International Journal of Multidisciplinary Research and Growth Evaluation.

Development and Validation of a New Analytical Rp-Hplc Method for the Estimation of Acotiamide in API form and Marketed Tablet Dosage form

Tayabba Mahtab [1*], C Srija [2], M Akshitha [3], M Rishi Kumar [4], V Shivani [5]
[1] Department of Pharmaceutical Analysis, Bhaskar Pharmacy College, Moinabad, R.R. District, Telangana, India, 500075
[2-5] Research scholar, Bhaskar Pharmacy College, Moinabad, R.R. District, Telangana, India, 500075

* Corresponding Author: **Tayabba Mahtab**

Article Info

ISSN (Online): 2582-7138
Impact Factor (RSIF): 7.98
Volume: 07
Issue: 01
Received: 10-11-2025
Accepted: 12-12-2025
Published: 14-01-2026
Page No: 441-448

Abstract
A new analytical simple, rapid, precise, accurate and reproducible RP-HPLC method for estimation of Acotiamide in bulk form and marketed pharmaceutical dosage forms. Separation of Acotiamide was successfully achieved on a Hypersil ODS C_{18} (4.6mm x 250mm, 5µm) column in an isocratic mode of separation utilizing Methanol: Water in the ratio of 60:40% v/v at a flow rate of 1.0 mL/min and the detection was carried out at 272nm. The method was validated according to ICH guidelines for linearity, sensitivity, accuracy, precision, specificity and robustness. The response was found to be linear in the drug concentration range of 10-50mcg/mL for Acotiamide. The correlation coefficient was found to be 0.999 for Acotiamide. The LOD and LOQ for Acotiamide were found to be 1.1µg/mL and 3.2µg/mL respectively. The proposed method was found to be good percentage recovery for Acotiamide, which indicates that the proposed method is highly accurate. The specificity of the method shows good correlation between retention times of standard solution with the sample solution. Therefore, the proposed method specifically determines the analyte in the sample without interference from excipients of pharmaceutical dosage forms.

DOI: https://doi.org/10.54660/.IJMRGE.2026.7.1.441-448

Keywords: Acotiamide, RP-HPLC, Accuracy, Precision, Robustness, ICH Guidelines

1. Introduction

Acotiamide is a gastroprokinetic drug used primarily for the treatment of Functional Dyspepsia (FD), Postprandial Distress Syndrome (PDS) type. It works by enhancing gastric motility and improving delayed stomach emptying. Acotiamide is a prescription medication primarily used for the treatment of functional dyspepsia (indigestion), a chronic digestive condition that causes upper abdominal discomfort with no obvious underlying cause. Acotiamide has been used in trials studying the treatment of Dyspepsia and Functional Dyspepsia. Acotiamide, sold under the brand names Acofide, and Dyspevict is a medication manufactured and approved in Japan and Russia for the treatment of postprandial fullness, upper abdominal bloating, and early satiation due to functional dyspepsia. It acts as an acetylcholinesterase inhibitor. The IUPAC Name of Acotiamide is N-{2-[bis (1-Methyl ethyl) amino] ethyl}-2-{[(2-hydroxy-4, 5-dimethoxy phenyl) carbonyl] amino}-1, 3-thiazole-4-carboxamide. The Chemical Structure of Acotiamide is shown in follows

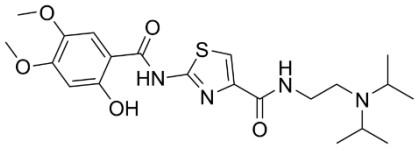

Fig 1: Chemical Structure of Acotiamide

Experimental

Instruments Used

Table 1: Instruments Used

S.No.	Instruments and Glass wares	Model
1	HPLC	WATERS Alliance 2695 separation module, Software: Empower 2, 996 PDA Detector.
2	pH meter	Labindia
3	Weighing machine	Sartorius
4	Volumetric flasks	Borosil
5	Pipettes and Burettes	Borosil
6	Beakers	Borosil
7	Digital Ultra Sonicator	Labman

Chemicals Used

Table 2: Chemicals Used

S.No.	Chemical	Providers
1	Acotiamide (Pure)	Synpharma Research Lab, Hyderabad
2	Water and Methanol for HPLC	LICHROSOLV (MERCK)
3	Acetonitrile for HPLC	Merck

HPLC Method Development:

Preparation of Standard Solution:

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

Further pipette 0.3ml of the above Acotiamide stock solutions into a 10ml volumetric flask and dilute up to the mark with Methanol.

Preparation of Sample Solution:

Take average weight of the Powder and weight 10 mg equivalent weight of Acotiamide sample into a 10mL clean dry volumetric flask and add about 7mL of Diluent and sonicate to dissolve it completely and make volume up to the mark with the same solvent.

Further pipette 0.3ml of the above Acotiamide 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 [32-33].

Mobile Phase Optimization:

Initially the mobile phase tried was methanol: Water and ACN: Water with varying proportions. Finally, the mobile phase was optimized to Methanol: Water 60:40% v/v respectively.

Optimization of Column:

The method was performed with various C18 columns like Symmetry, Zodiac and Xterra. Hypersil ODS C18 (4.6 x 250mm, 5µm) Column was found to be ideal as it gave good peak shape and resolution at 1ml/min flow.

Preparation of Mobile Phase:

Accurately measured 600 ml (60%) of HPLC Methanol and 400 ml of Water (40%) were mixed and degassed in a digital ultra sonicater for 15 minutes and then filtered through 0.45 µ filter under vacuum filtration [4].

Diluent Preparation:

The Mobile phase was used as the diluent.

Method Validation Parameters

System Suitability

Accurately weigh and transfer 10 mg of Acotiamide working standard into a 10ml of clean dry volumetric flasks add about 7mL of Diluents and sonicate to dissolve it completely and make volume up to the mark with the same solvent. (Stock solution)

Further pipette 0.3ml of the above Acotiamide stock solutions into a 10ml volumetric flask and dilute up to the mark with Methanol.

Procedure:

The standard solution was injected for five times and measured the area for all five injections in HPLC. The %RSD for the area of five replicate injections was found to be within the specified limits [5].

Specificity Study of Drug:

Preparation of Standard Solution:

Accurately weigh and transfer 10 mg of Acotiamide working standard into a 10ml of clean dry volumetric flasks add about 7ml of Diluents and sonicate to dissolve it completely and make volume up to the mark with the same solvent. (Stock solution)

Further pipette 0.3ml of the above Acotiamide stock solutions into a 10ml volumetric flask and dilute up to the mark with Methanol.

Preparation of Sample Solution:

Take average weight of the Powder and weight 10 mg equivalent weight of Acotiamide sample into a 10mL clean dry volumetric flask and add about 7mL of Diluent and sonicate to dissolve it completely and make volume up to the mark with the same solvent.

Further pipette 0.3ml of the above Acotiamide stock solutions into a 10ml volumetric flask and dilute up to the mark with

Methanol.

Procedure:

Inject the five replicate injections of standard and inject the three replicate injections sample solutions and calculate the assay by using formula [6]:

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

Preparation of Drug Solutions for Linearity:
Accurately weigh and transfer 10 mg of Acotiamide working standard into a 10ml of clean dry volumetric flasks add about 7ml of Diluents and sonicate to dissolve it completely and make volume up to the mark with the same solvent. (Stock solution)

Preparation of Level – I (10ppm of Acotiamide):
Take 0.1ml of stock solution in to 10ml of volumetric flask and make up the volume up to mark with diluent.

Preparation of Level – II (20ppm of Acotiamide):
Take 0.2ml of stock solution in to 10ml of volumetric flask and make up the volume up to mark with diluent [7].

Preparation of Level – III (30ppm of Acotiamide):
Take 0.3ml of stock solution in to 10ml of volumetric flask and make up the volume up to mark with diluent.

Preparation of Level – IV (40ppm of Acotiamide):
Take 0.4ml of stock solution in to 10ml of volumetric flask and make up the volume up to mark with diluent.

Preparation of Level – V (50ppm of Acotiamide):
Take 0.5ml of stock solution in to 10ml of volumetric flask and make up the volume up to mark with diluent.

Procedure:
Inject each level into the chromatographic system and measure the peak area [8].
Plot a graph of peak area versus concentration (on X-axis concentration and on Y-axis Peak area) and calculate the correlation coefficient [9].

Precision
Repeatability
Preparation of Acotiamide Product Solution for Precision:
Accurately weigh and transfer 10 mg of Acotiamide working standard into a 10ml of clean dry volumetric flasks add about 7ml of Diluents and sonicate to dissolve it completely and make volume up to the mark with the same solvent. (Stock solution)
Take 0.3ml of stock solution in to 10ml of volumetric flask and make up the volume up to mark with diluent.
The standard solution was injected for six times and measured the area for all six injections in HPLC. The %RSD for the area of six replicate injections was found to be within the specified limits [10].

Intermediate Precision:
To evaluate the intermediate precision (also known as Ruggedness) of the method, Precision was performed on different days by maintaining same conditions.

Procedure:
Analyst 1:
The standard solution was injected for six times and measured the area for all six injections in HPLC. The %RSD for the area of six replicate injections was found to be within the specified limits.

Analyst 2:
The standard solution was injected for six times and measured the area for all six injections in HPLC. The %RSD for the area of six replicate injections was found to be within the specified limits [11].

Accuracy:
For Preparation of 50% Standard Stock Solution:
Accurately weigh and transfer 10 mg of Acotiamide working standard into a 10ml of clean dry volumetric flasks add about 7mL of Diluents and sonicate to dissolve it completely and make volume up to the mark with the same solvent. (Stock solution)
Take 0.15ml of stock solution in to 10ml of volumetric flask and make up the volume up to mark with diluent.

For Preparation of 100% Standard Stock Solution:
Accurately weigh and transfer 10 mg of Acotiamide working standard into a 10ml of clean dry volumetric flasks add about 7mL of Diluents and sonicate to dissolve it completely and make volume up to the mark with the same solvent. (Stock solution)
Take 0.3ml of stock solution in to 10ml of volumetric flask and make up the volume up to mark with diluent.

For Preparation of 150% Standard Stock Solution:
Accurately weigh and transfer 10 mg of Acotiamide working standard into a 10ml of clean dry volumetric flasks add about 7mL of Diluents and sonicate to dissolve it completely and make volume up to the mark with the same solvent. (Stock solution)
Take 0.45ml of stock solution in to 10ml of volumetric flask and make up the volume up to mark with diluent.

Procedure:
Inject the Three replicate injections of individual concentrations (50%, 100%, 150%) were made under the

optimized conditions. Recorded the chromatograms and measured the peak responses. Calculate the Amount found and Amount added for Acotiamide and calculate the individual recovery and mean recovery values [12].

Robustness:
The analysis was performed in different conditions to find the variability of test results. The following conditions are checked for variation of results.

For Preparation of Standard Solution:
Accurately weigh and transfer 10 mg of Acotiamide working standard into a 10ml of clean dry volumetric flasks add about 7mL of Diluents and sonicate to dissolve it completely and make volume up to the mark with the same solvent. (Stock solution)
Take 0.3ml of stock solution in to 10ml of volumetric flask and make up the volume up to mark with diluent.

Effect of Variation of Flow Conditions:
The sample was analyzed at 0.9ml/min and 1.1ml/min instead of 1ml/min, remaining conditions are same. 20µl of the above sample was injected and chromatograms were recorded [13].

Effect of Variation of Mobile Phase Organic Composition:
The sample was analyzed by variation of mobile phase i.e. Methanol: Water was taken in the ratio and 65:35, 55:45 instead of 60:40, remaining conditions are same. 20µl of the above sample was injected and chromatograms were recorded.

Results and Discussion
Development of Analytical Method:
Optimized Chromatographic Condition:

Column	:	Hypersil ODS C18 (4.6 x 250mm, 5µm)
Column temperature	:	Ambient
Wavelength	:	272 nm
Mobile phase ratio (60:40% v/v)	:	Methanol: Water
Flow rate	:	1.0mL/min
Injection volume	:	20 µl
Run time	:	8 minutes

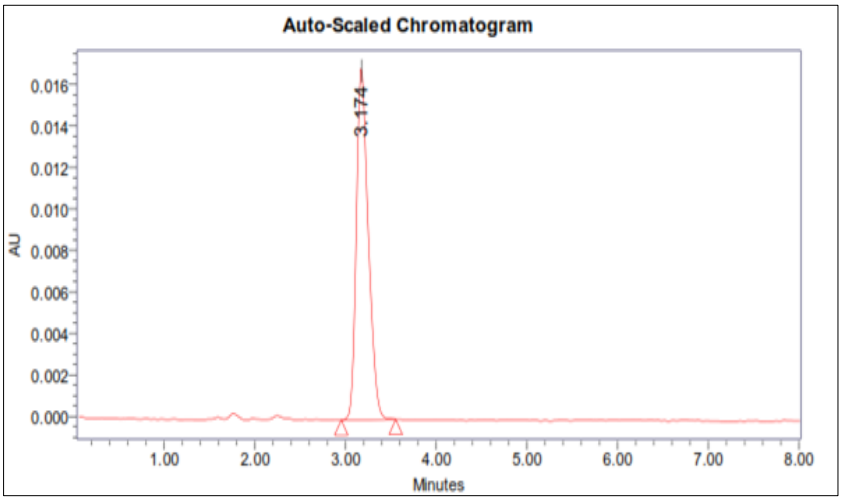

Fig 2: Optimized Chromatographic Condition

Analytical Method Validation:
The developed method was validated as per ICH guidelines in terms of specificity, linearity, accuracy, precision, limits of detection (LOD) and quantification (LOQ) and system suitability[32-33].

System Suitability:

Table 3: Results of System Suitability for Acotiamide

S.No.	Peak Name	RT	Area (µV*sec)	Height (µV)	USP Plate Count	USP Tailing
1	Acotiamide	3.192	225645	20584	6286	1.38
2	Acotiamide	3.146	225847	20965	6358	1.39
3	Acotiamide	3.123	228656	20758	6285	1.41
4	Acotiamide	3.167	228547	20859	6278	1.40
5	Acotiamide	3.158	229658	20968	6395	1.42
Mean			227670.6			
Std. Dev.			1810.899			
% RSD			0.795403			

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 [14-16].
Analytical method was tested for specificity to measure accurately quantitates Acotiamide in drug product.

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

= 99.24%

The % purity of Acotiamide in pharmaceutical dosage form was found to be 99.24%.

Linearity

Chromatographic Data for Linearity Study:

Table 4: Data for Linearity

Concentration µg/ml	Average Peak Area
10	78683
20	146545
30	213584
40	279895
50	346568

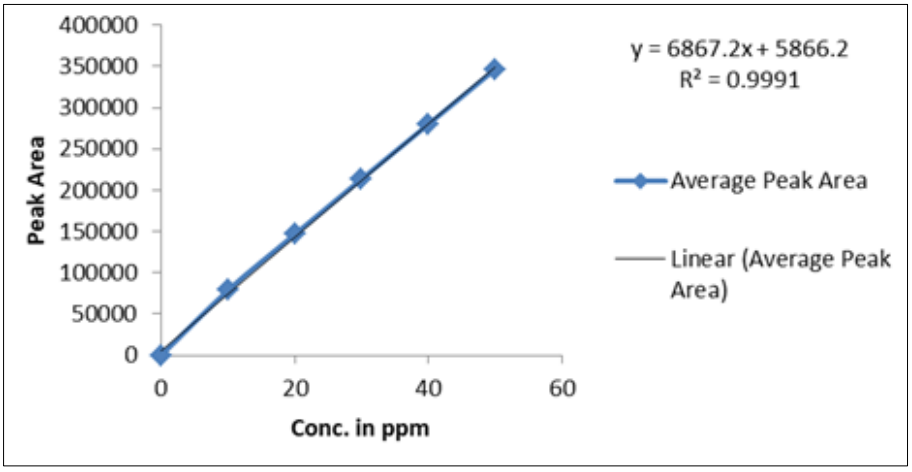

Fig 3: Calibration Curve of Acotiamide

Linearity Plot: The plot of Concentration (x) versus the Average Peak Area (y) data of Acotiamide is a straight line.
Y = mx + c
Slope (m) =6867
Intercept (c) = 5866
Correlation Coefficient (r) = 0.99

Validation Criteria: The response linearity is verified if the Correlation Coefficient is 0.99 or greater [17].

Conclusion: Correlation Coefficient (r) is 0.99, and the intercept is 5866. 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 [18-19].

Repeatability: Obtained Six (6) replicates of 100% accuracy solution as per experimental conditions. Recorded the peak areas and calculated % RSD.

Table 5: Results of Method Precision for Acotiamide:

S. No.	Peak name	Retention time	Area (µV*sec)	Height (µV)	USP Plate Count	USP Tailing
1	Acotiamide	3.165	225645	20562	6125	1.36
2	Acotiamide	3.163	225847	20645	6129	1.36
3	Acotiamide	3.158	226542	20534	6135	1.35
4	Acotiamide	3.167	226598	20564	6189	1.36
5	Acotiamide	3.171	226584	20549	6138	1.35
6	Acotiamide	3.181	226859	20685	6179	1.37
Mean			226345.8			
Std. Dev			482.1068			
%RSD			0.212996			

Intermediate Precision:
Analyst 1:

Table 6: Results of Ruggedness for Acotiamide

S.No.	Peak Name	RT	Area (µV*sec)	Height (µV)	USP Plate Count	USP Tailing
1	Acotiamide	3.165	226534	20653	6235	1.35
2	Acotiamide	3.163	226542	20598	6198	1.36
3	Acotiamide	30158	225989	20653	6254	1.36
4	Acotiamide	3.167	226512	20548	6281	1.35
5	Acotiamide	3.171	226531	20653	6199	1.36
6	Acotiamide	3.171	225898	20658	6253	1.35
Mean			226334.3			
Std. Dev.			304.2622			
% RSD			0.13443			

Analyst 2:

Table 7: Results of Intermediate Precision Analyst 2 for Acotiamide

S.No.	Peak Name	RT	Area (µV*sec)	Height (µV)	USP Plate count	USP Tailing
1	Acotiamide	3.173	225487	20542	6253	1.35
2	Acotiamide	3.134	225484	20532	6098	1.36
3	Acotiamide	3.161	225364	20541	6254	1.35
4	Acotiamide	3.174	226513	20534	6235	1.36
5	Acotiamide	3.199	225487	20549	6199	1.36
6	Acotiamide	3.199	226532	20451	6235	1.35
Mean			225811.2			
Std. Dev.			553.0524			
% RSD			0.244918			

Accuracy:
Accuracy at different concentrations (50%, 100%, and 150%) was prepared and the % recovery was calculated [20-22].

Table 8: The Accuracy Results for Acotiamide

%Concentration (at specification Level)	Area	Amount Added (ppm)	Amount Found (ppm)	% Recovery	Mean Recovery
50%	109283.3	15	15.060	100.40%	100.42%
100%	212732	30	30.124	100.413%	
150%	316263.3	45	45.201	100.446%	

Limit of Detection for Acotiamide
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 [23].

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

Where
σ = Standard deviation of the response
S = Slope of the calibration curve

Result:
= 0.597µg/ml

Limit of Quantitation for Acotiamide
The quantitation limit of an individual analytical procedure is the lowest amount of analyte in a sample which can be quantitatively determined [24].

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

Where
σ = Standard deviation of the response
S = Slope of the calibration curve

Result:
= 1.811µg/ml

Table 9: Results of LOD and LOQ

SE of Intercept	556.1832432
SD of Intercept	1243.66354
LOD	0.597636545
LOQ	1.811019833

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 Acotiamide [25-27]. 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 Acotiamide were injected by changing the conditions of chromatography. There was no significant change in the parameters like resolution, tailing factor, asymmetric factor, and plate count [28-31].

Table 10: Results for Robustness

Parameter used for Sample Analysis	Peak Area	Retention Time	Theoretical Plates	Tailing Factor
Actual Flow rate of 1.0 mL/min	225645	3.155	6125	1.36
Less Flow rate of 0.9 mL/min	236586	3.488	6452	1.38
More Flow rate of 1.1 mL/min	219865	2.877	6098	1.42
Less organic phase	235848	4.705	6126	1.43
More organic phase	241245	2.090	6324	1.39

Summary and Conclusion

The analytical method was developed by studying different parameters. First of all, maximum absorbance was found to be at 272nm and the peak purity was excellent. Injection volume was selected to be 20µl which gave a good peak area. The column used for study was Hypersil ODS C_{18} (4.6mm x 250mm, 5µm) because it was giving good peak. Ambient temperature was found to be suitable for the nature of drug solution. The flow rate was fixed at 1.0ml/min because of good peak area and satisfactory retention time. Mobile phase is Methanol: Water (60:40% v/v) was fixed due to good symmetrical peak. So this mobile phase was used for the proposed study. Run time was selected to be 8.0min because analyze gave peak around 3.174min and also to reduce the total run time. The percent recovery was found to be 98.0-102 was linear and precise over the same range. Both system and method precision were found to be accurate and well within range. The analytical method was found linearity over the range of 10-50µg/ml of the Acotiamide target concentration. The analytical passed both robustness and ruggedness tests. On both cases, relative standard deviation was well satisfactory.

The method was validated in accordance with ICH guidelines. The method is robust enough to reproduce accurate and precise results under different chromatographic conditions. Hence the proposed RP-HPLC method proved to be simple, accurate and reproducible for the determination of Acotiamide in a reasonable run time. The method was validated showing satisfactory data for all the method validation parameters tested. The developed method can be conveniently used by quality control laboratories.

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How to Cite This Article

Mahtab T, Srija C, Akshitha M, Kumar MR, Shivani V. Development and validation of a new analytical RP-HPLC method for the estimation of acotiamide in API form and marketed tablet dosage form. Int J Multidiscip Res Growth Eval. 2026;7(1):441–448. doi:10.54660/IJMRGE.2026.7.1.441-448.

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