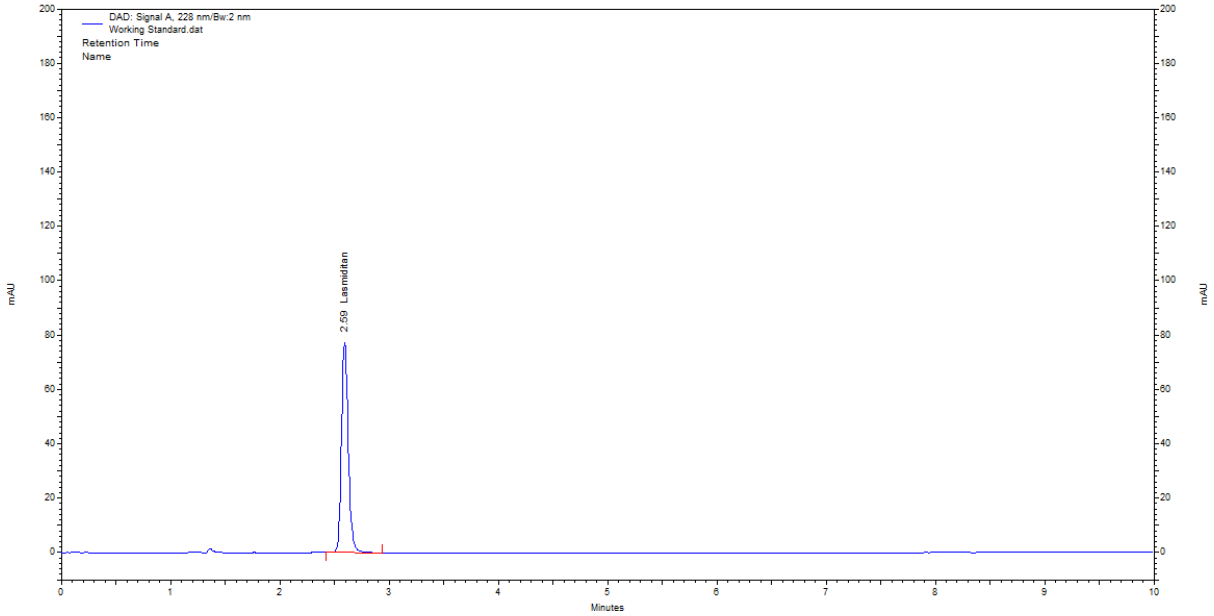

Figure 4: Working Standard Chromatogram

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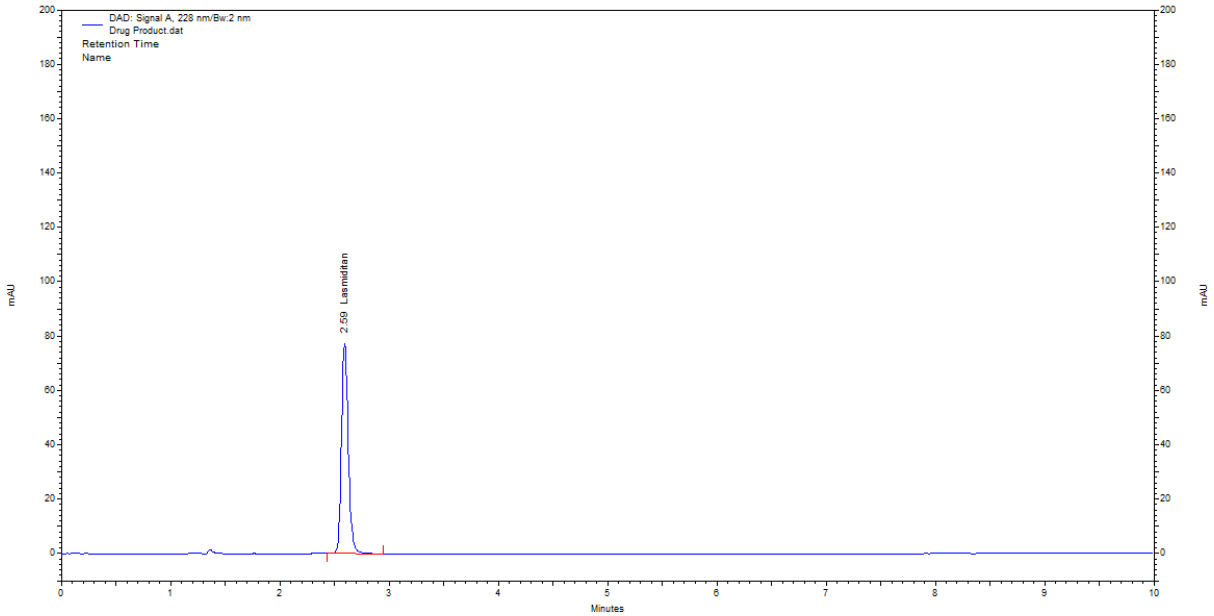

Figure 5: Drug Product Chromatogram

TABLE 4: Linearity for Lasmiditan

Lasmiditan		
% Level	Conc (ug/ml)	Peak Area
80	8	562676
90	9	631984
100	10	703791
110	11	772973
120	12	843955

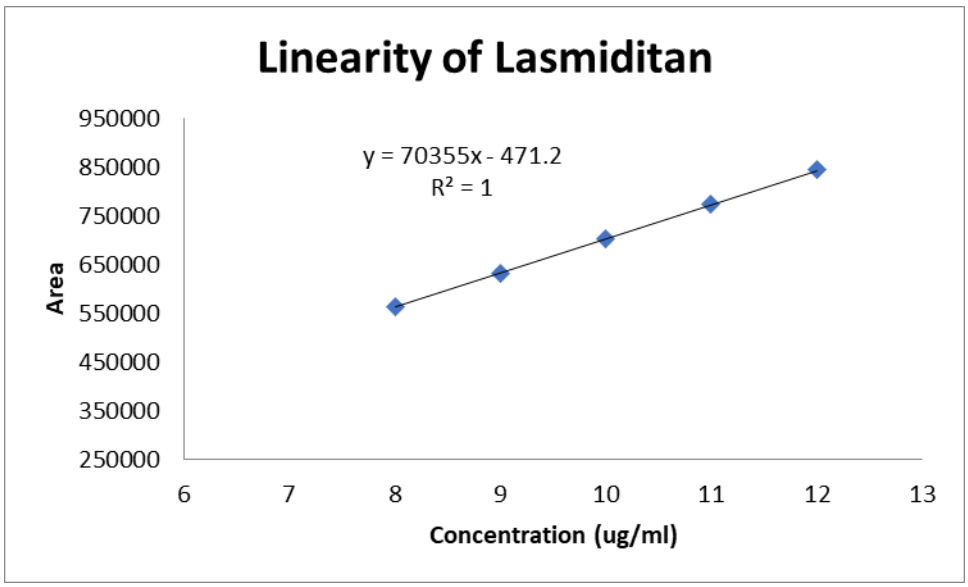

Figure 6: Linearity Graph for Lasmiditan

Linearity Trials:

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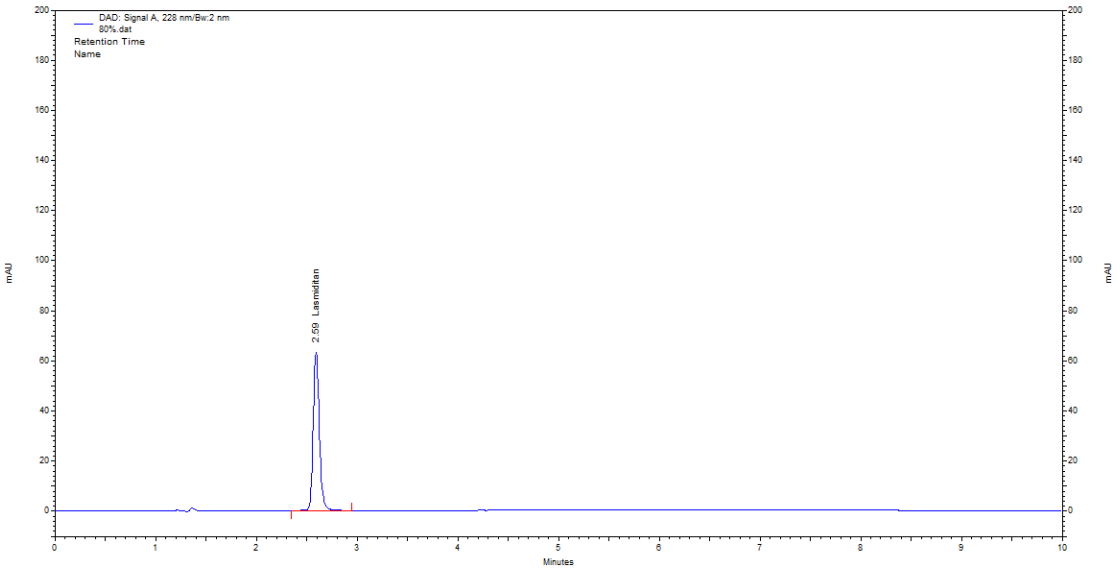

Figure 7: Linearity at 80% concentration

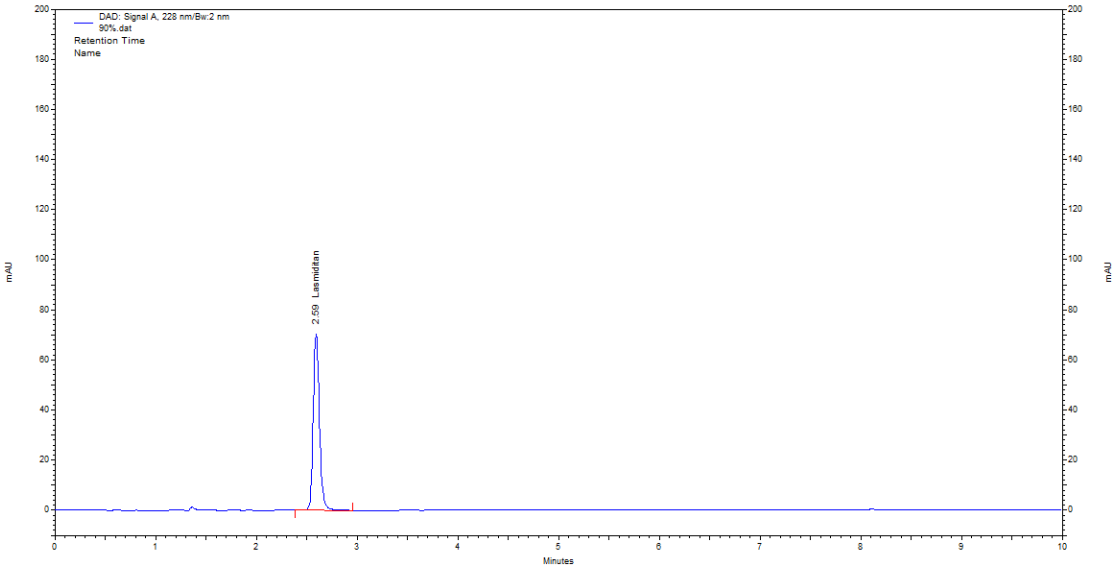

Figure 8: Linearity at 90% concentration

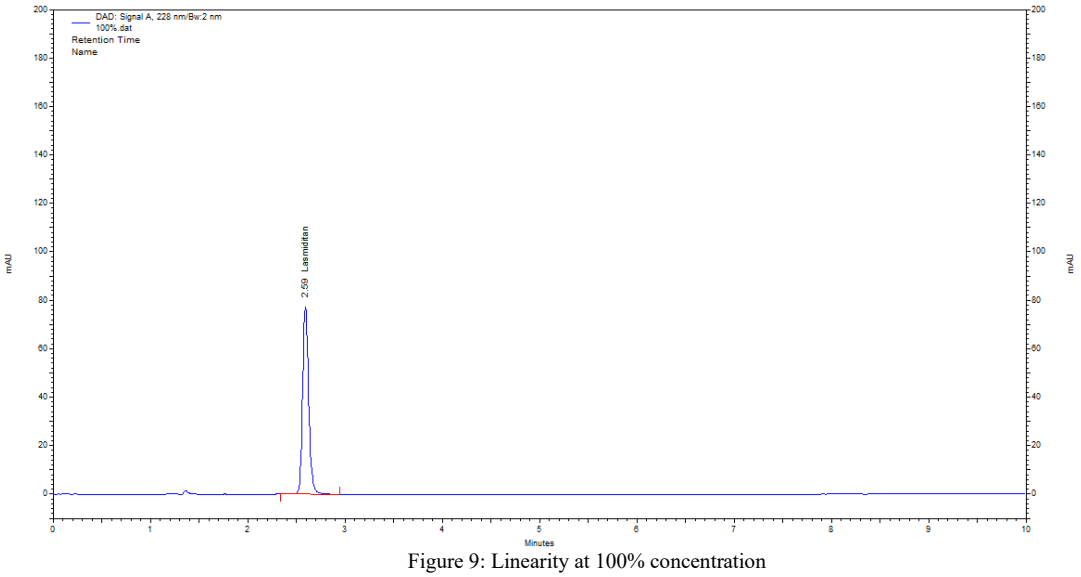

Figure 9: Linearity at 100% concentration

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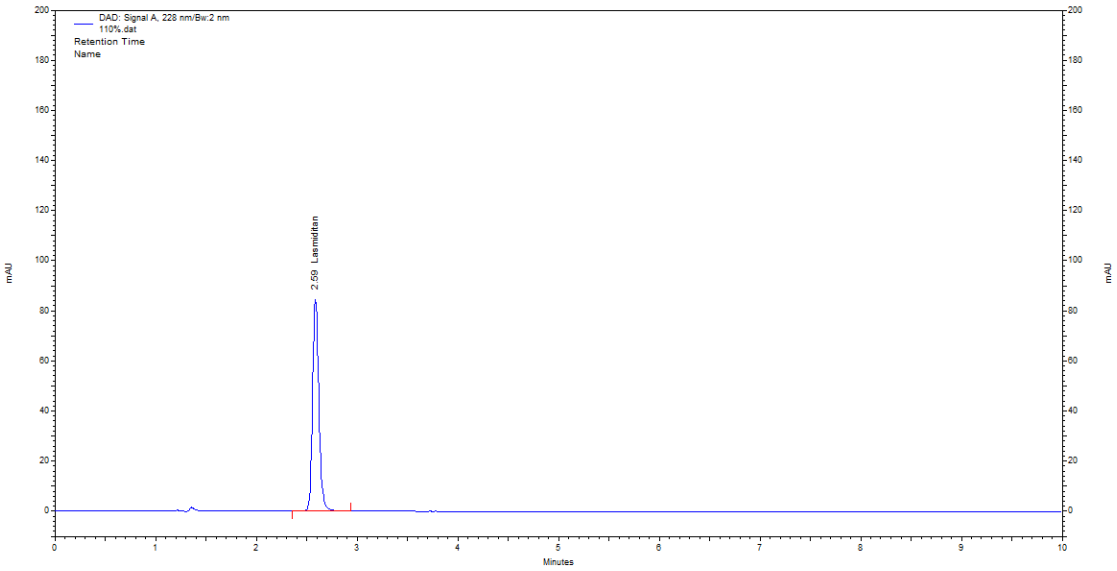

Figure 10: Linearity at 110% concentration

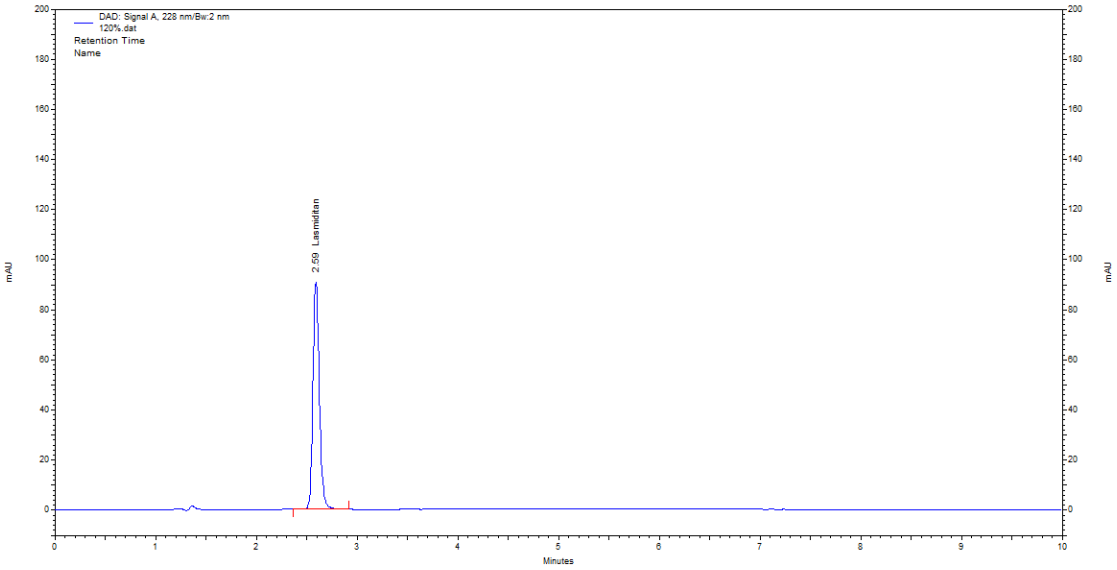

Figure 11: Linearity at 120% concentration

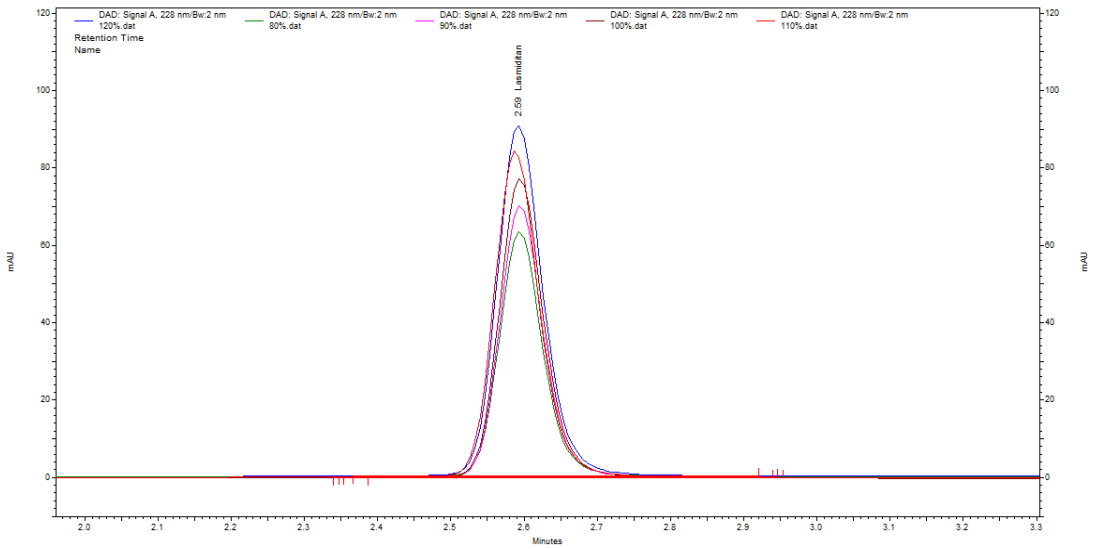

Figure 12: Linearity Overlay

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3.5 Accuracy

Accuracy was determined by the recovery method at 50%, 100%, and 150% concentration levels.

The percentage recovery values obtained at all concentration levels were within the acceptable range recommended by ICH guidelines. The percentage relative standard deviation remained below 2.0%, confirming satisfactory analytical accuracy.

TABLE 5: Accuracy data for Lasmiditan

Lasmiditan			
Std wt. (mg)	% Purity	Std Stock Conc. (ug/ml)	Working Std Area
10	99.9	99.9	700732

Sample ID	Reps	Spiked Conc. (ug/ml)	Peak Area	Amount Recovered (ug/ml)	% Recovery	AVG	STDEV	% RSD
80%	Rep 1	7.99	562676	8.02	100.37	100.36	0.011161	0.01
	Rep 2	7.99	562557	8.02	100.35			
	Rep 3	7.99	562583	8.02	100.36			
100%	Rep 1	9.99	703791	10.03	100.44	100.42	0.017331	0.02
	Rep 2	9.99	703652	10.03	100.42			
	Rep 3	9.99	703549	10.03	100.40			
120%	Rep 1	11.99	843955	12.03	100.37	100.35	0.016677	0.02
	Rep 2	11.99	843745	12.03	100.34			
	Rep 3	11.99	843689	12.03	100.33			

Accuracy Trials:

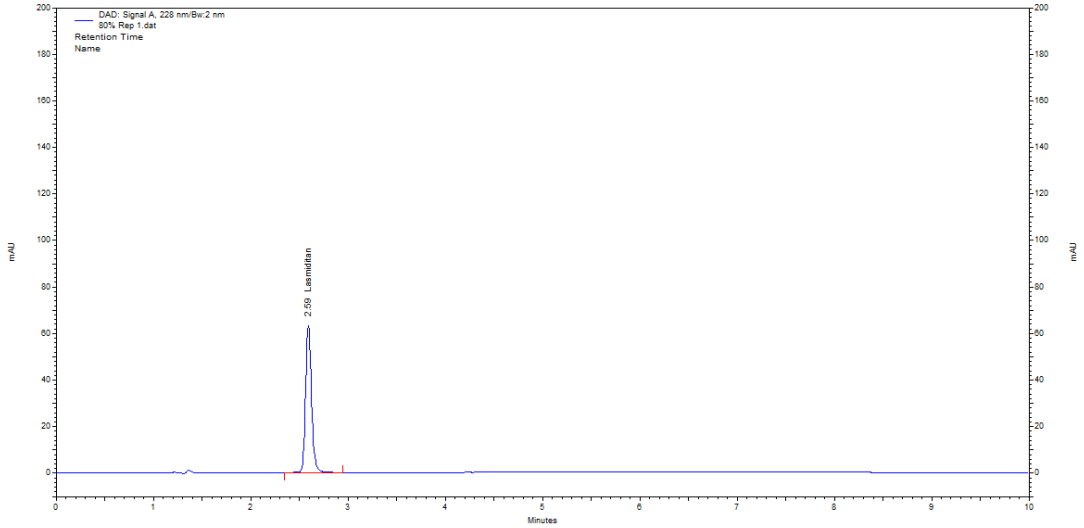

Figure 13: Accuracy 80% Rep 1

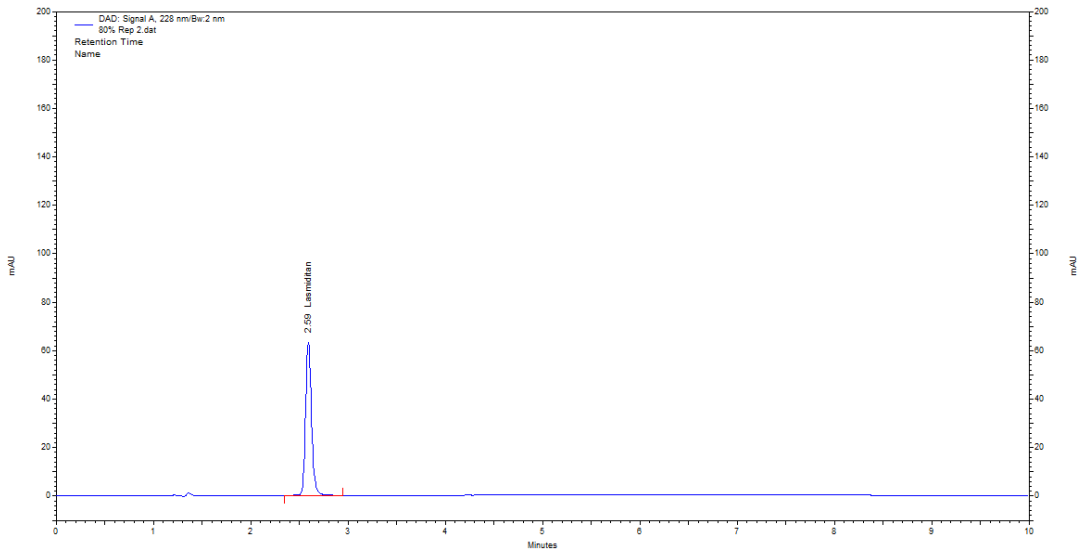

Figure 14: Accuracy 80% Rep 2

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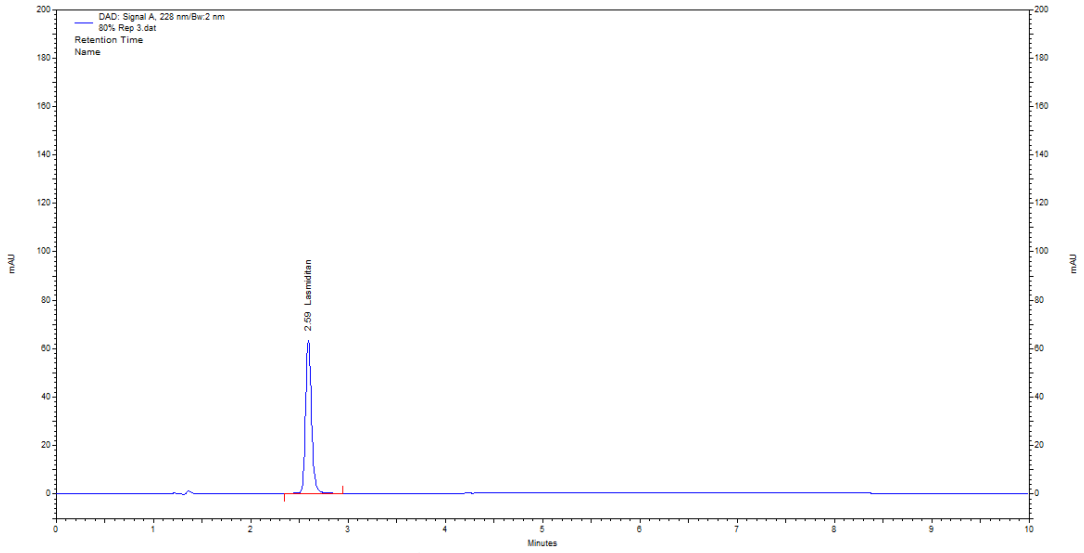

Figure 15: Accuracy 80% Rep 3

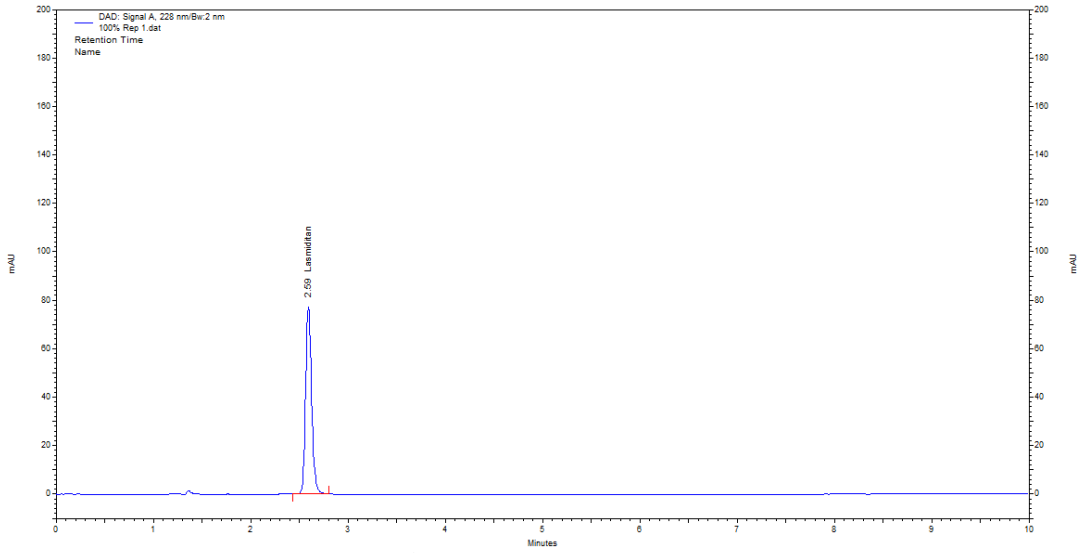

Figure 16: Accuracy 100% Rep 1

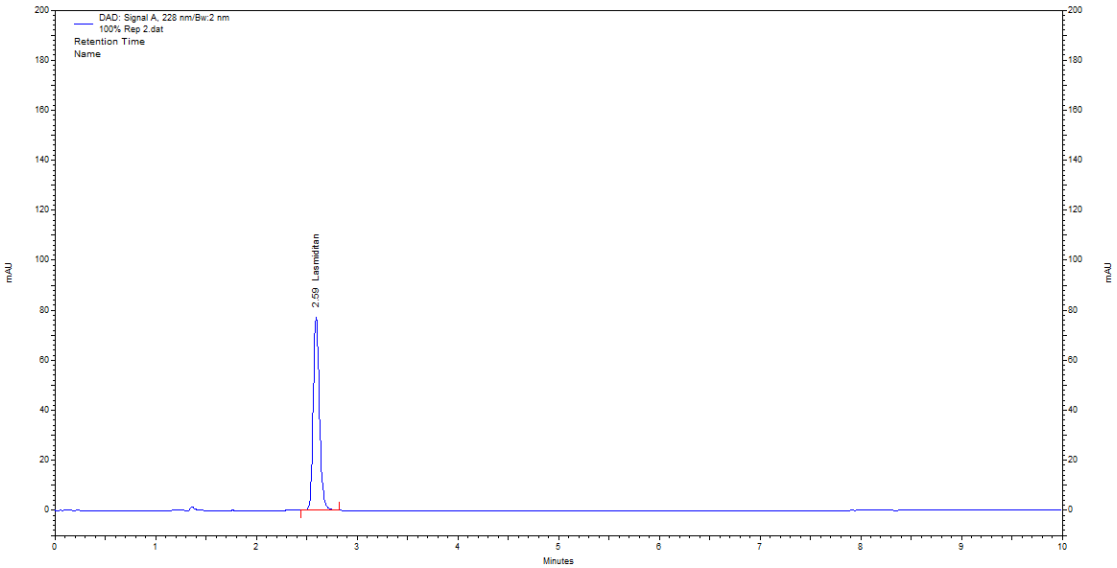

Figure 17: Accuracy 100% Rep 2

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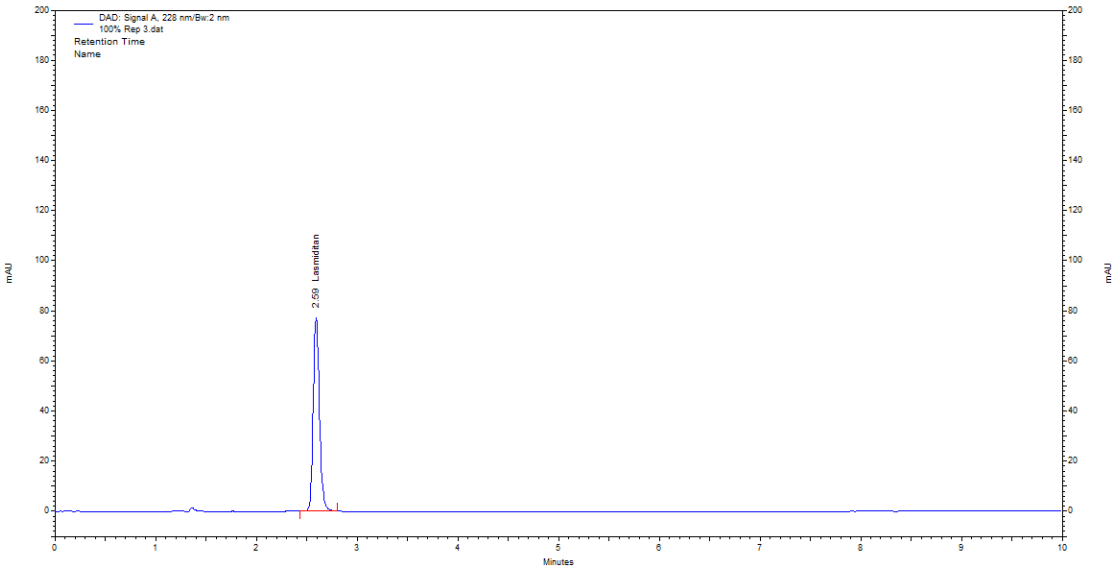

Figure 18: Accuracy 100% Rep 3

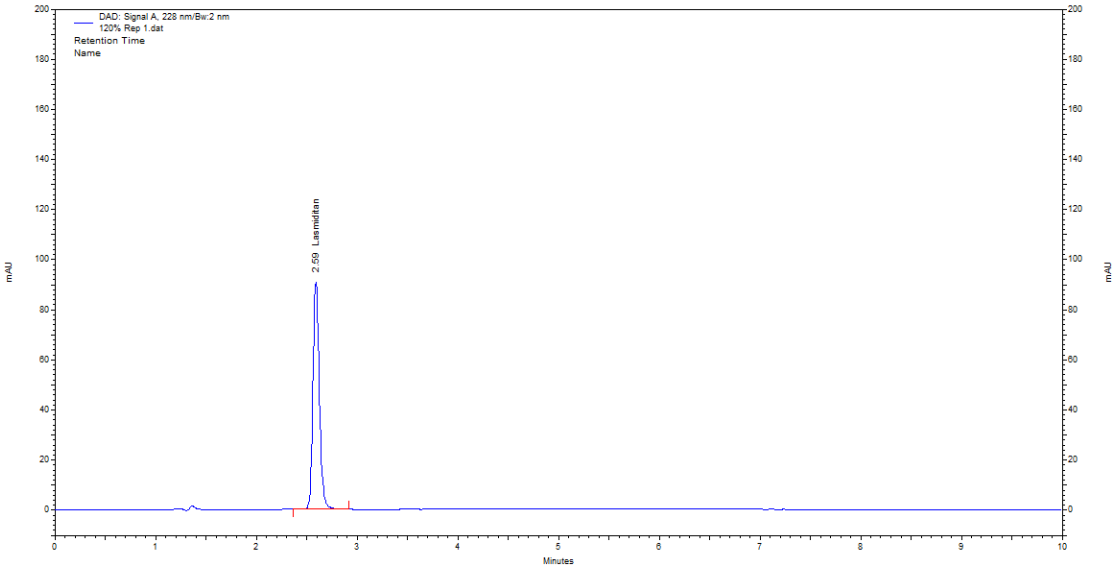

Figure 19: Accuracy 120% Rep 1

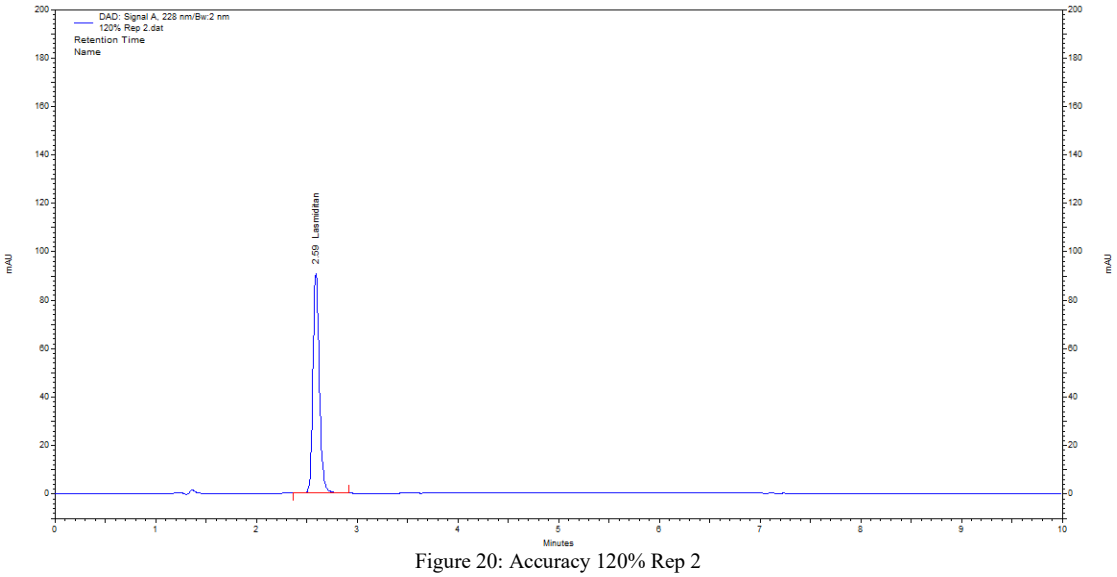

Figure 20: Accuracy 120% Rep 2

Sajid Jahangir Sayyad and Allabaksha Shaikh, "Development and Validation of a Stability-Indicating RP-HPLC Method for Quantitative Estimation of Lasmiditan in Bulk Drug and Pharmaceutical Dosage Forms," *International Research Journal of Pharmacy and Medical Sciences (IRJPMS)*, Volume 9, Issue 5, pp. 13-36, 2026.

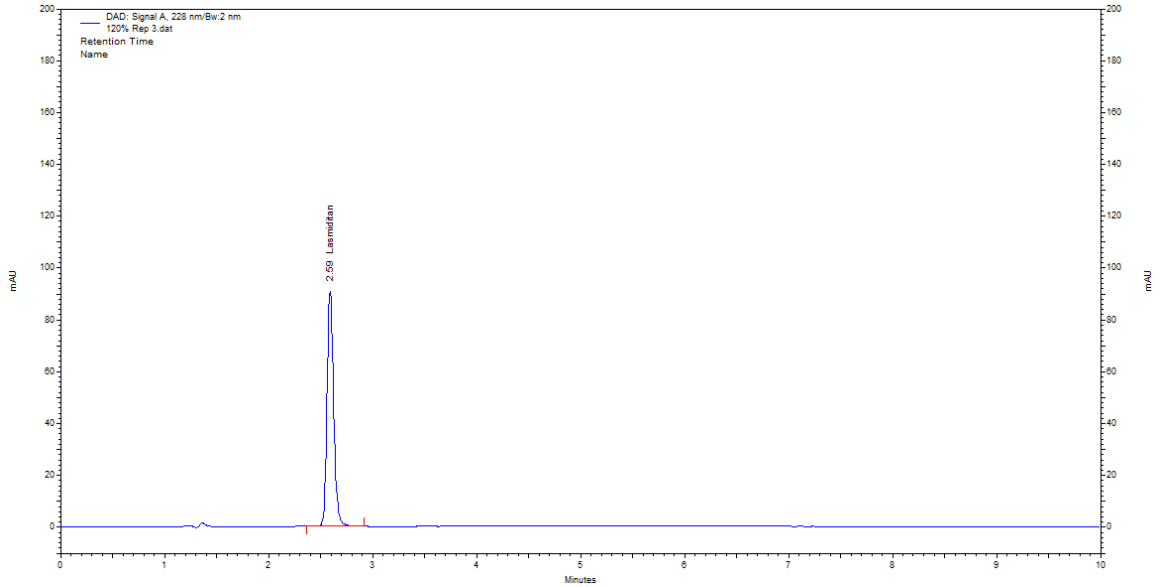

Figure 21: Accuracy 120% Rep 3

3.6 Precision

3.6.1 Repeatability

Repeatability was evaluated by six replicate injections of the standard solution.

The developed method demonstrated excellent repeatability with a mean retention time of 2.59 min, mean peak area of 698326, and %RSD of 0.04%. Theoretical plate count and asymmetry factor remained consistent throughout the analysis.

TABLE 6: Repeatability data of Lasmiditan

Lasmiditan					
Sample ID	Peak Area	RT	TP	Asymmetry	Peak Purity
100% Rep 1	698049	2.59	8524	1.18	1.00
100% Rep 2	698510	2.59	8533	1.15	1.00
100% Rep 3	698049	2.59	8542	1.17	1.00
100% Rep 4	698279	2.59	8557	1.14	1.00
100% Rep 5	698316	2.59	8552	1.16	1.00
100% Rep 6	698752	2.59	8544	1.14	1.00
AVG	698326	2.59			
STDEV	272.433	0			
% RSD	0.04	0.00			

Repeatability Trials:

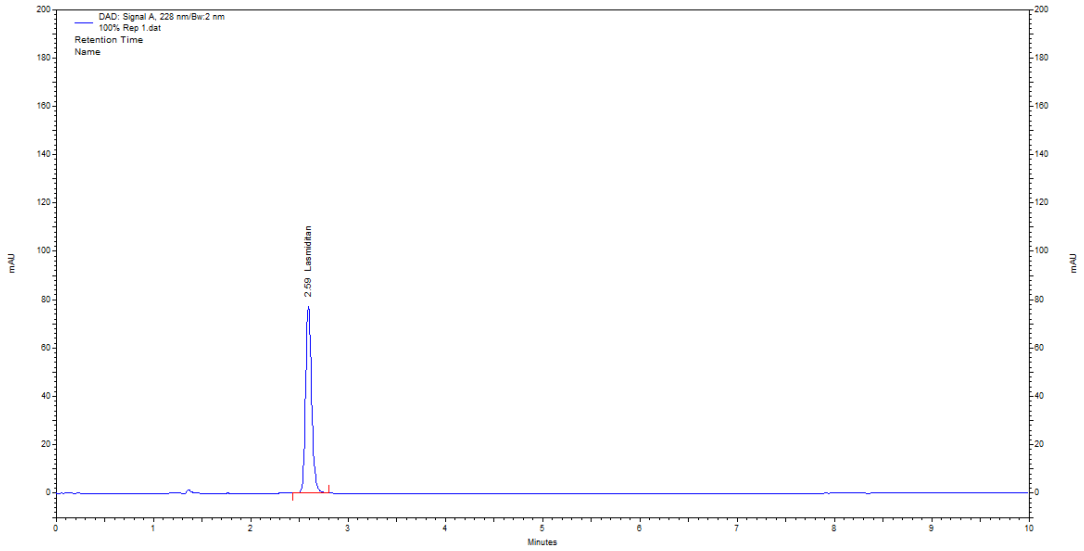

Figure 22: Repeatability Rep 1

Sajid Jahangir Sayyad and Allabaksha Shaikh, “Development and Validation of a Stability-Indicating RP-HPLC Method for Quantitative Estimation of Lasmiditan in Bulk Drug and Pharmaceutical Dosage Forms,” *International Research Journal of Pharmacy and Medical Sciences (IRJPMS)*, Volume 9, Issue 5, pp. 13-36, 2026.

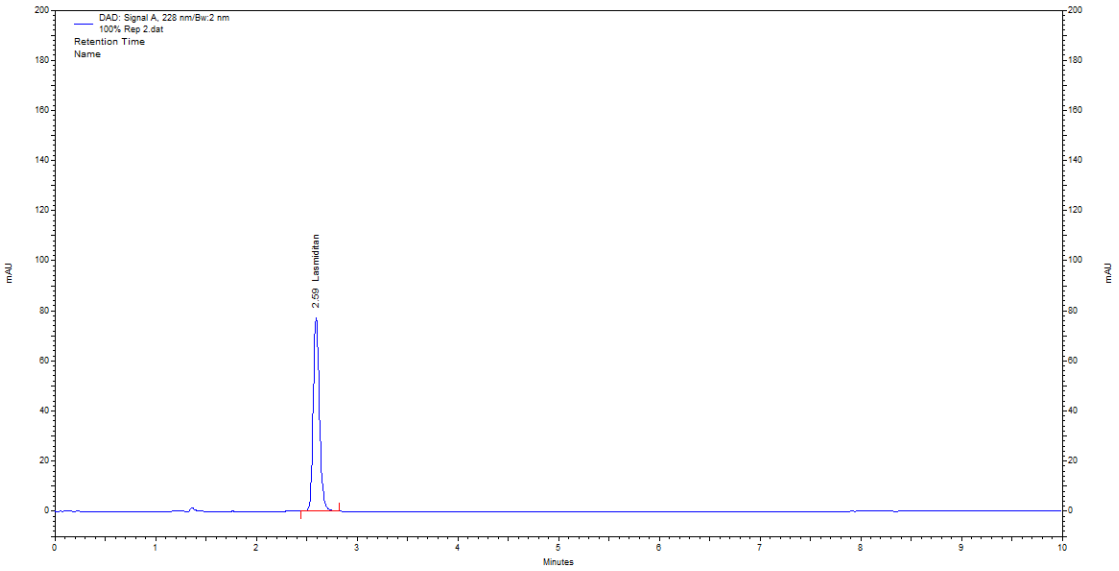

Figure 23: Repeatability Rep 2

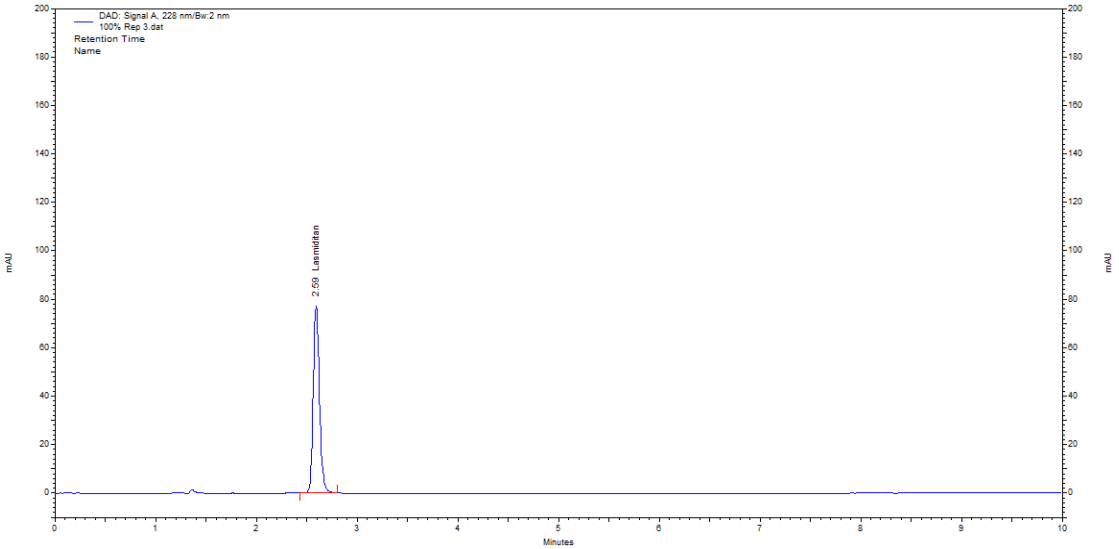

Figure 24: Repeatability Rep 3

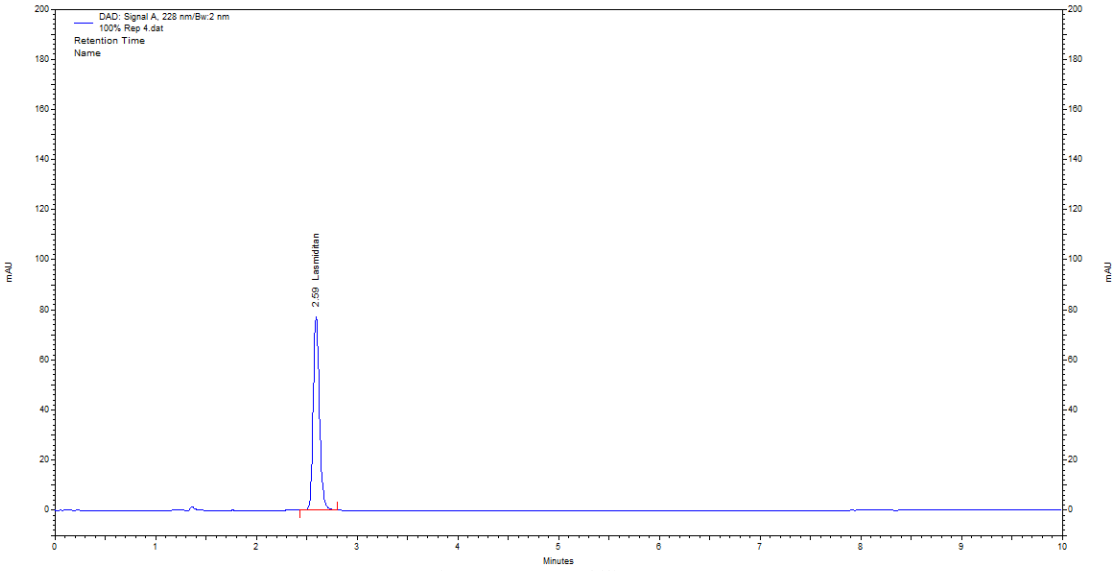

Figure 25: Repeatability Rep 4

Sajid Jahangir Sayyad and Allabaksha Shaikh, “Development and Validation of a Stability-Indicating RP-HPLC Method for Quantitative Estimation of Lasmiditan in Bulk Drug and Pharmaceutical Dosage Forms,” *International Research Journal of Pharmacy and Medical Sciences (IRJPMS)*, Volume 9, Issue 5, pp. 13-36, 2026.

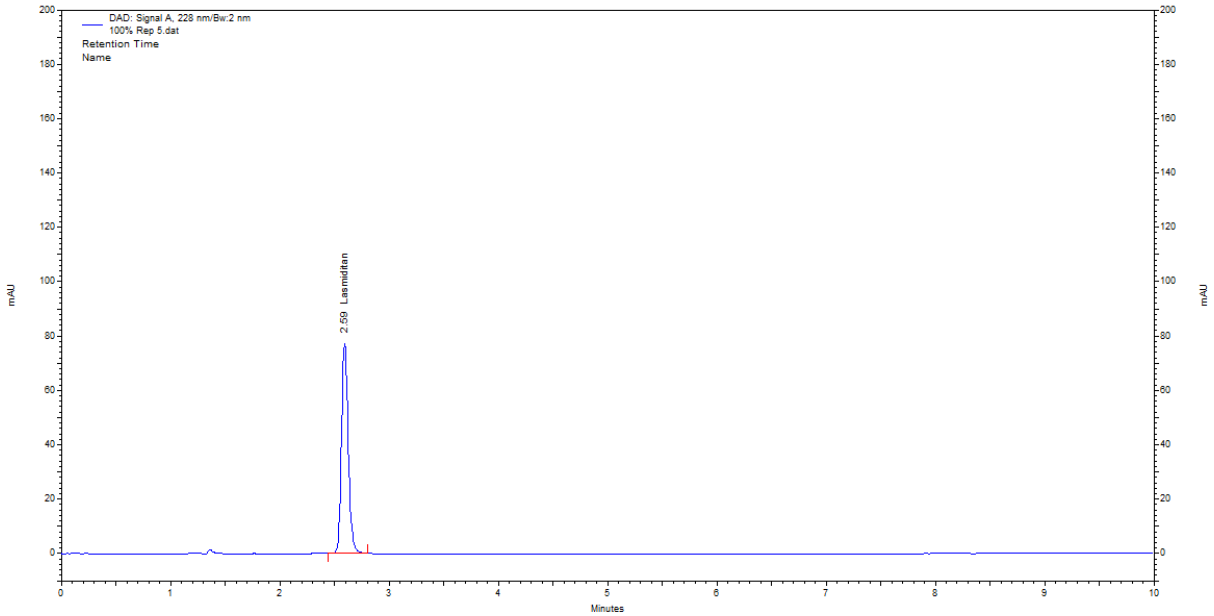

Figure 26: Repeatability Rep 5

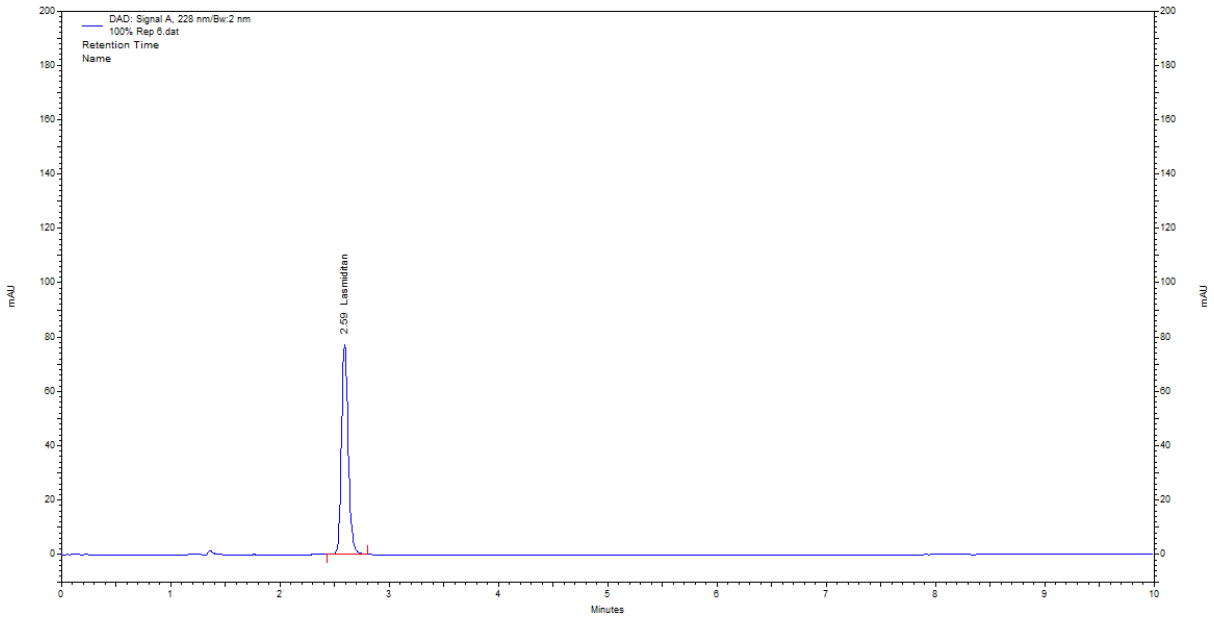

Figure 27: Repeatability Rep 6

3.6.2 Intermediate Precision

Intermediate precision was assessed by repeating the analysis on different days using the same chromatographic conditions.

The obtained %RSD values were within the acceptable limit (<2.0%), indicating satisfactory reproducibility of the developed analytical method.

3.7 Limit of Detection and Limit of Quantification

LOD and LOQ were determined according to ICH recommendations using the standard deviation of the response and the slope of the calibration curve.

The calculated LOD and LOQ values demonstrated adequate analytical sensitivity for quantitative estimation of lasmiditan.

TABLE 7: LOD and LOQ of Lasmiditan

LOD & LOQ of Lasmiditan	LOD	0.10	ug/ml
	LOQ	0.31	ug/ml

3.8 Robustness

Sajid Jahangir Sayyad and Allabaksha Shaikh, "Development and Validation of a Stability-Indicating RP-HPLC Method for Quantitative Estimation of Lasmiditan in Bulk Drug and Pharmaceutical Dosage Forms," *International Research Journal of Pharmacy and Medical Sciences (IRJPMS)*, Volume 9, Issue 5, pp. 13-36, 2026.

Robustness was evaluated by introducing deliberate variations in chromatographic conditions, including changes in flow rate, mobile-phase composition, and detection wavelength.

No significant changes in chromatographic performance were observed following these deliberate modifications. The %RSD values remained within acceptable limits, demonstrating that the developed method was robust and unaffected by small variations in analytical conditions.

TABLE 8: Robustness study for Lasmiditan – Variation on Column Oven temperature

Variation in Column temperature				
Condition	Sample ID	Retention Time	Peak Area	% Assay
28C	WS	2.59	700657	-
	DP	2.59	698745	99.73
30C	WS	2.59	700732	-
	DP	2.59	698430	99.67
32C	WS	2.59	700349	-
	DP	2.59	697423	99.58
AVG		2.59	699389	99.66
SD		0.00	1380.77	0.07
% RSD		0.00	0.20	0.07

TABLE 9: Robustness study for Lasmiditan – Variation on Wavelength

Variation in wavelength				
Condition	Sample ID	Retention Time	Peak Area	% Assay
230 nm	WS	2.59	700644	-
	DP	2.59	698546	99.70
228 nm	WS	2.59	700732	-
	DP	2.59	698430	99.67
226 nm	WS	2.59	700722	-
	DP	2.59	697745	99.58
AVG		2.59	699470	99.65
SD		0.00	1374.73	0.07
% RSD		0.00	0.20	0.07

Robustness Trials:

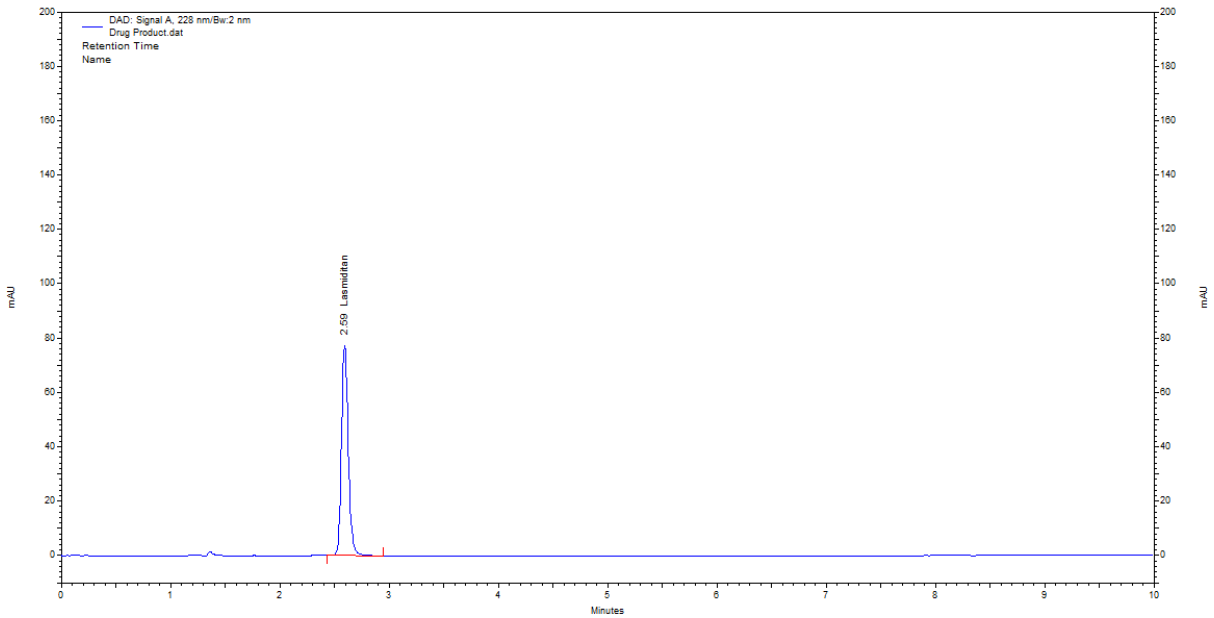

Figure 28: Robustness Normal DP

Sajid Jahangir Sayyad and Allabaksha Shaikh, "Development and Validation of a Stability-Indicating RP-HPLC Method for Quantitative Estimation of Lasmiditan in Bulk Drug and Pharmaceutical Dosage Forms," *International Research Journal of Pharmacy and Medical Sciences (IRJPMS)*, Volume 9, Issue 5, pp. 13-36, 2026.

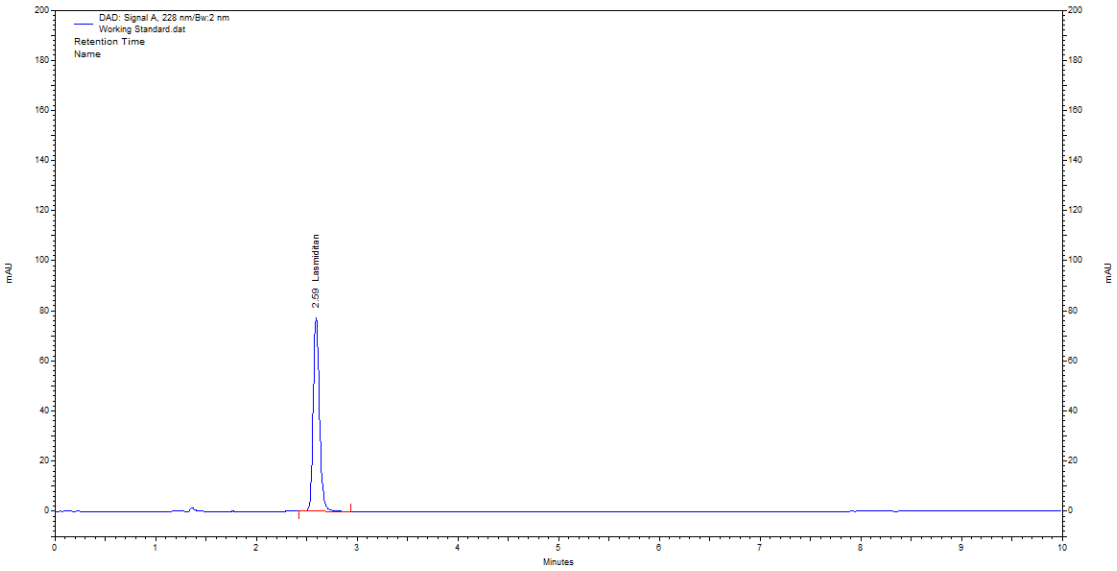

Figure 29: Robustness Normal WS

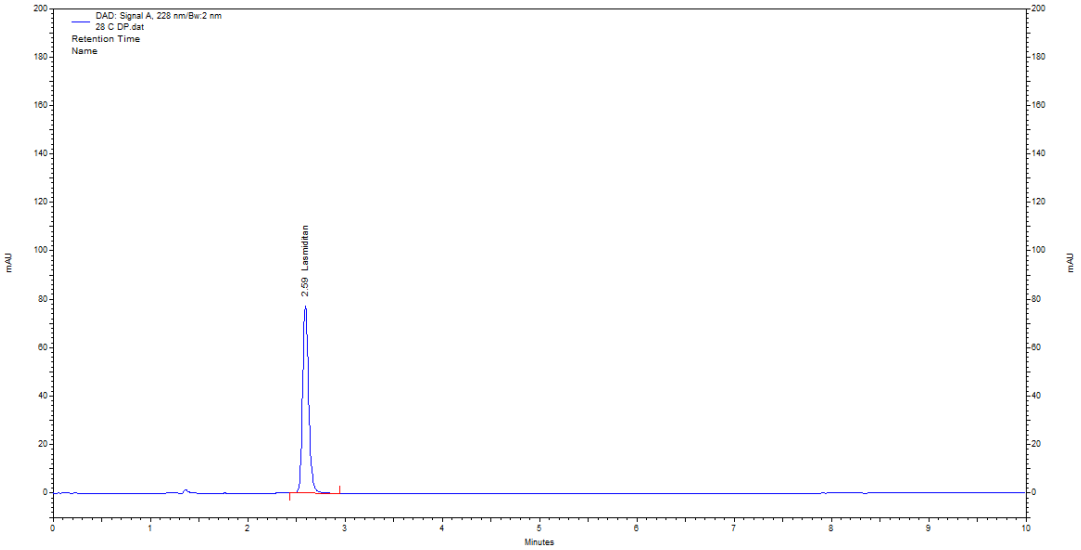

Figure 30: Robustness 28˚C DP

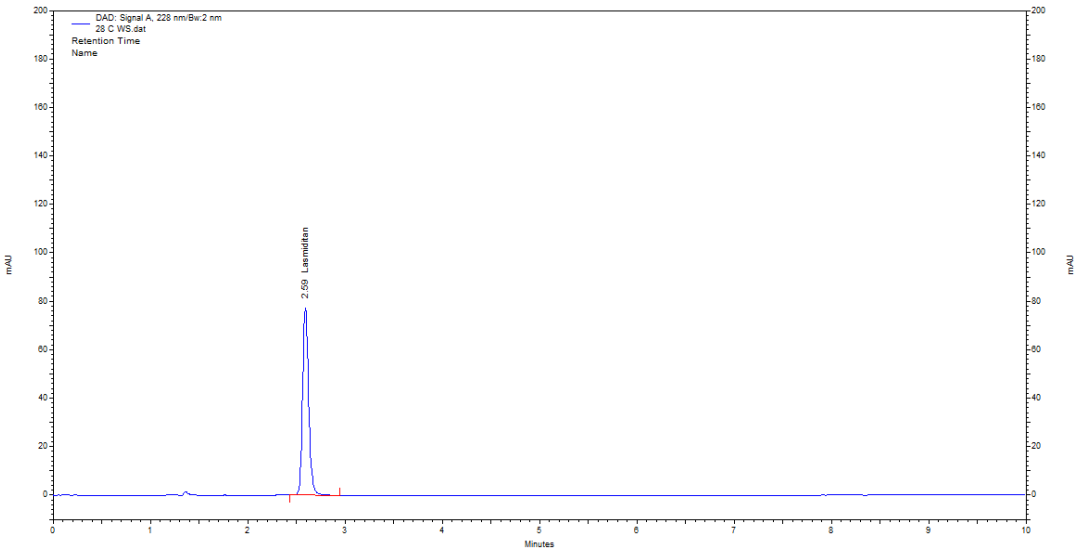

Figure 31: Robustness 28˚C WS

Sajid Jahangir Sayyad and Allabaksha Shaikh, “Development and Validation of a Stability-Indicating RP-HPLC Method for Quantitative Estimation of Lasmiditan in Bulk Drug and Pharmaceutical Dosage Forms,” *International Research Journal of Pharmacy and Medical Sciences (IRJPMS)*, Volume 9, Issue 5, pp. 13-36, 2026.

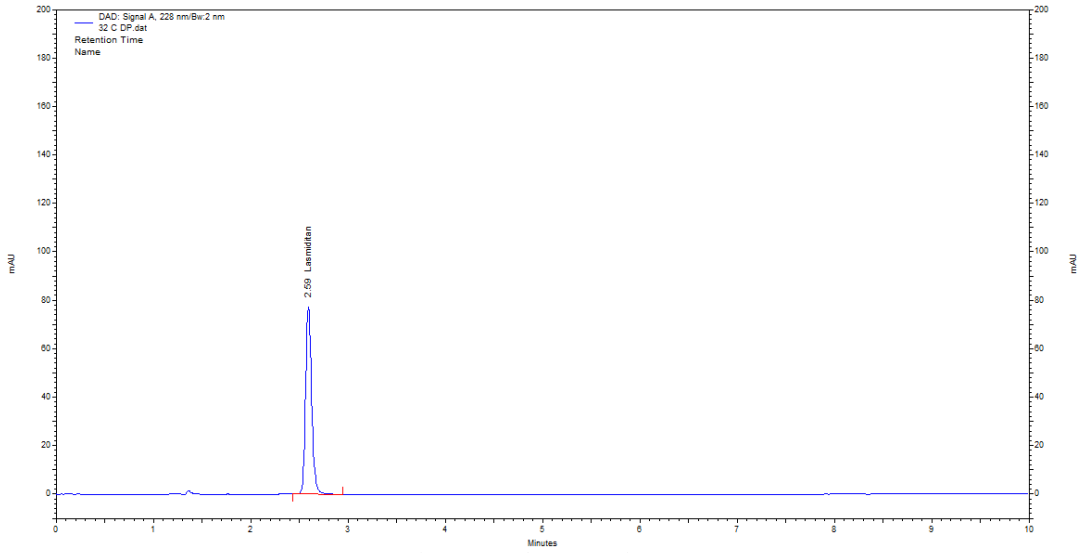

Figure 32: Robustness 32˚C DP

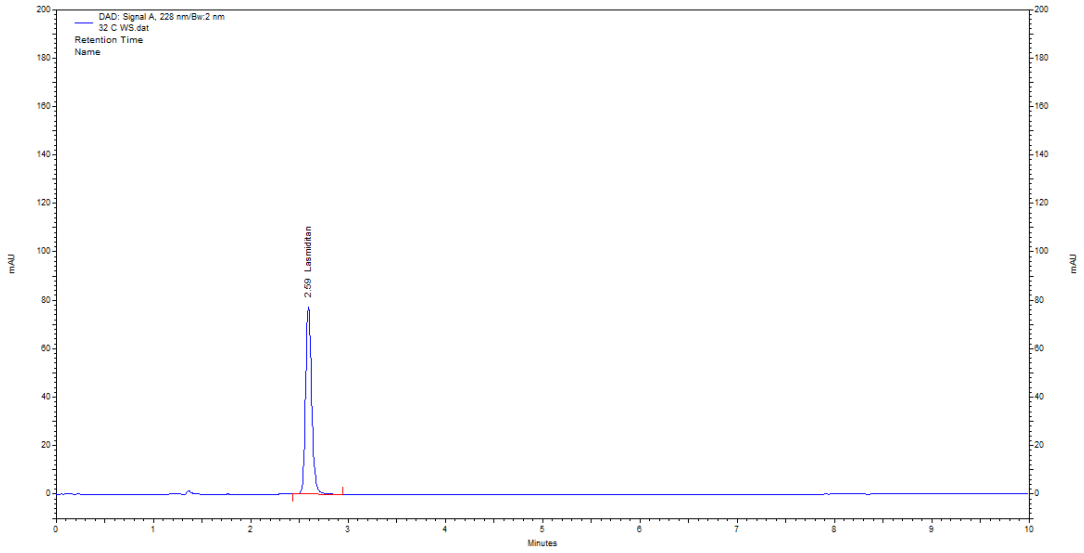

Figure 33: Robustness 32˚C WS

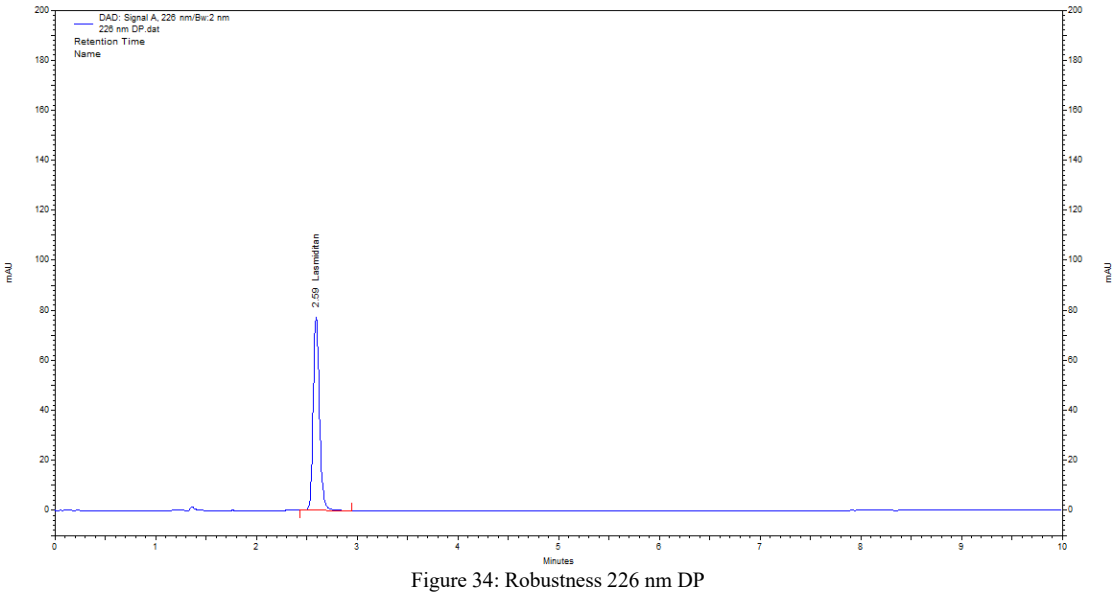

Figure 34: Robustness 226 nm DP

Sajid Jahangir Sayyad and Allabaksha Shaikh, “Development and Validation of a Stability-Indicating RP-HPLC Method for Quantitative Estimation of Lasmiditan in Bulk Drug and Pharmaceutical Dosage Forms,” *International Research Journal of Pharmacy and Medical Sciences (IRJPMS)*, Volume 9, Issue 5, pp. 13-36, 2026.

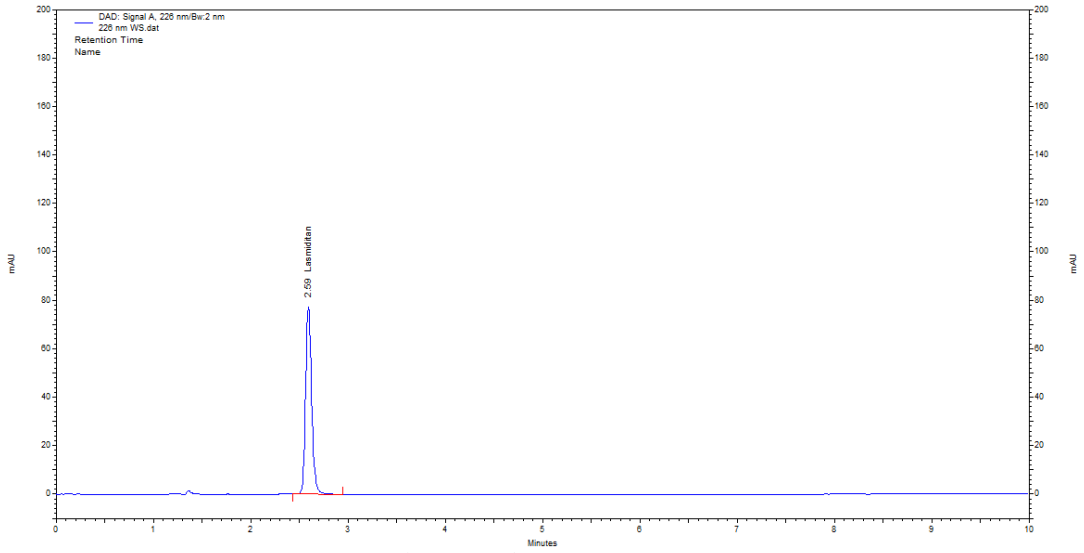

Figure 35: Robustness 226 nm WS

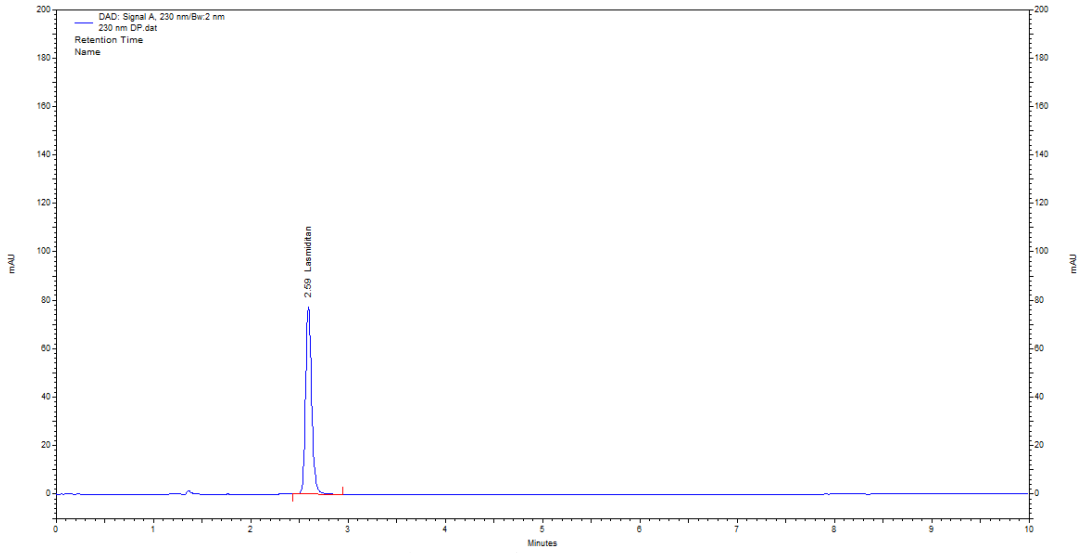

Figure 36: Robustness 230 nm DP

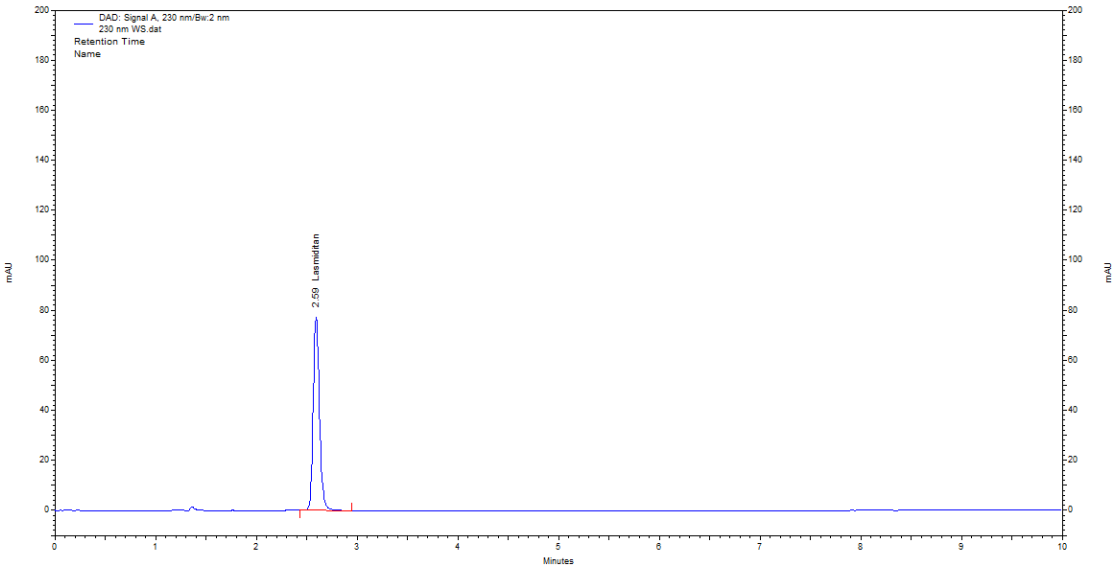

Figure 37: Robustness 230 nm WS

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3.9 Forced Degradation Studies

Forced degradation studies were performed under acidic, alkaline, oxidative, thermal, and photolytic stress conditions to evaluate the stability-indicating capability of the developed RP-HPLC method.

Lasmiditan exhibited varying degrees of degradation under the applied stress conditions. However, the analyte peak remained well resolved from all degradation products, confirming the stability-indicating nature of the developed RP-HPLC method.

TABLE 10: Force Degradation of Lasmiditan

Sample ID	Peak Area	% Assay	% Deg
Control WS	700732	100.00	-
Acid Sample	690879	98.59	1.41
Base Sample	682980	97.47	2.53
Peroxide Sample	699305	99.80	0.20
Dry heat Sample	693400	98.95	1.05
UV Sample	684379	97.67	2.33

Force Degradation Trials:

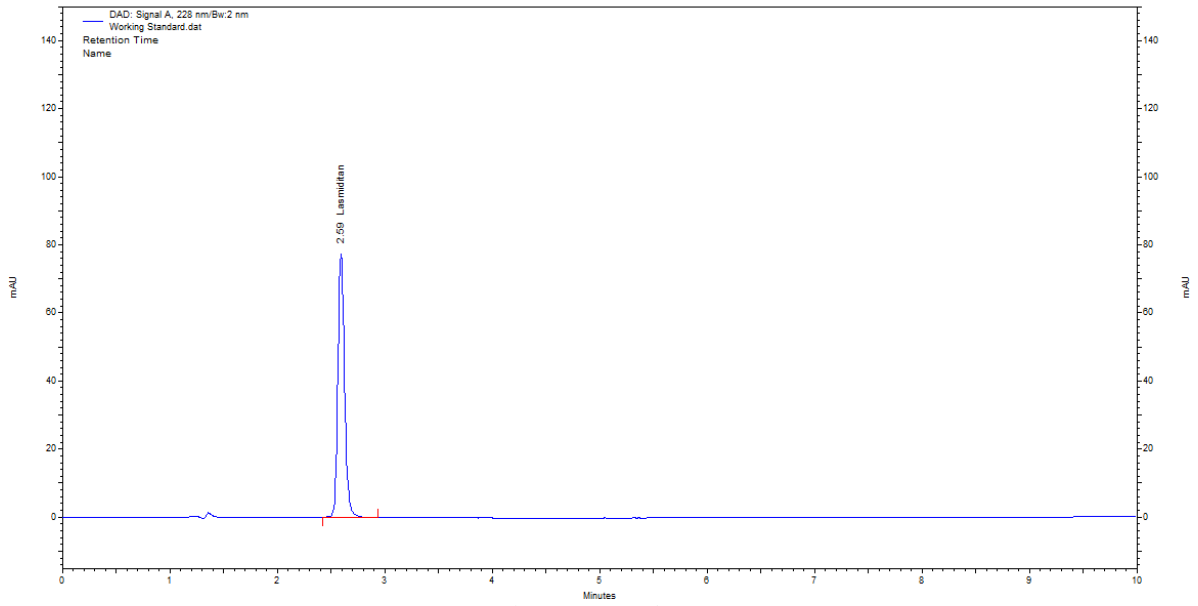

Figure 38: Control WS

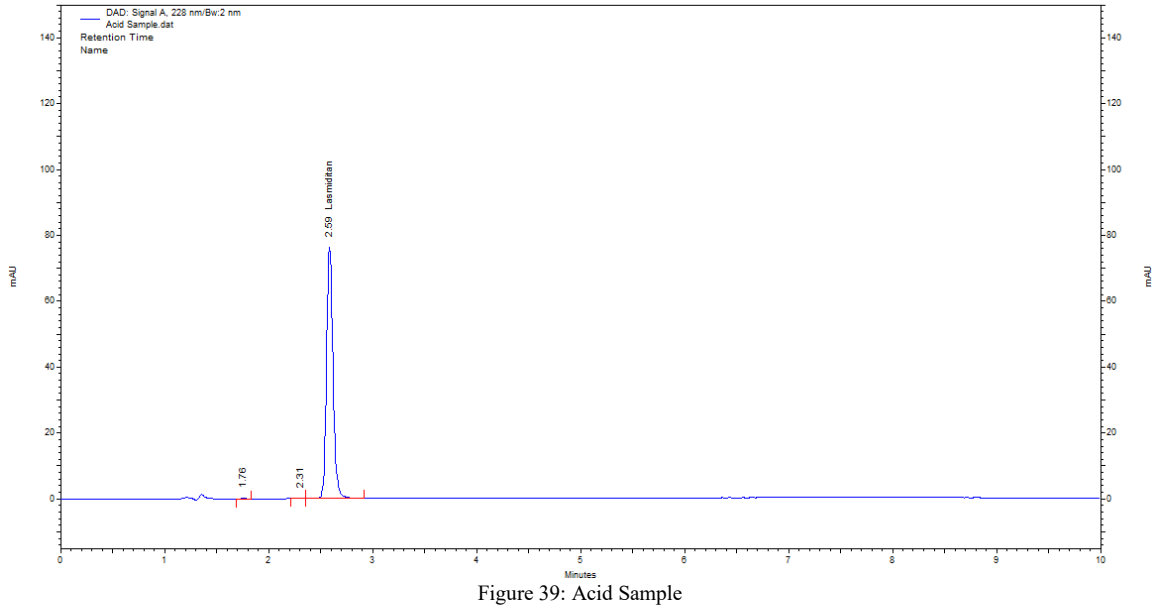

Figure 39: Acid Sample

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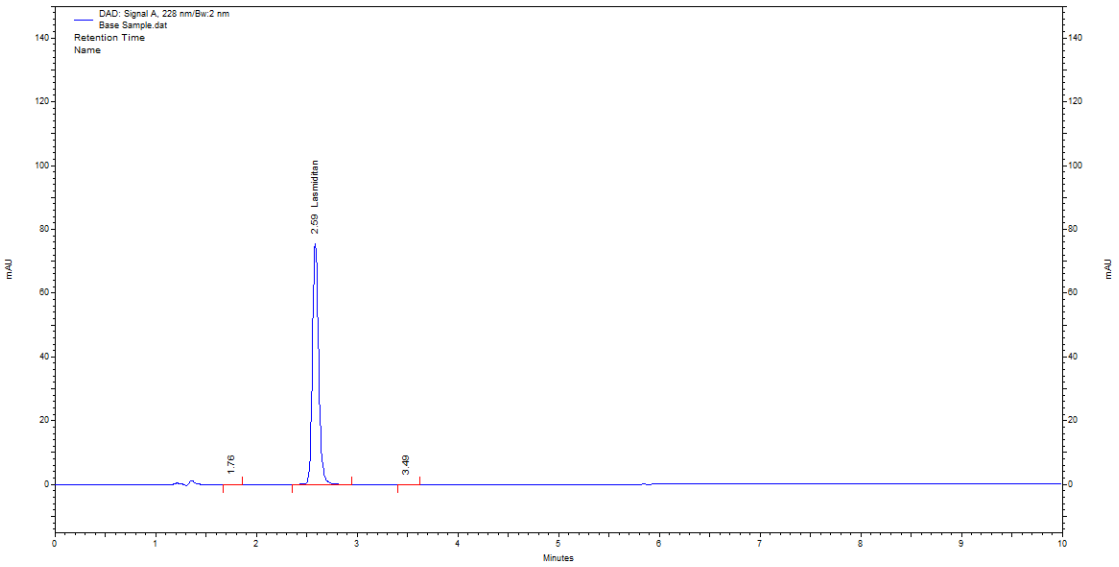

Figure 40: Base Sample

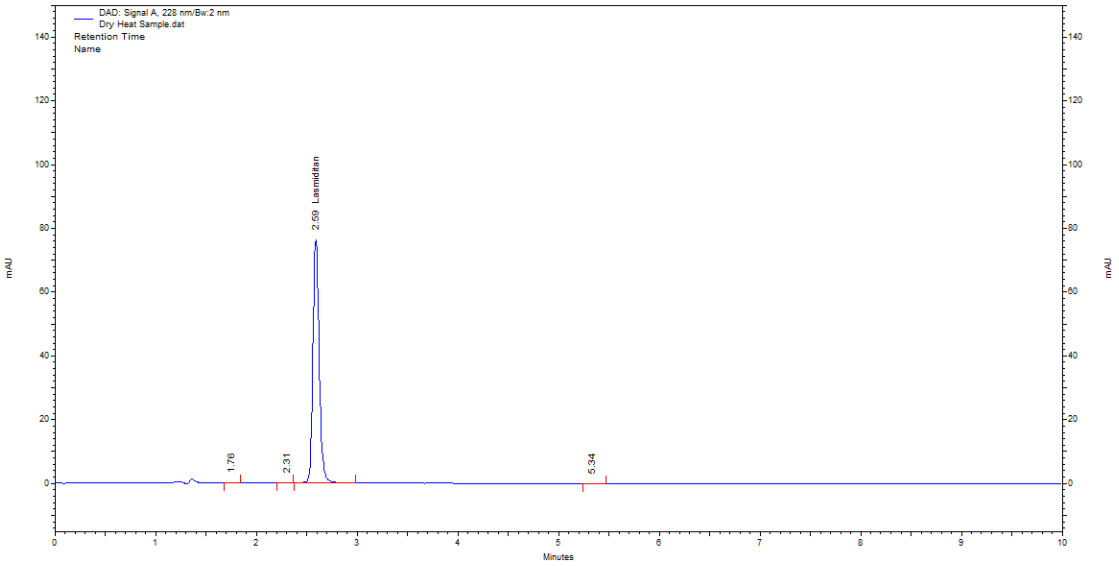

Figure 41: Dry Heat Sample

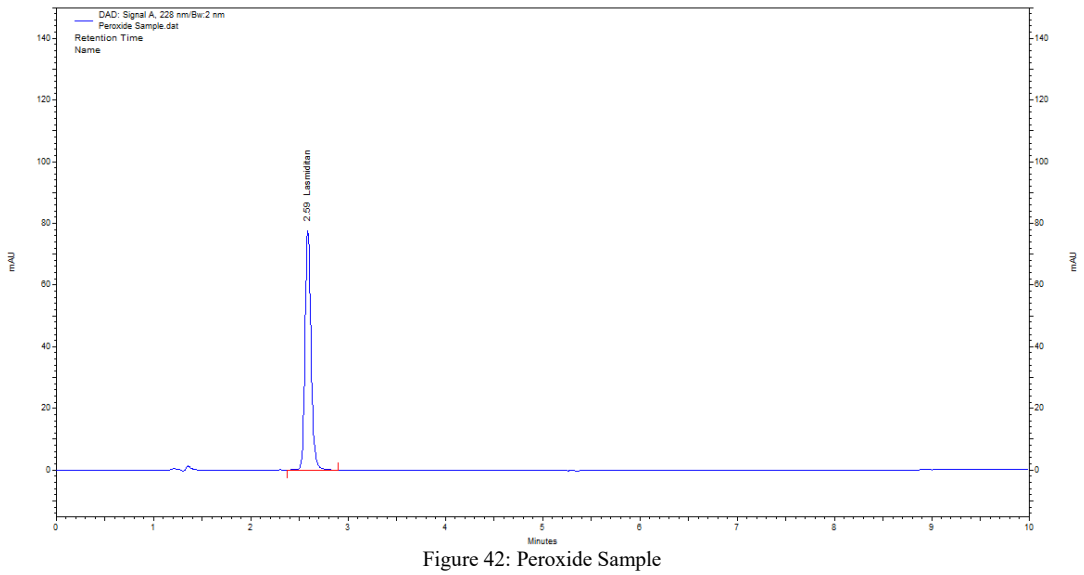

Figure 42: Peroxide Sample

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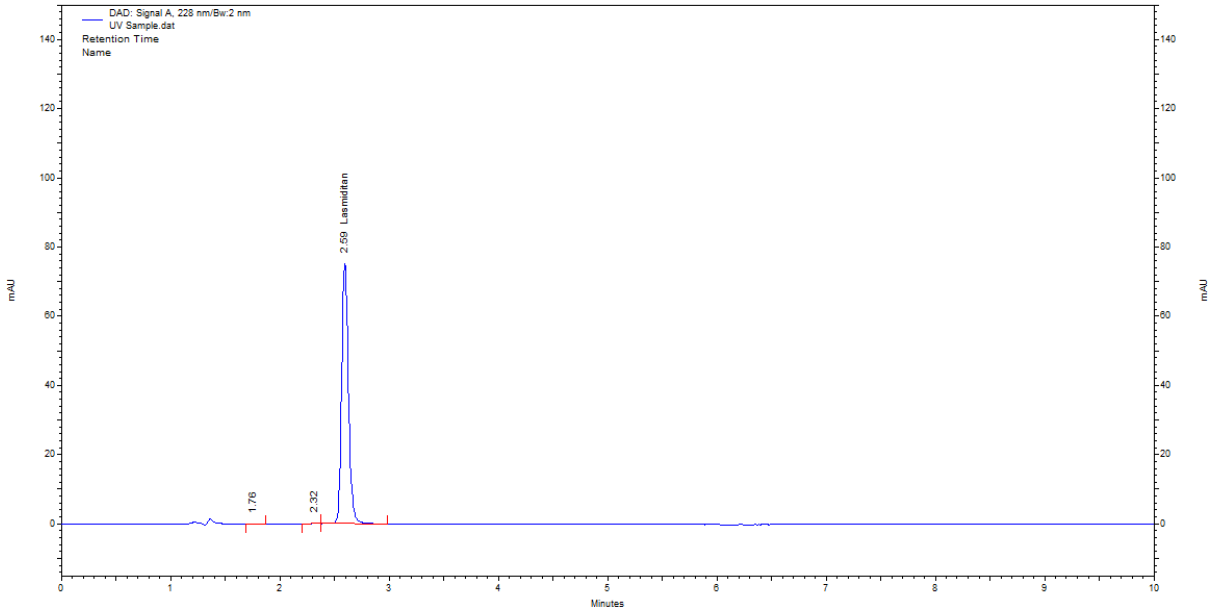

Figure 43: UV Sample

IV. Discussion

The present investigation successfully developed and validated a rapid, accurate, precise, robust, and stability-indicating RP-HPLC method for the quantitative estimation of lasmiditan in bulk drug substance and pharmaceutical dosage forms. The analytical method was systematically optimized by evaluating various chromatographic parameters to achieve satisfactory peak symmetry, high column efficiency, acceptable retention time, and complete separation of the analyte from formulation excipients and degradation products. The optimized chromatographic conditions produced a sharp and symmetrical lasmiditan peak with a retention time of approximately 2.59 min, demonstrating that the selected mobile phase composition was appropriate for routine pharmaceutical analysis.

System suitability testing confirmed excellent chromatographic performance throughout the analytical procedure. The mean retention time remained consistent during replicate injections, while the percentage relative standard deviation of peak area (0.04%) was considerably lower than the maximum acceptance criterion specified in ICH Q2(R1), indicating exceptional repeatability of the chromatographic system. Furthermore, the theoretical plate count exceeded 8500, reflecting excellent column efficiency, whereas the asymmetry factor remained close to unity, confirming symmetrical peak elution and minimal chromatographic distortion. These observations demonstrate that the optimized chromatographic conditions provide reliable and reproducible analytical performance suitable for routine quality-control applications. Similar chromatographic characteristics have been reported for previously published RP-HPLC methods developed for lasmiditan and other antimigraine drugs; however, the present method provides a comparatively shorter retention time while maintaining excellent chromatographic efficiency.[17,21–25]

Specificity studies demonstrated complete chromatographic selectivity of the developed analytical procedure. No interfering peaks were observed in the blank or placebo chromatograms at the retention time corresponding to lasmiditan, while the standard and sample chromatograms exhibited identical retention times with satisfactory peak purity. The diode array detector further confirmed peak homogeneity, indicating that the developed method is capable of accurately quantifying lasmiditan in the presence of formulation excipients. These findings establish the suitability of the proposed analytical method for routine assay determination and provide a strong foundation for its application as a stability-indicating method. Similar observations have been reported in earlier chromatographic investigations involving lasmiditan and related pharmaceutical compounds.[22–33]

The linearity study demonstrated an excellent correlation between analyte concentration and detector response over the investigated concentration range of 8–12 µg/mL. The regression equation ($y = 70354.7x - 471.2$) and correlation coefficient ($R^2 = 0.99997$) indicate an almost perfect linear relationship between concentration and chromatographic response. The observed regression statistics satisfy the recommendations of ICH Q2(R1) and confirm that the developed method is capable of producing reliable quantitative results throughout the intended analytical range. Comparable correlation coefficients have been reported in previously published RP-HPLC methods; however, the present method achieved excellent linearity using a relatively simple mobile-phase composition and shorter chromatographic run time.[22–33]

Accuracy studies performed by the standard addition method demonstrated excellent recovery of lasmiditan from the pharmaceutical formulation. The recovery values obtained at 50%, 100%, and 150% concentration levels were within the

acceptance limits recommended by ICH guidelines, while the corresponding percentage relative standard deviation values remained below 2.0%. It is verified that the formulation excipients had no impact on analyte quantification and that the analytical approach that was created is capable of producing precise assay data. Similar recovery values have been reported in previous RP-HPLC methods for lasmiditan and related pharmaceutical compounds, further supporting the reliability of the developed analytical procedure.[22–33]

Method precision and intermediate precision studies demonstrated excellent reproducibility of the developed chromatographic method. The very low percentage relative standard deviation observed during repeatability experiments confirms that the analytical procedure consistently produces highly reproducible results under identical operating conditions. Intermediate precision studies further established that the analytical performance remained unaffected by normal day-to-day laboratory variations, thereby demonstrating the ruggedness of the developed method. The high theoretical plate count and consistent asymmetry factor observed throughout precision studies further support the robustness of the optimized chromatographic conditions.

The calculated limit of detection and limit of quantification indicate that the proposed RP-HPLC method possesses sufficient analytical sensitivity for routine pharmaceutical analysis. The low detection limits achieved in the present investigation may be attributed to the optimized chromatographic conditions, efficient separation of lasmiditan, and appropriate selection of the analytical wavelength. Sensitive analytical methods are particularly advantageous for pharmaceutical quality-control laboratories because they facilitate accurate quantification of low analyte concentrations during assay determination, stability studies, and impurity investigations.

Robustness studies demonstrated that deliberate variations in chromatographic parameters, including minor changes in flow rate, mobile-phase composition, and detection wavelength, did not significantly influence chromatographic performance. The analytical results remained within acceptable limits, indicating that the developed RP-HPLC method is sufficiently robust for routine implementation in pharmaceutical quality-control laboratories. Robust analytical methods are particularly valuable during routine operation because minor experimental variations are unavoidable in day-to-day laboratory practice.

Application of the validated analytical method to the assay of commercially available lasmiditan tablets demonstrated satisfactory drug content within pharmacopeial acceptance limits. The absence of interfering peaks originating from formulation excipients confirms that the developed method is suitable for routine quality-control analysis of finished pharmaceutical products without requiring complicated sample preparation procedures.

One of the major strengths of the present investigation is the comprehensive evaluation of the stability-indicating capability of the developed RP-HPLC method. Forced degradation studies performed under acidic, alkaline, oxidative, thermal, and photolytic stress conditions demonstrated that lasmiditan undergoes degradation to varying extents depending upon the applied stress environment. Nevertheless, the parent drug peak remained completely resolved from all degradation products under each stress condition, thereby confirming the specificity and stability-indicating capability of the analytical method. These findings are consistent with the regulatory recommendations of ICH Q1A(R2), which require chromatographic methods intended for stability testing to demonstrate effective separation of degradation products from the active pharmaceutical ingredient.[11,17,21]

When compared with previously reported analytical methods, the developed RP-HPLC procedure offers several practical advantages. The method employs a simple mobile-phase composition without the need for complex buffer systems, provides a short retention time of approximately 2.59 min, demonstrates excellent chromatographic performance, and satisfies all validation requirements specified by ICH Q2(R1). These characteristics collectively reduce solvent consumption, shorten analysis time, improve laboratory throughput, and minimize overall analytical cost. Consequently, the proposed analytical procedure is well suited for routine pharmaceutical quality-control laboratories, formulation development, dissolution testing, and stability studies.

Overall, the results obtained during method development, validation, assay determination, and forced degradation studies collectively demonstrate that the developed RP-HPLC method is reliable, accurate, precise, robust, economical, and stability-indicating. The analytical performance achieved in the present investigation confirms its suitability for routine quantitative estimation of lasmiditan in bulk drug substances and pharmaceutical dosage forms while fulfilling current international regulatory expectations for validated pharmaceutical analytical methods.

V. CONCLUSION

The present investigation successfully developed and validated a rapid, accurate, precise, robust, and stability-indicating RP-HPLC method for the quantitative estimation of lasmiditan in bulk drug substance and pharmaceutical dosage forms. Systematic optimization of chromatographic conditions resulted in efficient separation of lasmiditan with excellent peak symmetry, high column efficiency, and a short retention time of approximately 2.59 min, making the analytical procedure suitable for high-throughput pharmaceutical analysis.

Validation of the developed method in accordance with the International Council for Harmonisation (ICH) Q2(R1) guideline demonstrated satisfactory performance for all evaluated validation parameters, including system suitability, specificity, linearity, accuracy, precision, robustness, sensitivity, and assay. The correlation coefficient obtained during linearity studies confirmed excellent proportionality between analyte concentration and detector response, while the low percentage relative standard deviation values observed during precision studies demonstrated outstanding analytical reproducibility. Recovery studies further established the

Sajid Jahangir Sayyad and Allabaksha Shaikh, "Development and Validation of a Stability-Indicating RP-HPLC Method for Quantitative Estimation of Lasmiditan in Bulk Drug and Pharmaceutical Dosage Forms," *International Research Journal of Pharmacy and Medical Sciences (IRJPMS)*, Volume 9, Issue 5, pp. 13-36, 2026.

accuracy of the developed method, indicating that pharmaceutical excipients did not interfere with analyte quantification.

The stability-indicating capability of the proposed RP-HPLC method was confirmed through comprehensive forced degradation studies performed under acidic, alkaline, oxidative, thermal, and photolytic stress conditions. The technique effectively separated lasmiditan from all degradation products produced during stress testing, exhibiting great chromatographic specificity and adherence to stability-indicating analytical procedures' present regulatory standards.

Compared with previously reported analytical methods, the developed RP-HPLC procedure offers several practical advantages, including a simple mobile-phase composition, rapid chromatographic separation, reduced solvent consumption, shorter analytical run time, and excellent chromatographic reproducibility. These characteristics significantly improve laboratory productivity while minimizing analytical cost, making the method particularly suitable for routine pharmaceutical quality-control laboratories.

Overall, the developed RP-HPLC method represents a reliable, economical, and regulatory-compliant analytical tool for the routine estimation of lasmiditan in bulk drug substances and pharmaceutical dosage forms. The validated analytical procedure may also be employed for stability studies, formulation development, quality-control testing, and future pharmaceutical research involving lasmiditan.

TABLE 11. Comparison of the proposed RP-HPLC method with previously reported analytical methods for Lasmiditan

Author	Column	Mobile Phase	RT (min)	Detection (nm)	Validation	Stability Indicating
Ref. 22	C18	---	---	---	Yes	Yes
Ref. 23	C18	---	---	---	Yes	No
Ref. 24	C18	---	---	---	Yes	Yes
Ref. 25	C18	---	---	---	Yes	No
Present Study	Phenomenex Kinetex XB-C18	0.1% Perchloric Acid : ACN (58:42)	2.59	228	Complete ICH	Yes

TABLE 12. Summary of ICH Validation Parameters

Validation Parameter	Acceptance Criteria	Obtained Result	Status
Specificity	No interference	Passed	✓
Linearity	$R^2 > 0.999$	0.99997	✓
Accuracy	98–102%	Passed	✓
Precision	%RSD < 2	Passed	✓
Robustness	%RSD < 2	Passed	✓
LOD	Report	Passed	✓
LOQ	Report	Passed	✓
Assay	98–102%	Passed	✓
Forced Degradation	Separation achieved	Passed	✓

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Conflict of Interest

The authors declare that there are no conflicts of interest regarding the publication of this manuscript.

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