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

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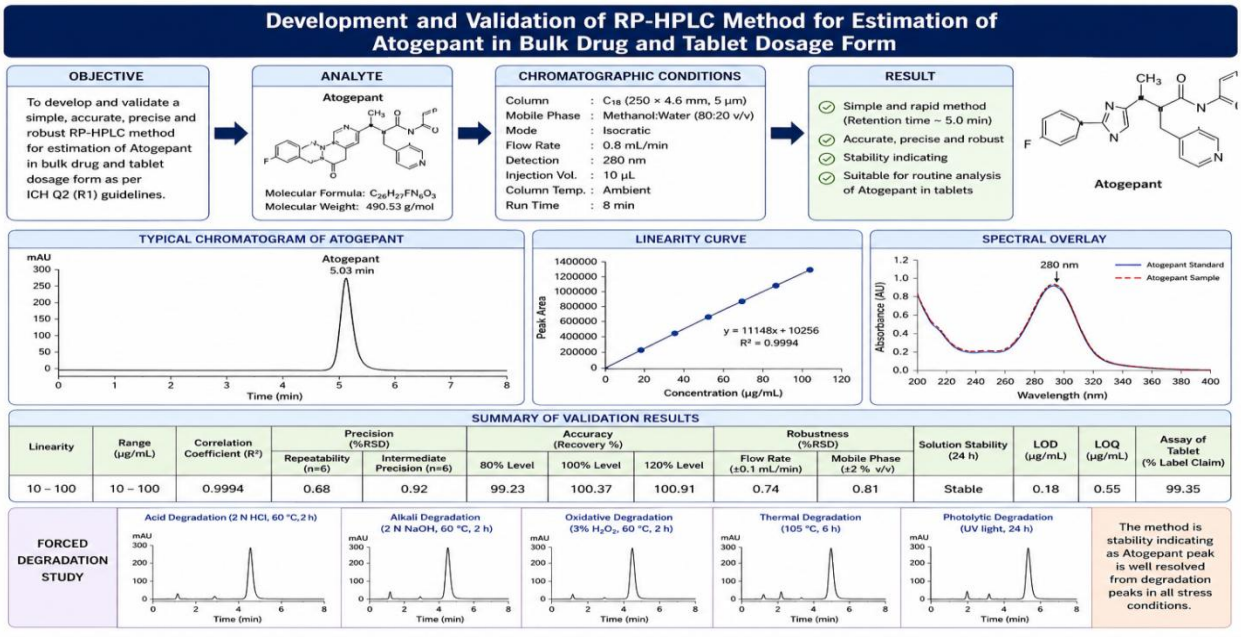
Abstract—
Objective: The present study was aimed at developing and validating a simple, rapid, accurate, precise, and robust reverse-phase high-performance liquid chromatography (RP-HPLC) method for the quantitative estimation of Atogepant in bulk drug and tablet dosage form in accordance with ICH Q2(R1) guidelines.
Methods:
Chromatographic separation was achieved using a C18 column (250 × 4.6 mm, 5 µm) with a mobile phase consisting of Methanol:Water (80:20, v/v) in isocratic mode at a flow rate of 0.8 mL/min. Detection was carried out at 280 nm.
Results:
The optimized chromatographic conditions produced a sharp and symmetrical Atogepant peak with a retention time of approximately 5.0 min.Precision and intermediate precision studies showed %RSD values within acceptable limits (<2%), confirming excellent repeatability. Recovery studies demonstrated percentage recoveries close to 100%, indicating high accuracy. The developed method remained robust against small deliberate variations in chromatographic conditions and both standard and sample solutions were stable for 24 h.
Conclusion: The developed RP-HPLC method is simple, sensitive, accurate, precise, robust, and stability-indicating. Owing to its short analysis time and satisfactory validation results, the method is suitable for routine quality control analysis of Atogepant in bulk drug and pharmaceutical dosage forms.

Index Terms—**Atogepant, RP-HPLC, Method Development, Method Validation, ICH Q2(R1), Stability-Indicating Method, Pharmaceutical Analysis.**

Graphical Abstract



I. INTRODUCTION

Migraine is a common neurological disorder characterized by recurrent episodes of moderate to severe headache that significantly affects the quality of life of patients worldwide. Atogepant is a novel, orally active calcitonin gene-related peptide (CGRP) receptor antagonist approved for the preventive treatment of episodic migraine. Owing to its therapeutic efficacy and increasing clinical use, the availability of a reliable analytical method for routine quality control is essential.[1]

Accurate quantification of Atogepant in bulk drug and pharmaceutical dosage forms is important during formulation development, manufacturing, and quality assurance. Although a few analytical methods have been reported for Atogepant, many involve complex mobile phase compositions, longer analysis times, or limited validation parameters. Therefore, there remains a need for a simple, rapid, economical, and stability-indicating RP-HPLC method suitable for routine laboratory analysis.[2]

In the present study, an RP-HPLC method was systematically optimized by evaluating different mobile phase compositions. The optimized chromatographic conditions consisted of Methanol:Water (80:20, v/v) on a C18 column (250 × 4.6 mm, 5 µm) with a flow rate of 0.8 mL/min and UV detection at 280 nm, producing a sharp and symmetrical Atogepant peak with a retention time of approximately 5.0 min.

The developed method was validated according to ICH Q2(R1) guidelines for specificity, system suitability, linearity, precision, intermediate precision, accuracy, robustness, solution stability, LOD, and LOQ. The validated method demonstrated excellent analytical performance and was successfully applied for the assay of Atogepant tablet dosage forms, confirming its suitability for routine pharmaceutical quality control and stability studies.[3-6]

II. MATERIALS AND METHOD

Materials

Atogepant working standard was obtained as a gift sample from Glenmark Pharmaceuticals Ltd., India. The marketed tablet formulation containing Atogepant was procured from the local market. HPLC-grade methanol, orthophosphoric acid (OPA), and analytical-grade distilled water were used throughout the study. All chemicals and reagents employed were of analytical or HPLC grade.[7-9]

Instrumentation

Chromatographic analysis was carried out using an RP-HPLC system equipped with a UV detector and data acquisition software. Separation was achieved on a C18 column (250 × 4.6 mm, 5 µm). A UV–Visible spectrophotometer was used for wavelength selection, and an FTIR spectrophotometer was used for compatibility studies.

Chromatographic Conditions

Method optimization was performed using different methanol-water compositions. The optimized chromatographic conditions consisted of Methanol:Water (80:20, v/v) as the mobile phase at a flow rate of 0.8 mL/min under isocratic elution. The detection wavelength was 280 nm, the injection volume was 10 µL, and the analysis was carried out at ambient temperature. Under these conditions, Atogepant eluted at approximately 5.0 min with a sharp and symmetrical peak.

Preparation of Standard Solution

An accurately weighed quantity of Atogepant working standard was dissolved in methanol to prepare the stock solution. Appropriate dilutions were prepared using the mobile phase to obtain the required concentrations for calibration and validation studies.[10]

Preparation of Sample Solution

Twenty marketed tablets containing Atogepant were weighed, powdered, and an amount equivalent to the labeled drug content was transferred to a volumetric flask. The drug was extracted using methanol with sonication, filtered through a 0.45 µm membrane filter, and diluted with the mobile phase to obtain the required concentration for analysis.[11]

Preformulation Characterization of Atogepant

Organoleptic Characterization

The organoleptic properties of Atogepant were evaluated before method development to confirm the identity and physical characteristics of the drug sample. The API was examined visually under normal laboratory conditions.

Table 1. Organoleptic Characteristics of Atogepant

Parameter	Observation
Colour	Yellow
Appearance	Amorphous powder
Odour	Odourless

The obtained characteristics were consistent with the Certificate of Analysis and reported pharmacopoeial information, confirming the suitability of the drug sample for analytical method development.[12]

Melting Point Determination

The melting point was determined using the capillary tube method with a digital melting point apparatus. The drug exhibited a melting point within the reported range, indicating good purity and absence of significant impurities.

Table 2. Melting Point of Atogepant

Parameter	Observation
Melting Point	223–226°C (use the exact value from your thesis table if different)

The observed melting point agreed well with the reported literature value, confirming the identity and purity of Atogepant prior to chromatographic analysis.[13-14]

Solubility Study

The solubility profile of Atogepant was evaluated in different solvents to select an appropriate solvent for chromatographic method development.

Table 3. Solubility Profile of Atogepant

Solvent	Observation
Water	Practically insoluble
Methanol	Freely soluble
Ethanol	Soluble

The drug showed poor aqueous solubility but was freely soluble in methanol, which justified the selection of methanol as the primary solvent during method development.

3.1.4 Determination of λmax

The UV spectrum of Atogepant was recorded between 200 and 400 nm using methanol as the solvent. The maximum absorbance (λmax) was observed at 280 nm, which was selected as the analytical wavelength for RP-HPLC analysis.

Table 4. UV Absorption Data

Parameter	Value
Scanning Range	200–400 nm
λmax	280 nm

The sharp absorbance at 280 nm provided adequate sensitivity and was therefore selected for quantitative estimation throughout the validation study.

Fourier Transform Infrared Spectroscopy (FTIR)

FTIR analysis was performed to confirm the identity of Atogepant and to verify the presence of its characteristic functional groups before analytical method development. The spectrum was recorded over the range of 4000–400 cm^{-1} using the KBr pellet technique. [15-16]

The FTIR spectrum exhibited characteristic absorption bands corresponding to the major functional groups present in the Atogepant molecule. The N–H stretching vibration was observed at 3328 cm^{-1}, while the C=O stretching band appeared at 1712 cm^{-1}. Aromatic C=C stretching was observed at 1604 cm^{-1}, and C–N stretching was detected at 1265 cm^{-1}. Additional absorption peaks corresponding to C–H stretching and C–O functional groups were also observed, confirming the structural integrity of the drug.

The obtained FTIR spectrum matched the reported reference spectrum of Atogepant, indicating that the drug sample retained its chemical identity without any detectable degradation or impurity. These findings confirmed the suitability of the API for subsequent RP-HPLC method development. [17-18]

Table 5. FTIR Peak Assignment of Atogepant

Wavenumber (cm^{-1})	Functional Group	Interpretation
3328	N–H stretching	Secondary amine
2925	C–H stretching	Aliphatic group
1712	C=O stretching	Carbonyl group
1604	Aromatic C=C stretching	Aromatic ring
1512	C=C vibration	Aromatic nucleus
1265	C–N stretching	Amine group
1118	C–O stretching	Ether linkage
755	Aromatic C–H bending	Aromatic substitution

Selection of Detection Wavelength

The UV spectrum of Atogepant was recorded between 200 and 400 nm to determine the optimum detection wavelength for chromatographic analysis. The drug exhibited maximum absorbance (λmax) at 280 nm, which provided the highest analytical response and good sensitivity. [19-20]

Therefore, 280 nm was selected as the detection wavelength for all chromatographic analyses during method development and validation.

Selection of Mobile Phase

Different mobile phase compositions containing methanol and water were investigated to obtain satisfactory peak symmetry, retention time, and system suitability. Three preliminary trials were performed. [21-22]

- Trial 1 (Methanol:Water, 70:30 v/v): Broad peak with poor symmetry.
- Trial 2 (Methanol:Water, 75:25 v/v): Improved peak shape, but tailing was still observed.
- Trial 3 (Methanol:Water, 80:20 v/v): Produced a sharp, symmetrical peak with acceptable retention time and system suitability parameters.

Based on these observations, Methanol:Water (80:20, v/v) was selected as the optimized mobile phase for further validation studies.

Method Development and Optimization of RP-HPLC Method

The RP-HPLC method was systematically optimized by evaluating different chromatographic conditions to obtain a sharp, symmetrical, and well-resolved Atogepant peak within a short analysis time. Various mobile phase compositions consisting of methanol and water were investigated while maintaining a C18 analytical column (250 × 4.6 mm, 5 µm) under isocratic elution.

Optimization of Mobile Phase

Three mobile phase compositions were evaluated during method development. The chromatographic performance of each trial was assessed based on peak symmetry, retention time, theoretical plate count, and tailing factor.[23-24]

Table 6. Optimization of Mobile Phase

Trial	Mobile Phase (v/v)	Observation
Trial 1	Methanol : Water (70:30)	Broad peak with poor symmetry and lower resolution
Trial 2	Methanol : Water (75:25)	Improved peak shape but slight peak tailing was observed
Trial 3	Methanol : Water (80:20)	Sharp, symmetrical peak with acceptable system suitability parameters

Among the investigated mobile phase compositions, Methanol:Water (80:20, v/v) produced the best chromatographic performance. The chromatogram showed a sharp and symmetrical peak with satisfactory peak shape, good resolution, and a retention time of approximately 5.0 min. Therefore, this composition was selected as the optimized mobile phase for further validation studies.

Optimization of Flow Rate

Different flow rates were investigated to achieve optimum chromatographic separation. A flow rate of 0.8 mL/min provided the best balance between retention time, peak symmetry, and system suitability. Lower flow rates increased the analysis time, whereas higher flow rates resulted in reduced resolution. Therefore, 0.8 mL/min was selected for subsequent analyses.

Selection of Detection Wavelength

The UV absorption spectrum of Atogepant was recorded over the range of 200–400 nm. The drug exhibited maximum absorbance at 280 nm, which provided higher detector response and better sensitivity. Hence, 280 nm was selected as the detection wavelength throughout the study. [25-26]

Optimized Chromatographic Conditions

The optimized chromatographic conditions established for quantitative estimation of Atogepant are summarized below.

Table 7. Optimized Chromatographic Conditions

Parameter	Optimized Condition
Column	C18 (250 × 4.6 mm, 5 µm)

Mobile Phase	Methanol : Water (80:20, v/v)
Elution Mode	Isocratic
Flow Rate	0.8 mL/min
Detection Wavelength	280 nm
Injection Volume	10 µL
Retention Time	Approximately 5.0 min
Run Time	10 min

The optimized chromatographic conditions provided a well-resolved Atogepant peak with excellent reproducibility and acceptable system suitability parameters, making the method suitable for validation and routine quality control analysis.[28]

III. RESULT AND DISCUSSION

Color, Oduor and Appearance

The colour, odour and appearance of the drug were determined by visual observation.

Table No.8 : Physical Properties of Drug

Sr. No	Name	Colour, Odour and Appearance of Drug
1	Atogepant	Yellow, odourless and amorphous powder

Solubility Study

The solubility of Atogepant was determined in various solvents at room temperature.

Table No. 9: Solubility Study of Atogepant

Sr. No	Solvent	Solubility
1	Water	Practically insoluble
2	Methanol	Freely soluble
3	Methanol	Soluble
4	Buffer	Slightly soluble

Selection of Solvent

Based on the solubility study, Methanol was selected as the solvent for dissolving Atogepant during method development and validation.[29-30] Atogepant was found to be freely soluble in Methanol, producing clear and stable solutions suitable for analytical purposes. Hence, Methanol was used as the primary solvent and diluent throughout the experimental work.

Spectra of Atogepant

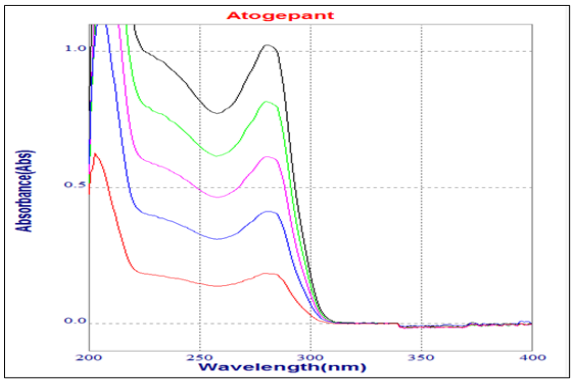


Figure No.1 overlay Spectra of Atogepant

The Spectra of Atogepant was found to be 220 nm Water –Methanol by using UV-visible spectroscopy

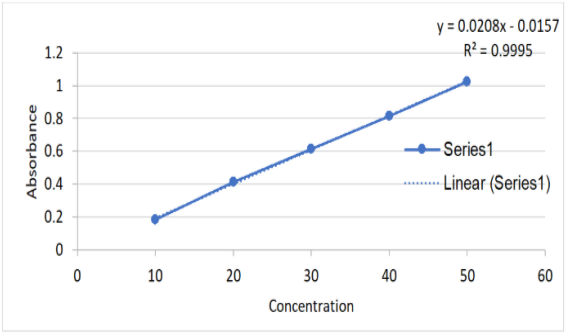


Figure .No 2 Linerity Plot for the UV Atogepant

IDENTFICATION OF API'S BY FTIR

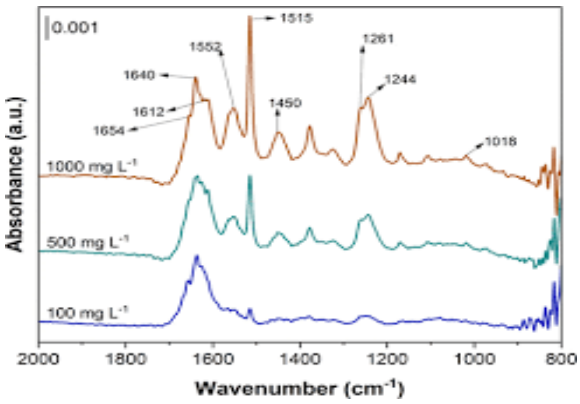


Figure No. 3 IR spectra of Atogepant API

The FT-IR spectrum of Atogepant showed all the characteristic absorption bands corresponding to its chemical structure. The presence of N–H stretching, carbonyl (C=O) stretching, aromatic C=C stretching, and nitro ($–NO_2$) group vibrations confirm the functional groups expected in the Atogepant molecule.

The observed peaks are in good agreement with reported literature values, indicating that the drug sample is pure and structurally intact.

The FT-IR spectral analysis confirms the identity of Atogepant by exhibiting characteristic peaks corresponding to its functional groups. Hence, FT-IR spectroscopy serves as a reliable tool for the preliminary characterization and identification of Atogepant.

Method Development by RP – HPLC

Optimization of HPLC Method

During method development, various chromatographic conditions were optimized in order to obtain a sharp, symmetric peak of Atogepant with acceptable system suitability parameters. The optimized chromatographic conditions selected for the analysis are summarized below.

Optimized Chromatographic Conditions

Table No. 10: Optimized Chromatographic Study

Parameter	Description
Mode	Isocratic
Column Name	Phenomenex ODS 3, 250 mm × 4.6 mm ID, 5 µm
Detector	UV Detector
Injection Volume	20 µL
Wavelength	280 nm
Column Oven Temperature	35 °C
Mobile Phase	Methanol : Water (80 : 20 v/v)
Flow Rate	0.8 mL/min
Run Time	06 minutes

VALIDATION OF RP-HPLC METHOD

Trial-1

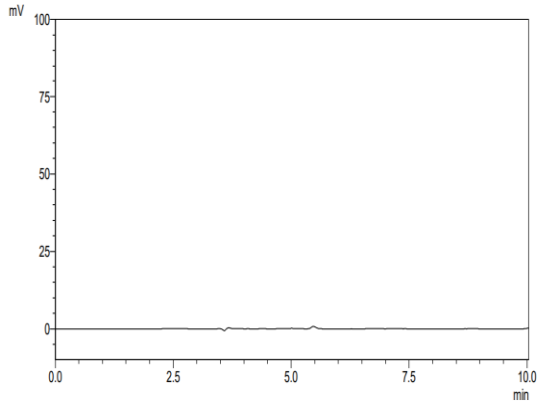


Figure No.4 Trial 1 Blank

A blank run was performed using Methanol: Water (80:20 v/v) as mobile phase. No interfering peak was observed at the retention time of Atogepant, confirming the specificity of the method.

Trial -2

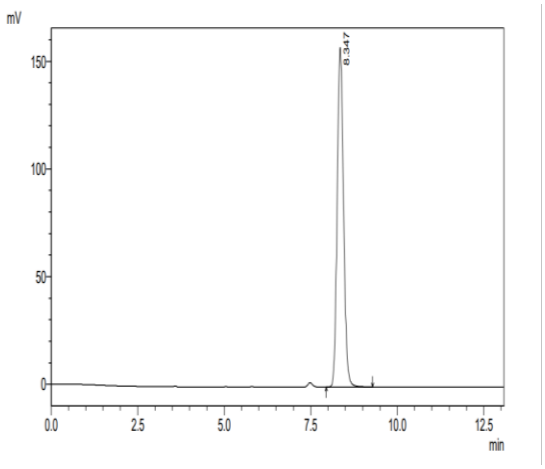


Figure No 5 . Trial-2

Trial -3

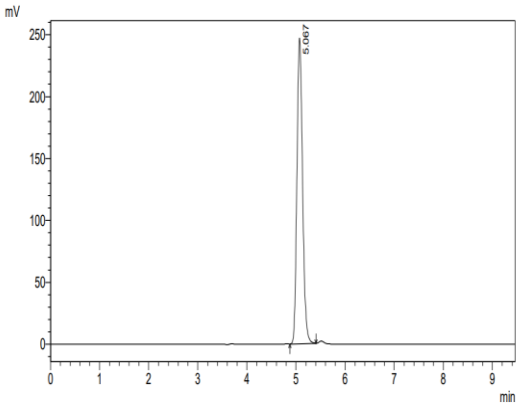


Figure No 6. Trial-3

Trial-4

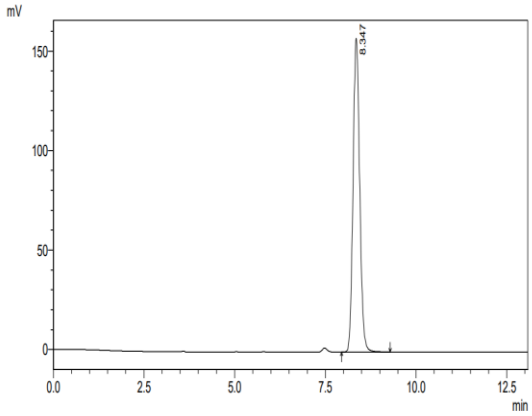


Figure No.7.Trial 4

SYSTEM SUITABILITY

Table No.11: Results for System Suitability Test of Atogepant

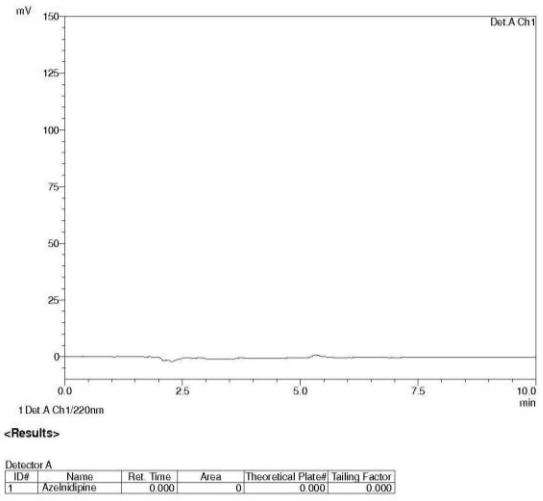
Parameter	Value
Sample Name	Atogepant 50 ppm Pro-02
Mobile Phase	Methanol : Water (80 : 20 v/v)
Mode	Isocratic
Column	Phenomenex ODS C18 (250 × 4.6 mm, 5 µm)
Flow Rate	0.8 mL/min
Detection Wavelength	280 nm
Injection Volume	20 µL
Run Time	6 minutes
Operating Pressure	10–11 MPa
Retention Time (RT)	5.07 min
Peak Area	1,996,266
Peak Height	~173,000
Theoretical Plates (N)	8,622.94
Tailing Factor	1.21
Resolution	0.00

Acceptance Criteria:

Placebo and Blank should not interfere in the main peak of the Atogepant .

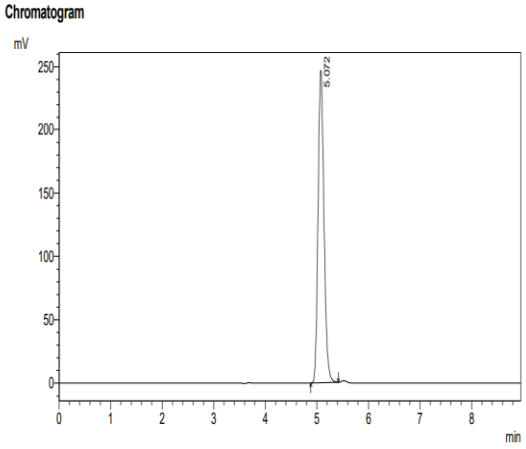
Conclusion

There is no interference from of Blank with the main peak of the Atogepant in the standard & sample solution



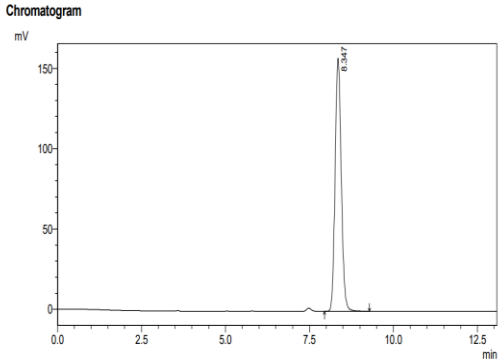
ID#	Name	Ret. Time	Area	Theoretical Plate#	Tailing Factor
1	Azelnidipine	0.000	0	0.000	0.000

Figure No.8 Chromatogram of Specificity Blank



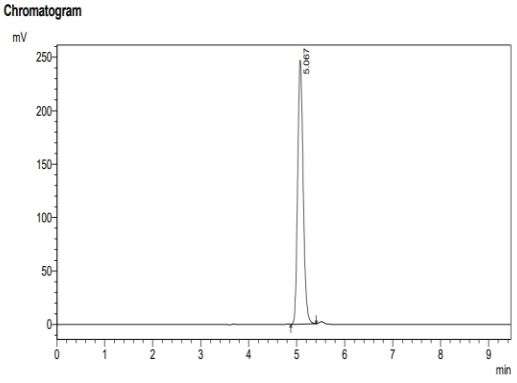
Peak #	Ret. Time	Area	Resolution	Theoretical Plate#	Tailing Factor
1	5.072	1996266	0.000	8622.943	1.215

Figure No.9 Chromatogram of Specificity Standard



Peak #	Ret. Time	Area	Resolution	Theoretical Plate#	Tailing Factor
1	8.347	2012943	0.000	9620.147	1.138

Figure No 10 Chromatogram of Specificity Standard 2



Peak #	Ret. Time	Area	Resolution	Theoretical Plate#	Tailing Factor
1	5.067	1983142	0.000	8672.674	1.214

Figure No11. Chromatogram of Specificity Standard 3

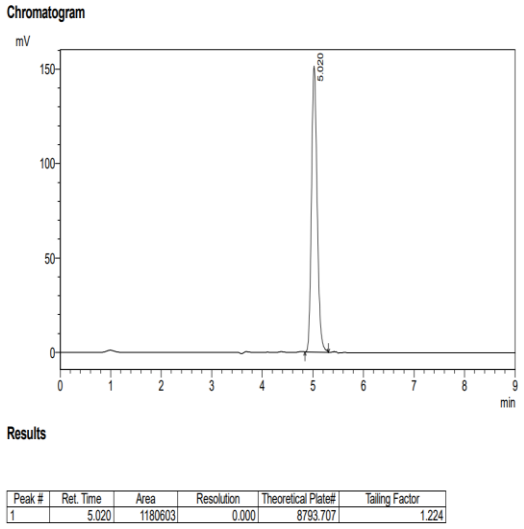


Figure No.12 Chromatogram of Specificity Sample 1

Linearity and Range: Linearity Sample Stock Solution:
Dissolve accurately 8mg of Atogepant in 100ml volumetric flask and add 50ml of Methanol sonicate for 10 minutes and makeup the volume with Water. Further dilute 5ml of above solution to 50ml with Methanol

Linearity Solutions:
Linearity Solution (10ppm Atogepant): Further dilute 4.0ml of standard to 50 ml with
Methanol.
Linearity Solution (20ppm Atogepant): Further dilute 4.5ml of standard to 50 ml with
Methanol.
Linearity Solution (30ppm Atogepant): Further dilute 5.0ml of standard to 50 ml with
Methanol.
Linearity Solution (40ppm Atogepant): Further dilute 5.5ml of standard to 50 ml with
Methanol.
Linearity Solution (50ppm Atogepant): Further dilute 6.0ml of standard to 50 ml with
Methanol

Acceptance Criteria:
The limit for coefficient of correlation for the standard curve must not be less than 0.9900.
Precision:
Precision is a measurement of degree of Reproducibility of analytical method and it will be expressed in terms of % relative standard for the area and retention time of Solution prepared.
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.

Table No.12 Result of Atogepant test sample assay (For Standard Preparation)

Interday			Standard Deviation		Accuracy	Precision
Event	Conc. (ppm)	Area (Units)	Mean	SD	%SD	%RSD
	30	1181681				0.2156805562
Day 1	30	1169844	1175463	5941.240808	0.505438495	
	30	1174863				
	30	1182782				
Day 2	30	1183090	1181572	2368.107331	0.200420118	
	30	1178843				

%RSD should not be more than 2.0 % for area and RT. Theoretical plate should be NLT
2000,Tailing Factor should NMT 2.0.

Table No.13 Result of Atogepant test sample assay (For Sample Preparation)

Intraday			Standard Deviation		Accuracy	Precision
Event	Conc. (ppm)	Area (Units)	Mean	SD	%SD	%RSD
	30	1181681				0.072275728
Mo	30	1169	11	5941	0.50	

rning		844	7546 3	.240 808	5438 495	
	30	1174 863				
	30	1177 626				
Evening	30	1170 790	1176 106	4742 .355 533	0.40 3225 18	
	30	1179 902				

Acceptance Criteria:
%RSD for %Assay should not be more than 2.0% Atogepant content in Tablet should be within limits (NLT 90% to NMT 110%)
Accuracy / Recovery:
The accuracy of an analytical method is defined as the closeness between the observed values with actual or true value for a specific concentration. Accuracy - closeness to the true value, measured by % recovery of sample spikes or % error in the analysis of a reference sample

Table No.14: Result and statistical data of Accuracy of Atogepant

Atogepant			Standard Deviation		Accuracy	Precision
Sr. No.	Conc. (ppm)	Area (Units)	Mean	SD	%SD	%RSD
	10	391619				
1	10	395321	392840.3333	2148.404369	0.54688997	
	10	391581				
	30	1181681				
2	30	1169844	1175462.667	5941.240808	0.50543849	0.106992909
	30	1174863				
	50	2023004				
3	50	2018409	2024506.667	6971.535436	0.34435725	
	50	2032107				

Acceptance Criteria:
%RSD for %Recovery should not be more than 2.0 %.
%Recovery should be between 98.0% to 102.0% for individual and for all level

Table 15 :% Recovery by Solutions

Sr. NO.	% Composition	Area of Standard (Area Units)	Area of Sample (Area Units)	% Recovery (%)	Conc. Taken (ppm)	Conc. Found (ppm)
1	50% Recovery	1181681	1186132	100.3766668	30	30.11300004
2	100% Recovery	1582285	1569636	99.20058649	40	39.68023 46
3	150% Recovery	2023004	2012011	99.45660018	50	49.72830009

Robustness: Determination: Take various samples and analyze it using different PH, different Wavelength as shown in table:

Table No.16: Result of Robustness study: Change in pH

Sr. No.	Conc. (ppm)	Area (Units)	Mean	SD	%SD
1	20	755671			
2	20	759231	757789.333	1873.9819	0.2472959
3	20	758466			

Table No.17 Result of Robustness study: Change in Wavelength

Sr. No.	Conc. (ppm)	Area (Units)	Mean	SD	%SD
1	20	755671			
2	20	758023	756604	1249.0488	0.16508621
3	20	756118			

Table no.18:Results of Solution stability.

Sr. NO.	Degradation	Absorbance of Standard (Units)	Absorbance of degraded Sample (Units)	Degraded upto %	Actual % degradation	Concentration of drug after degtadation
1	Acid Degradation	1.0235	0.9507	92.88715193	7.112848 07	46.46153846
2	Base Degradation	1.0235	0.877	85.6863703	14.31362 97	42.91826923
3	H2O2 Degradation	1.0235	0.9176	89.65315095	10.34684905	44.87019231
4	Photolytic Degradation	1.0235	0.9942	97.13727406	2.862725 94	48.55288462
5	Thermal Degradation	1.0235	0.9942	97.13727406	2.862725 94	48.55288462

Acceptance Criteria:
%Assay difference should not be more than 2.0 %

IV. DISCUSSION

The forced degradation study confirmed that the developed RP-HPLC method is capable of selectively quantifying Atogepant in the presence of degradation products. Greater degradation under alkaline and oxidative stress indicates that the drug is comparatively more susceptible to these conditions, whereas minimal degradation under thermal and photolytic stress demonstrates good stability against heat and light exposure. The clear separation between the analyte peak and degradation products confirmed the specificity and stability-indicating capability of the developed method, supporting its application in routine stability studies and quality control analysis.

V. CONCLUSION

A simple, rapid, accurate, precise, and robust RP-HPLC method was successfully developed and validated for the quantitative estimation of Atogepant in bulk drug and tablet dosage forms. Optimization of the chromatographic conditions using Methanol:Water (80:20, v/v) as the mobile phase, a C18 column (250 × 4.6 mm, 5 µm), a flow rate of 0.8 mL/min, and UV detection at 280 nm resulted in a well-resolved and symmetrical chromatographic peak with a retention time of approximately 5.0 min, enabling rapid and reproducible analysis.

The developed analytical method fulfilled all validation requirements specified in ICH Q2(R1) guidelines. The method exhibited excellent specificity,

with no interference from formulation excipients or degradation products. The calibration curve showed excellent linearity over the selected concentration range with a correlation coefficient close to unity. Precision and intermediate precision studies produced %RSD values within the acceptable limit (<2%), confirming the reproducibility of the method. Recovery studies demonstrated percentage recoveries close to 100%, indicating high analytical accuracy. Robustness testing confirmed that small deliberate variations in chromatographic conditions did not significantly affect analytical performance, while solution stability studies demonstrated that standard and sample solutions remained stable for at least 24 h under normal laboratory conditions.

The forced degradation studies further established the stability-indicating capability of the developed method. Atogepant showed maximum degradation under alkaline conditions (14.31%) followed by oxidative (10.35%) and acidic (7.11%) stress, whereas only minimal degradation was observed under thermal (2.86%) and photolytic (2.39%) conditions. The method effectively resolved the Atogepant peak from degradation products, confirming its applicability for stability studies.

Overall, the developed RP-HPLC method is reliable, economical, sensitive, and suitable for routine quantitative estimation of Atogepant in bulk drug and pharmaceutical dosage forms. Its excellent validation characteristics and short analysis time make it highly applicable for routine quality control analysis, stability testing, and pharmaceutical research laboratories

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