ISSN: 2347-6567

International Journal of Allied Medical Sciences and Clinical Research (IJAMSCR)

IJAMSCR |Vol. 14 | Issue 3| Jul- Sep- 2026

www.ijamscr.com

DOI : https://doi.org/10.61096/ijamscr.v14.iss3.2026.1155-1168

RP-HPLC Analytical Method Development and Validation for Estimation of Pravastatin and Niacin in API and Pharmaceutical Formulation

P.Amani[*1], Sadurla Uday Kumar[1], Salagari Ashwini[1], Shattamoni Bharath[1], Shifa Tahniyath[1], Singaram Manisha[1], Dr. Kantlam

[1]*Department of Pharmaceutical Analysis, Brilliant Grammar School Educational Society's Group of Institutions (Engineering and Pharmacy), Abdullapur (V), Abdullapurmet (M), Rangareddy (D), Hyderabad - 501 505.*

*Corresponding Author: **P. Amani***
Email: amanipaduri0002@gmail.com

Published on: 08.07.2026
Published by: Futuristic Publications
2026| All rights reserved.

Creative Commons Attribution 4.0 International License.

Abstract: A reliable and efficient reverse phase high-performance liquid chromatographic (RP-HPLC) method was developed for the simultaneous estimation of Pravastatin and Niacin in active pharmaceutical ingredients and combined pharmaceutical dosage forms. Method development involved systematic optimization of chromatographic conditions to achieve adequate resolution, symmetrical peak shapes, and acceptable retention times for both analytes. Separation was accomplished using a suitable C18 stationary phase with an optimized mobile phase composition, and detection was carried out at an appropriate ultraviolet wavelength.

The developed method was validated in accordance with ICH Q2 (R1) guidelines. Validation studies demonstrated excellent specificity, with no interference from formulation excipients. The method exhibited linearity over the selected concentration ranges for both Pravastatin and Niacin, with satisfactory correlation coefficients. Accuracy was confirmed through recovery studies, while precision was established by repeatability and intermediate precision assessments. Sensitivity of the method was evidenced by low limits of detection and quantification. Robustness studies indicated that minor deliberate variations in chromatographic parameters did not significantly affect method performance.

The proposed RP-HPLC method is simple, precise, accurate, and reproducible, making it suitable for routine quality control analysis, assay determination, and stability studies of Pravastatin and Niacin in bulk drugs and pharmaceutical formulations.

Key Words: Pravastatin; Niacin; RP-HPLC; Method Development; Validation; Pharmaceutical Analysis; ICH Guidelines.

1. INTRODUCTION

High-Performance Liquid Chromatography (HPLC) is one of the most powerful and indispensable analytical techniques in contemporary chemical and biochemical analysis. It is extensively employed for the separation, identification, and quantitative determination of chemical constituents present in complex mixtures. The technique has gained universal acceptance due to its exceptional resolution, sensitivity, accuracy, reproducibility, and versatility. Unlike gas chromatography, HPLC is particularly suitable for compounds that are thermally unstable, non-volatile, or possess high molecular weights, making it applicable across a wide range of scientific disciplines including pharmaceuticals, environmental science, food technology, biotechnology, and clinical research [1]

The rapid growth of industrial manufacturing, pharmaceutical development, and environmental monitoring has intensified the demand for reliable analytical methods capable of producing precise and reproducible results. Regulatory authorities worldwide, including the United States Food and Drug Administration (FDA), European Medicines Agency (EMA), and International Council for Harmonisation (ICH), recognize HPLC as a gold-standard analytical tool for quality control, stability testing, impurity profiling, and method validation [2]. Consequently, HPLC has become deeply integrated into both academic research and industrial quality assurance laboratories.

The fundamental principle of HPLC is rooted in chromatography, a separation science based on the differential distribution of analytes between a stationary phase and a mobile phase. In HPLC systems, the stationary phase is packed within a column composed of small, uniformly sized particles, while the mobile phase is a liquid solvent delivered at high pressure. As the mobile phase flows through the column, analytes interact differently with the stationary phase based on their physicochemical properties, leading to differential migration rates and effective separation [3].

The term "high-performance" refers not only to the high operating pressures employed but also to the superior separation efficiency achieved through advancements in column technology, solvent delivery systems, and detection mechanisms. Early forms of liquid chromatography operated under gravity or low pressure, resulting in poor resolution and long analysis times. The introduction of high-pressure pumps and small-particle stationary phases revolutionized liquid chromatography, giving rise to modern HPLC systems capable of rapid, high-resolution separations [4].

One of the defining characteristics of HPLC is its adaptability. By modifying operational parameters such as column chemistry, mobile phase composition, flow rate, temperature, and detection technique, analysts can tailor the method to suit a wide variety of analytical challenges. This flexibility allows HPLC to operate under multiple chromatographic modes, including normal-phase, reversed-phase, ion-exchange, and size-exclusion chromatography. Among these, reversed-phase HPLC has emerged as the most widely used mode due to its robustness, reproducibility, and compatibility with aqueous samples [5].

Technological innovations have continuously shaped the evolution of HPLC. Modern systems are equipped with precision pumps capable of delivering solvent at pressures exceeding 400 bar, automated sample injectors for reproducible sample introduction, advanced column chemistries for enhanced selectivity, and highly sensitive detectors. Furthermore, the integration of computerized data acquisition and processing systems has significantly improved analytical accuracy, method validation, and regulatory compliance [6].

In pharmaceutical analysis, HPLC plays a pivotal role throughout the entire drug development lifecycle, from early-stage discovery to post-marketing surveillance. It is routinely used for assay determination, impurity profiling, dissolution testing, bioavailability studies, and stability analysis. The ability of HPLC to separate closely related compounds makes it indispensable for ensuring drug safety, efficacy, and quality [7].

Environmental analysis represents another critical area of HPLC application. The technique enables the detection and quantification of pesticides, herbicides, industrial pollutants, pharmaceuticals, and emerging contaminants in environmental matrices such as water, soil, and air. Given the increasing concern over environmental pollution and public health, HPLC has become a vital tool for regulatory monitoring and environmental risk assessment [8].

In food science and technology, HPLC is extensively used for the analysis of additives, preservatives, vitamins, amino acids, sugars, and contaminants such as mycotoxins. The technique ensures compliance with food safety regulations and supports quality control processes in food manufacturing industries [9]. Similarly, in biotechnology and life sciences, HPLC is fundamental for the analysis and purification of biomolecules including proteins, peptides, nucleic acids, and metabolites.

Despite its numerous advantages, the effective application of HPLC requires a comprehensive understanding of chromatographic theory, instrumentation, method development strategies, and system maintenance. Factors such as improper column selection, inadequate mobile phase optimization, detector incompatibility, or poor system maintenance can significantly compromise analytical performance. Therefore, a thorough theoretical and practical understanding of HPLC is essential for achieving reliable and reproducible results [10].

The objective of this Introduction is to provide a detailed and systematic overview of High-Performance Liquid Chromatography as a foundational analytical technique. The discussion encompasses the historical development of HPLC, its theoretical principles, instrumental components, methodological considerations, and its significance in modern analytical science. By presenting both theoretical and practical perspectives, this Introduction aims to establish a strong conceptual framework for understanding advanced applications and innovations in HPLC technology.

EXPERIMENTAL METHODS

INSTRUMENTS USED

HPLC detector.	WATERS Alliance 2695 separation module, Software: Empower 2, 996 PDA
pH meter	Lab India
Weighing machine	Sartorius
Volumetric flasks	Borosil
Pipettes and Burettes	Borosil
Beakers	Borosil
Digital ultra sonicator	Lab man

CHEMICALS USED:

Pravastatin	Pravachol
Niacin	Niaspan
Water and Methanol for HPLC	LICHROSOLV (MERCK)
Acetonitrile for HPLC	Merck
Placeda tablets 0.5/10mg (Marketed product)	Mankind Pharma

HPLC METHOD DEVELOPMENT:

TRAILS

Preparation of standard solution:

Accurately weigh and transfer 10 mg of Pravastatin and Niacin working standard into a 10ml of clean dry volumetric flasks add about 7ml of Methanol and sonicated to dissolve and removal of air completely and make volume up to the mark with the same Methanol.

Further pipette 0.2ml of Pravastatin and 0.6ml of Niacin from the above stock solutions into a 10ml volumetric flask and dilute up to the mark with Methanol.

Procedure:

Inject the samples by changing the chromatographic conditions and record the chromatograms, note the conditions of proper peak elution for performing validation parameters as per ICH guidelines.

Mobile Phase Optimization:

Initially the mobile phase tried was Methanol: Water and ACN: Water with varying proportions. Finally, the mobile phase was optimized to Acetonitrile and Acetate buffer (pH-4.3) in proportion 35:65 v/v respectively.

Optimization of Column:

The method was performed with various C18 columns like Symmetry, X terra and ODS column. Develosil C18 (4.6mm×250mm) 5µm particle size Column was found to be ideal as it gave good peak shape and resolution at 1ml/min flow.

OPTIMIZED CHROMATOGRAPHIC CONDITIONS:

Instrument used	:	Waters Alliance 2695 HPLC with PDA Detector 996 model.
Temperature	:	Ambient
Column	:	Develosil C18 (4.6 mm×250 mm) 5µm particle size Column
Mobile phase	:	Acetonitrile and Acetate buffer (pH-4.3) (35:65% v/v)
Flow rate	:	1 ml/min
Wavelength	:	238 nm
Injection volume	:	20 µl
Run time	:	6minutes

VALIDATION

PREPARATION OF MOBILE PHASE:

Preparation of mobile phase:

Accurately measured 350ml of Acetonitrile (35%) of and 650ml of Acetate buffer (65%) were mixed and degassed in a digital ultra sonicated for 20 minutes and then filtered through 0.45 µ filter under vacuum filtration.

Diluent Preparation:

The Mobile phase was used as the diluent.

RESULTS AND DISCUSSION

Optimized Chromatogram (Standard)

Mobile phase ratio : Acetonitrile and Acetate buffer (pH-4.3) (35:65% v/v)
Column : Develosil C18 (4.6 mm × 250 mm) 5µm particle size Column
Column temperature : Ambient
Wavelength : 238nm
Flow rate : 1ml/min
Injection volume : 20µl
Run time : 6minutes

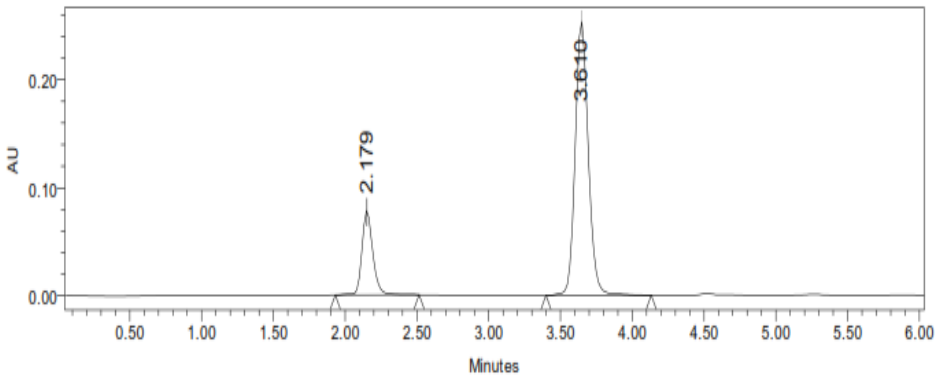

Figure: Optimized Chromatogram (Standard)

Table: Optimized Chromatogram (Standard)

S. No	Name	RT	Area	Height	USPTailing	USPPlate Count	Resolution
1	Pravastatin	2.179	513567	78659	1.2	4536	
2	Niacin	3.610	1625892	265321	1.1	7985	9.8

Observation: From the above chromatogram it was observed that the Pravastatin and Niacin peaks are well separated and they show proper retention time, resolution, peak tail and plate count. So it's optimized trial.

Optimized Chromatogram

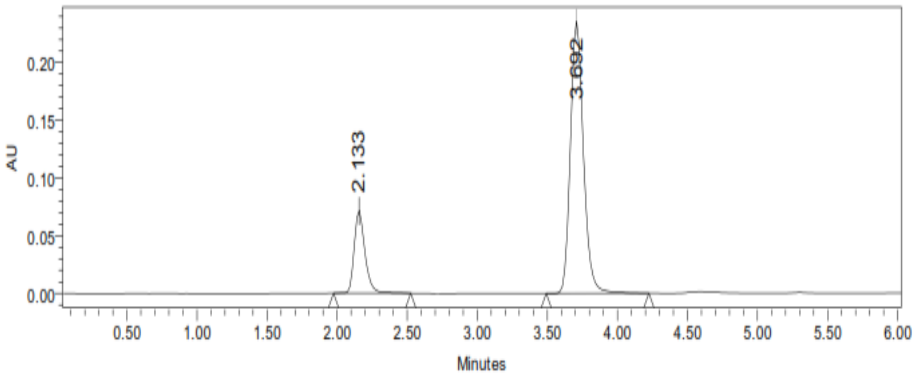

Figure: Optimized Chromatogram (Sample)

Table: Optimized Chromatogram (Sample)

S. No	Name	Rt	Area	Height	USPTailing	USPPlate Count	Resolution
1	**Pravastatin**	**2.133**	**512659**	**78956**	**1.2**	**4652**	
2	**Niacin**	**3.692**	**1615985**	**263587**	**1.1**	**7982**	**10.3**

Acceptance criteria:

- Resolution between two drugs must be not less than 2.
- Theoretical plates must be not less than 2000.
- Tailing factor must be not less than 0.9 and not more than 2.
- It was found from above data that all the system suitability parameters for developed method were within the limit.

METHOD VALIDATION

Blank:

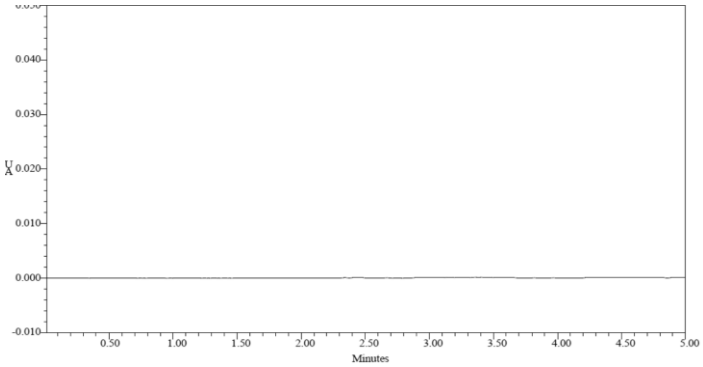

Fig: Chromatogram showing blank (mobile phase preparation)

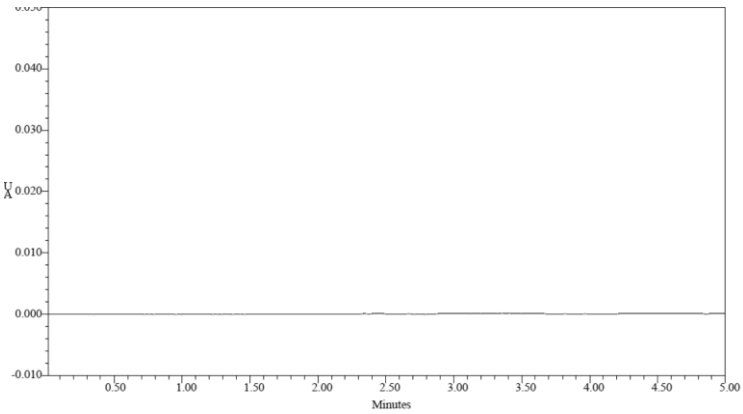

Fig: Chromatogram showing Placebo

System Suitability:

Table: Results of system suitability for Pravastatin

S. No	PeakName	RT	Area (µV*sec)	Height (µV)	USP Plate Count	USP Tailing
1	Pravastatin	2.152	513652	78542	4698	1.2
2	Pravastatin	2.157	513524	78654	4785	1.2
3	Pravastatin	2.141	513425	78541	4682	1.2
4	Pravastatin	2.133	513647	78454	4854	1.2
5	Pravastatin	2.166	514824	78655	4872	1.2
Mean			513814.4			
Std.Dev.			572.2004			
%RSD			0.111363			

Acceptance criteria:

- %RSD of five different sample solutions should not more than 2.
- The %RSD obtained is within the limit, hence the method is suitable.

Table: Results of system suitability for Niacin

S. No	Peak Name	RT	Area (µV*sec)	Height (µV)	USP Plate Count	USP Tailing	Resolution
1	Niacin	3.674	1635285	265421	7985	1.1	10.1
2	Niacin	3.631	1635241	265484	7898	1.1	10.1
3	Niacin	3.625	1652547	253498	7954	1.1	10.1
4	Niacin	3.692	1658458	265241	7965	1.1	10.1
5	Niacin	3.629	1652894	265348	7985	1.1	10.1
Mean			1646885				
Std.Dev.			10865.58				
%RSD			0.659766				

Acceptance criteria:

- %RSD of five different sample solutions should not more than 2.
- The %RSD obtained is within the limit, hence the method is suitable.

SPECIFICITY

The ICH documents define specificity as the ability to assess unequivocally the analyte in the presence of components that may be expected to be present, such as impurities, degradation products, and matrix components.

Analytical method was tested for specificity to measure accurately quantitated Pravastatin and Niacinin drug product.

Assay (Standard):

Table: Peak results for assay standard of Pravastatin

S. No	Name	RT	Area	Height	USP Tailing	USP Plate Count	Injection
1	Pravastatin	2.152	513538	78074	1.2	4562	1
2	Pravastatin	2.198	513975	79001	1.2	4620	2
3	Pravastatin	2.179	513283	78048	1.2	4652	3

Table: Peak results for assay standard of Niacin

S. No	Name	RT	Area	Height	USP Tailing	USP Plate Count	Injection
1	Niacin	3.646	1625632	265325	1.1	7949	1
2	Niacin	3.604	1635458	265423	1.1	7919	2
3	Niacin	3.610	1635241	265874	1.1	7926	3

Assay (Sample):

Table: Peak results for Assay sample of Pravastatin

S. No	Name	RT	Area	Height	USP Tailing	USP Plate Count	Injection	% of Assay
1	Pravastatin	3.651	513265	78548	1.2	4582	1	100.1
2	Pravastatin	2.150	513254	78547	1.2	4658	2	100.1
3	Pravastatin	2.187	513876	78498	1.2	4597	3	99.9

Table: Peak results for Assay sample of Melitracen

S. No	Name	RT	Area	Height	USPTailing	USPPlateCount	Injection	% of Assay
1	Niacin	3.646	1625284	78569	1.1	7985	1	100.0
2	Niacin	3.651	1624613	78547	1.1	7898	2	100.7
3	Niacin	3.601	1625874	78462	1.1	7854	3	100.6

Table: Showing Assay Results

S.No.	Name of Compound	Label Claim	Amount Taken (from Combination Tablet)	% Purity
1	Pravastatin	0.5mg	0.4	99.57%
2	Niacin	10 mg	9.8	99.57%

$$\%ASSAY = \frac{\text{Sample area}}{\text{Standard area}} \times \frac{\text{Weight of standard}}{\text{Dilution of standard}} \times \frac{\text{Dilution of sample Purity}}{\text{Weight of sample 100}} \times \frac{\text{Weight of tablet}}{\text{Label claim}} \times 100$$

The % purity of Pravastatin and Niacinin pharmaceutical dosage form was found to be 99.57%

LINEARITY

CHROMATOGRAPHIC DATA FOR LINEARITY STUDY OF PRAVASTATIN:

Concentration µg/ml	Average Peak Area
10	245899
15	365687
20	481526
25	589854
30	705882

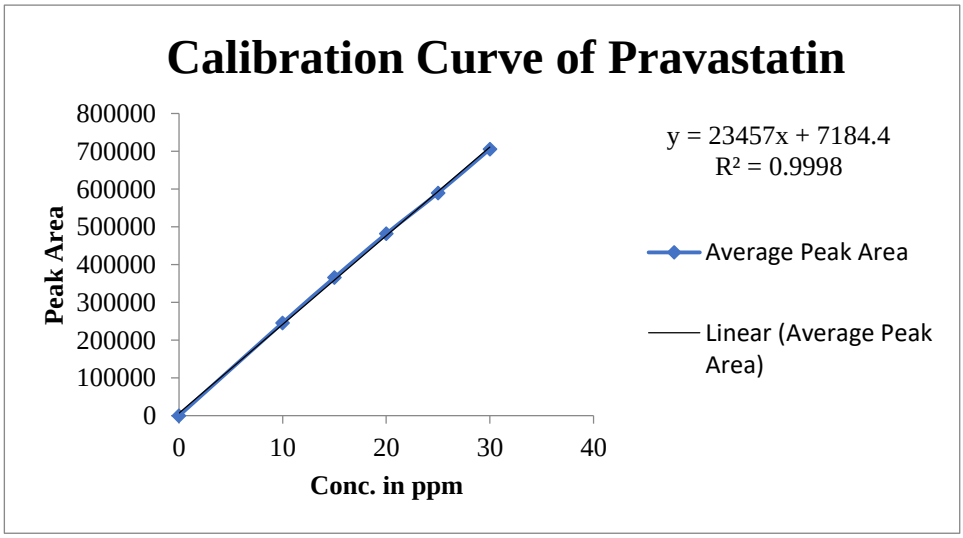

Fig: Calibration Graph of Pravastatin

LINEARITY PLOT:

The plot of Concentration (x) versus the Average Peak Area (y) data of Pravastatin is a straight line.

Y = mx + c

Slope (m) = 23457

Intercept (c) = 7184

Correlation Coefficient (r) = 0.999

VALIDATION CRITERIA: The response linearity is verified if the Correlation Coefficient is 0.99 or greater.

CONCLUSION: Correlation Coefficient (r) is 0.99, and the intercept is 7184. These values meet the validation criteria.

CHROMATOGRAPHIC DATA FOR LINEARITY STUDY OF MELITRACEN:

Concentration µg/ml	Average Peak Area
30	863094
45	1249397
60	1678592
75	2050412
90	2468444

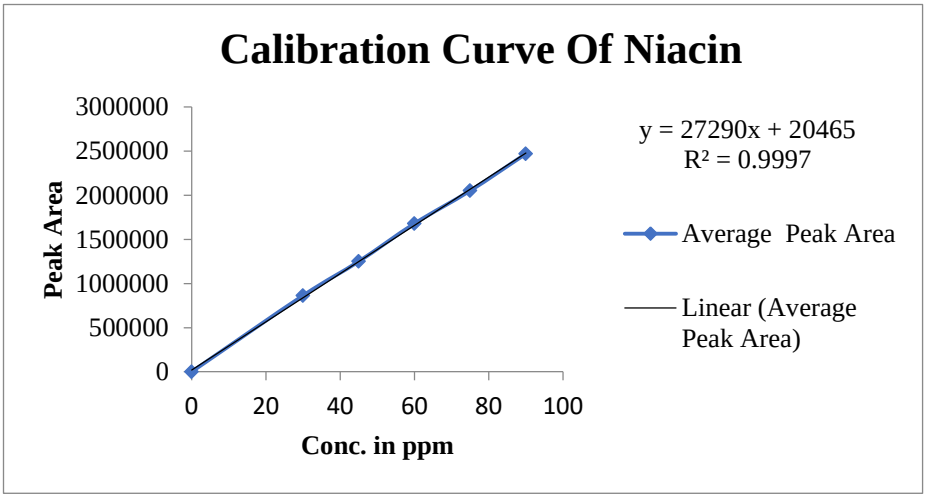

Fig: Calibration Curve of Niacin

LINEARITY PLOT:

The plot of Concentration (x) versus the Average Peak Area (y) data of Niacin is a straight line.
Y = mx + c

Slope (m) = 27290

Intercept (c) = 20465

Correlation Coefficient (r) = 0.99

VALIDATION CRITERIA: The response linearity is verified if the Correlation Coefficient is 0.99 or greater.

CONCLUSION: Correlation Coefficient (r) is 0.99, and the intercept is 20465. These values meet the validation criteria.

Precision:

The precision of an analytical procedure expresses the closeness of agreement (degree of scatter) between a series of measurements obtained from multiple sampling of the same homogeneous sample under the prescribed conditions.

REPEATABILITY

Obtained Five (5) replicates of 100% accuracy solution as per experimental conditions. Recorded the peak areas and calculated % RSD.

Table: Results of repeatability for Pravastatin:

S. No	Peak name	Retention time	Area (µV*sec)	Height (µV)	USP Plate Count	USP Tailing
1	Pravastatin	2.157	513568	78546	1.2	4528
2	Pravastatin	2.159	513685	78541	1.2	4572
3	Pravastatin	2.186	513659	79852	1.2	4598
4	Pravastatin	2.160	513254	78498	1.3	4529
5	Pravastatin	2.170	513647	77898	1.2	4572
Mean			513562.6			
Std.dev			177.9475			
%RSD			0.03465			

Acceptance criteria:

- %RSD for sample should be NMT 2.
- The %RSD for the standard solution is below 1, which is within the limits hence method is precise.

Table: Results of repeatability for Melitracen:

S. No	**Peak name**	**Retention time**	**Area(µV*sec)**	**Height (µV)**	**USP Plate Count**	**USP Tailing**
1	Niacin	3.603	1635625	265325	1.1	7985
2	Niacin	3.608	1658744	264588	1.1	7859
3	Niacin	3.600	1652985	265985	1.2	7845
4	Niacin	3.696	1645898	264898	1.1	7969
5	Niacin	3.629	1652364	268489	1.1	7846
Mean			1649123			
Std.dev			8811.631			
%RSD			0.534322			

Intermediate precision:

Day 1:

Table: Results of Intermediate precision for Pravastatin

S.No.	**PeakName**	**RT**	**Area (µV*sec)**	**Height (µV)**	**USP Plate count**	**USPTailing**
1	Pravastatin	2.198	514658	78698	4658	1.2
2	Pravastatin	2.196	514354	78599	4598	1.2
3	Pravastatin	2.160	513985	79854	4652	1.2
4	Pravastatin	2.160	514875	79879	4561	1.2
5	Pravastatin	2.160	514658	79865	4659	1.2
6	Pravastatin	2.186	516452	79854	4589	1.2
Mean			514830.3			
Std.Dev.			852.3705			
% RSD			0.165563			

Acceptance criteria:

- % RSD of five different sample solutions should not more than 2.

Table: Results of Intermediate precision for Niacin

S. No	**PeakName**	**Rt**	**Area (µV*sec)**	**Height (µV)**	**USP Plate count**	**USP Tailing**	**Resolution**
1	Niacin	3.623	1645875	266589	7985	1.1	10.1

2	Niacin	3.611	1658554	265898	8001	1.1	10.1
3	Niacin	3.696	1649854	265415	7985	1.1	10.1
4	Niacin	3.696	1659842	265154	7956	1.1	10.1
5	Niacin	3.696	1645985	266598	7985	1.1	10.1
6	Niacin	3.642	1659852	265341	8002	1.1	10.1
Mean			1653327				
Std.Dev.			6838.733				
% RSD			0.413635				

Acceptance criteria:

- %RSD of five different sample solutions should not more than 2.

Day 2:

Table: Results of Intermediate precision Day 2 for Pravastatin

S. No	Peak Name	RT	Area (µV*sec)	Height (µV)	USPlate count	USPTailing
1	Pravastatin	2.198	514658	78572	4672	1.2
2	Pravastatin	2.196	514895	78516	4639	1.2
3	Pravastatin	2.178	514658	78572	4783	1.2
4	Pravastatin	2.142	514784	78372	4623	1.2
5	Pravastatin	2.177	515268	78592	4639	1.2
6	Pravastatin	2.177	514598	78526	4737	1.2
Mean			514810.2			
Std.Dev.			248.5224			
% RSD			0.048275			

Acceptance criteria:

- %RSD of five different sample solutions should not more than 2.

Table: Results of Intermediate precision Day 2 for Niacin

S. No	PeakName	RT	Area (µV*sec)	Height (µV)	USPPlate count	USPTailing	Resolution
1	Niacin	3.611	1638732	264384	7985	1.1	10.1
2	Niacin	3.623	1637438	265827	7946	1.1	10.1
3	Niacin	3.684	1638474	266382	7943	1.1	10.1
4	Niacin	3.697	1634273	269183	7964	1.1	10.1
5	Niacin	3.684	1636372	261931	7968	1.1	10.1
6	Niacin	3.684	1639283	264356	7982	1.1	10.1
Mean			1637429				
Std. Dev.			1860.366				
% RSD			0.113615				

Acceptance criteria:

- % RSD of five different sample solutions should not more than 2.

ACCURACY:

Accuracy at different concentrations (50%, 100%, and 150%) was prepared and the % recovery was calculated.

% Concentration (at specification Level)	Area	Amount Added (ppm)	Amount Found (ppm)	% Recovery	Mean Recovery
50%	245954	10	10.179	101.79%	101.36%
100%	483747	20	20.316	101.58%	
150%	715961	30	30.	100.72%	

Acceptance Criteria:

- The percentage recovery was found to be within the limit (98-102%).

Table: The accuracy results for Niacin

% Concentration (at specification Level)	Area	Amount Added (ppm)	Amount Found (ppm)	% Recovery	Mean Recovery
50%	842287	30	30.114	100.38%	100.26%
100%	1659744	60	60.068	100.113%	
150%	2483885	90	90.268	100.297%	

The results obtained for recovery at 50%, 100%, 150% are within the limits. Hence method is accurate.

LIMIT OF DETECTION

The detection limit of an individual analytical procedure is the lowest amount of analyte in a sample which can be detected but not necessarily quantitated as an exact value.

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

Where

σ = Standard deviation of the response

S = Slope of the calibration curve

PRAVASTATIN

Result:

= 1.0µg/ml

NIACIN

Result:

= 11.0µg/ml

QUANTITATION LIMIT

The quantitation limit of an individual analytical procedure is the lowest amount of analyte in a sample which can be quantitatively determined.

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

Where

σ = Standard deviation of the response

S = Slope of the calibration curve

PRAVASTATIN

Result:

=3.1µg/ml

NIACIN

Result:

=3.2µg/ml

ROBUSTNESS

The robustness was performed for the flow rate variations from 0.9 ml/min to 1.1ml/min and mobile phase ratio variation from more organic phase to less organic phase ratio for Pravastatin and Niacin. The method is robust only in less flow condition and the method is robust even by change in the Mobile phase ±5%. The standard and samples of Niacin and Pravastatin were injected by changing the conditions of chromatography. There was no significant change in the parameters like resolution, tailing factor and plate count.

Variation in flow

Table: Results for Robustness

PRAVASTATIN

Parameter used for sample analysis	Peak Area	Retention Time	Theoretical plates	Tailing factor
Actual Flow rate of 1.0 mL/min	513567	2.179	4536	1.2
Less Flow rate of 0.9 mL/min	523652	2.210	4462.3	0.9
More Flow rate of 1.1 mL/min	502146	2.184	4325.1	1.0
Less organic phase	521574	2.200	4632.4	0.9
More Organic phase	502416	2.172	4190.8	0.8

Acceptance criteria:

The tailing factor should be less than 2.0 and the number of theoretical plates (N) should be more than 2000.

NIACIN

Parameter used for sample analysis	Peak Area	Retention Time	Theoretical plates	Tailing factor
Actual Flow rate of 1.0 mL/min	1625892	3.610	4536	1.1
Less Flow rate of 0.9 mL/min	1758455	4.498	4426.4	0.9
More Flow rate of 1.1 mL/min	1742514	3.505	4421.5	0.8
Less organic phase	1726451	4.504	4355.1	0.9
More organic phase	1725466	3.512	4426.6	0.9

Acceptance criteria:

The tailing factor should be less than 2.0 and the number of theoretical plates (N) should be more than 2000.

SUMMARY AND CONCLUSION

SUMMARY

The present research work focused on the systematic development and validation of a reverse phase high-performance liquid chromatographic (RP-HPLC) method for the simultaneous estimation of Pravastatin and Niacin in active pharmaceutical ingredients and combined pharmaceutical dosage forms. Method development was carried out through careful optimization of chromatographic parameters, including selection of stationary phase, mobile phase composition, flow rate, and detection wavelength, to achieve efficient separation with acceptable resolution and peak symmetry.

The optimized chromatographic conditions enabled clear and reproducible separation of Pravastatin and Niacin within a reasonable run time, making the method suitable for routine analysis. Validation of the developed method was performed in accordance with ICH Q2 (R1) guidelines. The method demonstrated excellent specificity with no interference from excipients, confirming its suitability for formulation analysis. Linearity was observed over the selected concentration ranges with strong correlation coefficients, indicating reliable quantitative performance.

Accuracy studies showed satisfactory recovery of both drugs, while precision studies confirmed the repeatability and intermediate precision of the method. The low values of limit of detection and limit of quantification highlighted the sensitivity of the method. Robustness testing indicated that minor deliberate variations in chromatographic conditions did not significantly affect the analytical performance, demonstrating the reliability and stability of the method.

Overall, the developed RP-HPLC method proved to be simple, precise, accurate, and reproducible for the simultaneous estimation of Pravastatin and Niacin in bulk and pharmaceutical dosage forms.

CONCLUSION

A novel and efficient RP-HPLC analytical method was successfully developed and validated for the simultaneous estimation of Pravastatin and Niacin in API and pharmaceutical formulations. The method provides effective separation with high analytical sensitivity and consistent performance under varied conditions. Validation results confirmed that the method meets regulatory requirements for specificity, linearity, accuracy, precision, robustness, and sensitivity.

Compared to previously reported methods, the developed method offers advantages in terms of simplicity, reduced analysis time, and suitability for routine quality control analysis. Its ability to accurately quantify both drugs in combined dosage forms makes it a valuable tool for pharmaceutical analysis and regulatory compliance.

The validated RP-HPLC method can be confidently applied for routine quality control testing, stability studies, and assay determination of Pravastatin and Niacin in bulk drugs and finished pharmaceutical products, thereby supporting consistent product quality and patient safety.

ACKNOWLEDGEMENT

The Authors are thankful to the Management and Principal, Brilliant Grammar School Educational Society's Group of Institutions (Engineering and Pharmacy), Abdullapur (V), Abdullapurmet (M), Rangareddy (D), Hyderabad., for extending support to carry out the research work. Finally, the authors express their gratitude to the Sura Pharma Labs, Dilsukhnagar, Hyderabad, for providing research equipment and facilities.

BIBLIOGRAPHY

1. Snyder, L. R., Kirkland, J. J., & Dolan, J. W. (2011). Introduction to modern liquid chromatography (3rd ed.). John Wiley & Sons.
2. Dong, M. W. (2010). Liquid chromatography: Principles, techniques, and applications (2nd ed.). John Wiley & Sons.
3. Poole, C. F. (2012). Chromatography today (2nd ed.). Elsevier.
4. Kazakevich, Y., & Lobrutto, R. (2007). HPLC for pharmaceutical scientists. John Wiley & Sons.
5. Meyer, V. R. (2010). Practical high-performance liquid chromatography (5th ed.). John Wiley & Sons.
6. Skoog, D. A., Holler, F. J., & Crouch, S. R. (2014). Principles of instrumental analysis (6th ed.). Cengage Learning.
7. Swartz, M. E., & Krull, I. S. (2012). Analytical method development and validation. CRC Press.
8. Moldoveanu, S. C., & David, V. (2015). Modern sample preparation for chromatography. Elsevier.
9. Nollet, L. M. L., & Toldrá, F. (2012). Food analysis by HPLC (3rd ed.). CRC Press.
10. McNair, H. M., & Miller, J. M. (2009). Basic gas chromatography (2nd ed.). John Wiley & Sons.
11. Tswett, M. (1906). Adsorption chromatography and its applications in plant pigment separation. Berichte der Deutscher Chemischen Gesellschaft, 39, 1491–1495.
12. Snyder, L. R., Kirkland, J. J., & Dolan, J. W. (2011). Introduction to modern liquid chromatography (3rd ed.). John Wiley & Sons.
13. Jorgenson, J. W., & Lukacs, K. D. (1971). High-performance liquid chromatography: Theory and practice. Science, 173(3996), 122–129.
14. Knox, J. H. (1979). Development of silica-based bonded-phase columns for HPLC. Journal of Chromatography A, 173(1), 3–14.
15. Dong, M. W. (2010). Liquid chromatography: Principles, techniques, and applications (2nd ed.). John Wiley & Sons.

16. Guichon, G., Felinger, A., Shirazi, D., & Katti, A. M. (2006). Fundamentals of preparative and nonlinear chromatography. Elsevier.
17. McNair, H. M., & Miller, J. M. (2009). Basic gas chromatography (2nd ed.). John Wiley & Sons.
18. Meyer, V. R. (2010). Practical high-performance liquid chromatography (5th ed.). John Wiley & Sons.
19. Van Deemter, J. J., Zuiderweg, F. J., & Klinkenberg, A. (1956). Longitudinal diffusion and resistance to mass transfer as causes of nonideal chromatography. Chemical Engineering Science, 5(6), 271–289.
20. Skoog, D. A., Holler, F. J., & Crouch, S. R. (2014). Principles of instrumental analysis (6th ed.). Cengage Learning.
21. Swartz, M. E., & Krull, I. S. (2012). Analytical method development and validation. CRC Press.
22. Skoog, D. A., Holler, F. J., & Crouch, S. R. (2014). Principles of instrumental analysis (6th ed.). Cengage Learning.
23. Kazakevich, Y., & Lobrutto, R. (2007). HPLC for pharmaceutical scientists. John Wiley & Sons.
24. Dong, M. W. (2010). Liquid chromatography: Principles, techniques, and applications (2nd ed.). John Wiley & Sons.
25. Meyer, V. R. (2010). Practical high-performance liquid chromatography (5th ed.). John Wiley & Sons.