International Journal of Current Innovations in Advanced Research

(International Multidisciplinary Tri-annual Research Journal)

Content Available at www.ijciar.com ISSN (O) 2636-6282 ISSN (P) 2659-1553

DEVELOPMENT AND VALIDATION OF A GREEN UV - SPECTROPHOTOMETRIC METHOD FOR THE ESTIMATION OF ACOTIAMIDE IN TABLET DOSAGE FORM USING WATER AS A GREEN SOLVENT

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Received: 24 Mar 2026 Revised: 11 Apr 2026 Accepted: 03 May 2026

ABSTRACT

This study describes the Development And Validation of an eco -friendly UV-Spectrophotometric method for the estimation of acotiamide in tablet formulation in accordance with ICH Q2(R1) guidelines. The main aim of this study was to develop simple, accurate, precise and rapid, cost-effective validation method using water as an eco friendly solvent. Water was used as a green solvent to minimize the use of hazardous organic solvents and support a sustainable analytical approach. The method was validated for linearity, accuracy, precision, specificity, Robustness, Ruggedness LOD,LOQ.An eco-friendly uv spectrophotometric method used for estimation of acotiamide in tablet formulations. In this method the λmax of acotiamide was determined by scanning the standard solution over the wavelength range of 200-400nm .The standard and sample solutions were prepared and their absorbance was measured using uv spectrophotometer .Acotiamide exhibited maximum absorbance at 217nm. This method obeyed Beer – lambert's law and exhibits a good linearity over the concentration range of 3-11µg/ml with regression equation A = 0.0574C + 0.0836 And a correlation coefficient R^2 of 0.9999.The accuracy of method was evaluated by recovery studies the percentage recovery was found in the range of 99.0%-99.2 %and the method demonstrated good precison the %RSD values were found to be less than 2%. Based on the above results the eco friendly UV spectrophotometric validation method is suitable for routine quality control analysis. The developed method is suitable for routine quality control analysis and assay determination of acotiamide tablets.

Keywords: *Acotiamide; UV spectroscopy; Eco -friendly Analytical method; Green analytical chemistry; Method development and validation; ICH Q2(R1); Beer lambert law; Quality control.*

INTRODUCTION

Functional dyspepsia (FD) is a highly prevalent condition associated with a considerable burden on patients' quality of life as well as healthcare systems. The time consensus proposed to subdivided FD into postprandial distress syndrome (PDS), characterized by meal – related symptoms and epigastric pain syndrome, symptoms include epigastric pain, epigastric burning, postprandial fullness, vomiting, bleeding, previously there is no therapeutic agent had approved for treatment of this condition, Acotiamide is the first drug that introduces to treat this condition [1, 2].

The IUPAC Name of acotiamide is. N-[2-[bus(1-methylethyl) amino] ethyl]-2-[(2-hydroxy-4,5dimethoxybenzoyl) amino] thiazole-4-carboxamide. The molecular formula of acotiamide is $C_{21}H_{30}N_4O_4S$ (Figure -1) [1,3,4]. It is a prokinetic drug used in the management of functional dyspepsia. It's selectively inhibits acetylcholinesterase activity and acts as an antagonist at M1 and M2 muscarinic receptors, thereby enhancing acetylcholine release and improving gastric motility and accommodation. The drug is indicated for oral treatment of postprandial distress syndrome associated with functional dyspepsia [2,3].

There is a various analytical methods were developed for estimation of acotiamide in pharmaceutical formulations [3,4-6],among these up spectrophotometry method is simple and accurate, cost-effective and doesn't require complex sample preparation [3-5]. Literature survey reveals that there are only few analytical methods are developed on uv spectrophotometer so the present study focuses on the Development of simple, accurate, precise, and economical UV spectrophotometric method for the estimation of acotiamide in tablet dosage form by using water as a green solvent as per ICH Q2(R1) guidelines [7,11,13].

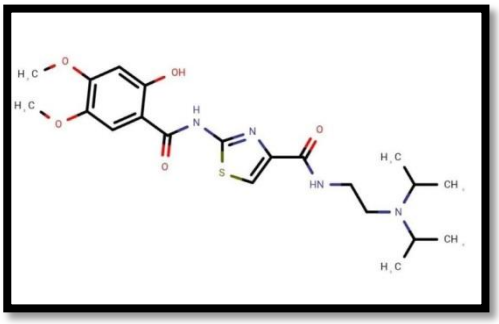

Figure 01: structure of acotiamide

MATERIALS AND METHODS

Materials: Acotiamide hydrochloride tablet containing 100mg of drug was purchased from local market. Distilled water used as the only solvent used throughout the study no other solvent or other chemicals or other organic solvents were used.

Instrumentation:

All the glassware and instruments necessary for analysis such as UV – visible spectrophotometer, analytical balance, solicitor, and volumetric apparatus will be arranged and calibrated before use. An up visible double beam spectrophotometer with 1 cm matched quartz cells were used for all absorbance measurements and all the glassware and instruments necessary.

Preparations of standard solution:

Accurately weighed 10 mg of Acotiamide pure drug and transferred into a 100 mL volumetric flask. The drug was dissolved in a small quantity of distilled water with the aid of sonication, and the volume was made up to the mark with distilled water to obtain a stock solution having a concentration of 100 µg/ml.

Determination of λmax of Acotiamide:

1 ml was pipetted out into a 10 ml volumetric flask from the above standard solution and diluted up to the mark with distilled water to obtain a concentration of 10 µg/ml. The resulting solution was scanned in the Wavelength range of 200–400 nm using distilled water as blank in a UV-Visible spectrophotometer. The wavelength showing maximum absorbance was selected as λmax and was found to be 217 nm.

Procedure for plotting calibration curve

Aliquots of 0.2 ,0.3,0.4,0.5 ,0.6 ,0.7 ,0.8 ,0.9 ,1 and 1.1 ml were withdrawn from the 100 µg/ml and transferred into a 10 ml volumetric flask and the volume was made unto the mark with distilled water to obtain concentrations 2,3,4,5,6,7,8,9,10,11 µg/ml. The absorbance was measured at 217nm against distilled water as a blank in up visible spectrometer. A calibration curve was plotted between concentration and absorbance, and the correlation coefficient was determined.

Assay of acotiamide tablet

Ten tablets of Acotiamide were accurately weighed and finely powdered using a mortar and pestle. The total weight of the powdered tablets was noted and the average tablet weight was calculated. An amount of tablet powder equivalent to 10 mg of Acotiamide (41.3mg) was accurately weighed and transferred into a 100 mL volumetric flask. A small quantity of distilled water was added to the flask and the mixture was sonicated to ensure complete dissolution of the drug. The volume was then made up to the mark with distilled water and mixed thoroughly to obtain a uniform sample solution. The prepared solution was filtered through Whatman filter paper to remove insoluble excipients.

From the filtrate, 1 ml was pipetted into a 10 mL volumetric flask and diluted up to the mark with distilled water to obtain a final concentration of 10 µg/ml. The absorbance of standard and sample solutions was measured at λmax 217 nm using distilled water as blank. The amount of drug present in the tablet formulation was calculated by comparing the absorbance of sample with standard by using this Formula and the results were expressed as a percentage of the labelled claim.

$$\text{Assay (\%)} = \frac{\text{Absorbance of Standard}}{\text{Absorbance of sample}} \times 100$$

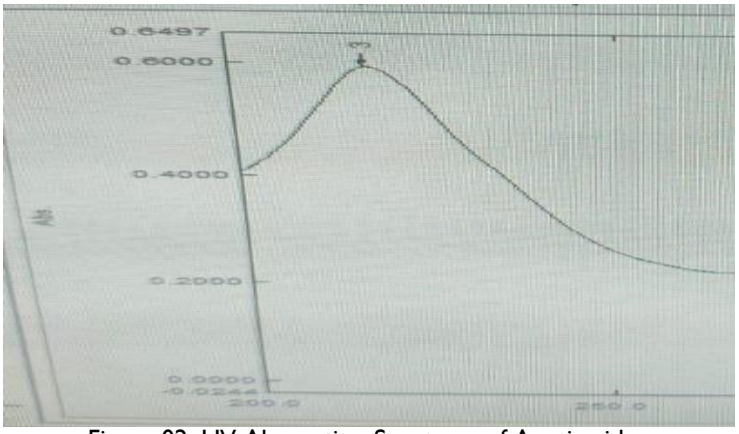

Figure 02: UV Absorption Spectrum of Acotiamide

RESULTS AND DISCUSSION

Evaluation of Method Validation Characteristics

1. Linearity

For Linearity nine different concentrations over the range of 3-11 µg/ml were prepared by taking 0.3 -1.1 ml stock solutions and absorbance of each solution was measured at λmax 217nm using distilled water as a blank in uv spectrophotometer and calibration curve was plotted between concentration and absorbance and the correlation coefficient was determined. (Figure 03**)**

Table 01: Linearity Results of Acotiamide by Uv Method

S. No	Concentration µg/ml	Absorbance
1	3	0.256
2	4	0.313
3	5	0.371
4	6	0.428
5	7	0.486
6	8	0.543
7	9	0.601
8	10	0.658
9	11	0.999

Table 02: Regression Analysis

Parameter	Value
Maximum wavelength (λmax)	217nm
Linearity range	3-11µg/ml
Regression equation	Y=0.0574+ 0.0836
Slope (m)	0.0574
Intercept (c)	0.0836
Correlation coefficient (R^2)	0.999

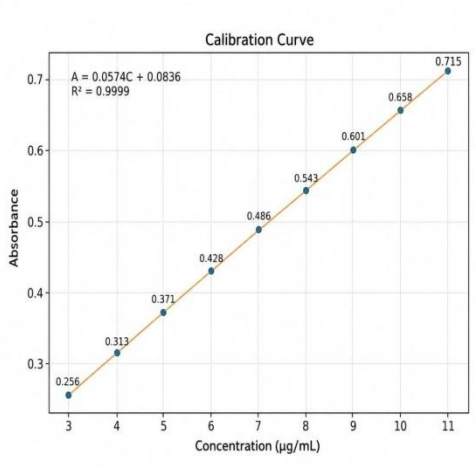

Figure 03: Calibration curve for Acotiamide

2. Accuracy

Accuracy is the closeness of the test results obtained by the method to the true value. To study the accuracy of the proposed method, recovery studies were performed. Appropriate aliquots of standard stock solutions were transferred into a series of 10 mL volumetric flasks containing preanalyzed sample solution to obtain 80%, 100%, and 120% concentration levels. The volume was made up to the mark with distilled water. The absorbance of the resulting solutions was measured at λmax 217 nm using distilled water as the blank. The percentage recovery was calculated and the results were found to be within acceptable limits indicating that the method is accurate".

Table 03: Determination of Accuracy of Acotiamide Tablet

Tablet name	Concentration of sample µg/mL	Level of addition (%)	Amount of drug added µg/mL	Amount recovered µg/mL	% recovery ± SD
Acotiamide	10	80	8	7.92	99.0 ± 0.06
	10	100	10	9.91	99.1 ± 0.05
	10	120	12	11.90	99.2 ± 0.07

3. Precision

Intermediate precision was evaluated by intraday and inter- day studies using six replicated acotiamide hydrochloride at a concentrations of 8µg/ml on the same day under the same experimental conditions. As shown in the table 3, the mean 0.5430 with a standard deviation of 0.00141 and %RSD of 0.26. While the inter - day precision was assessed by analyzing six replicate samples at the same concentrations on three different days the results in the table 04 showed a mean absorbance of 0.5427, SD of 0.00216, %RSD of 0.40. As per the ICH Q2 (R1) guidelines, the percentage RSD for precision studies should be less than 2.0%.

Table 04: Results of Intraday precision

S. No	Concentration µg/ml	Absorbance
1	8	0.541
2	8	0.544
3	8	0.543
4	8	0.545
5	8	0.542
6	8	0.543

Mean	:0.5430
SD	: 0.00141
%RSD	: 0.26

Table 04: Results Of Inter Day Precision

S:NO	Concentration µg/ml	Absorbance
1	8	0.540
2	8	0.544
3	8	0.542
4	8	0.546
5	8	0.543
6	8	0.541
Mean : 0.5427 **SD** : 0.00216 **% RSD** :0.40		

Table 05: Precision Calculation

Parameter	Result
Mean absorbance	0.5435
Standard deviation	0.00105
%RSD	0.19
Acceptance criteria	NMT 2.0%
Result	Pass

Limit of detection (LOD)

LOD was determined by using the standard deviation of response and slope method as per ICH guidelines. The Limit of Detection was found to be 0.12 µg/ml. (Table 06)

Limit of Quantification (LOQ)

LOQ was determined by using the standard deviation of response and slope method as per ICH guidelines. The Limit of Quantification was found to be 0.36 µg/ml. (Table 06)

Table 06: Results of LOD and LOQ

Parameter	Result
LOD	0.12µg/ml.
LOQ	0.36µg/ml.

Ruggedness

Ruggedness of the developed UV spectrophotometric method for the estimation of Acotiamide was determined by carrying out the analysis under deliberately varied conditions such as different analysts and different days. The purpose of this study was to evaluate the reproducibility of the method under normal operational variations. For analyst variation, the same sample solution of Acotiamide Hydrochloride at a concentration of 8 µg/ml was prepared and analyzed independently by two different analysts following the same experimental procedure. The absorbance was recorded at the selected λmax 217 nm using a UV Visible spectrophotometer.

Table 07: Results of Ruggedness

Sample .No	Concentration µg/ml.	Analyst I	Analyst II
1	Concentration 10 µg/ml.	0.543	0.545
2		0.544	0.542
3		0.542	0.546
4		0.545	0.544
5		0.543	0.543
6		0.544	0.545
	Mean	0.5435	0.5442
	SD	0.00105	0.00147
	% RSD	0.19	0.27

Robustness

Robustness of the developed UV spectrophotometric method for Acotiamide tablet was evaluated by making small deliberate changes in the Wavelength (± nm) on the absorbance of Acotiamide Hydrochloride. A standard Solution of 10µg/ml was prepared using water as the sole solvent and analyzed at 215nm, 217 nm and 219 nm. Acceptance criteria % SD should be less than 2%.

Table 08: Results of Robustness Study

Wavelength	Concentration µg/ml	Trial 1	Trial 2	Mean	SD	RSD
215 nm	10µg/ml	0.482	0.480	0.481	0.001	0.21%
217 nm		0.486	0.485	0.485	0.0005	0.10%
219 nm		0.478	0.476	0.477	0.001	0.21%

COMPARISION WITH PREVIOUSLY REPORTED METHODS

The developed UV Spectrophotometric method for the estimation of Acotiamide was compared with previously reported analytical methods available in the literature. The reported methods generally employed organic solvents such as methanol and ethanol, water mixtures, HCL. The proposed UV spectrophotometric method employing water as a solvent offers significant advantages over conventional hydrochloric acid-based methods. Water is non-toxic, inexpensive, environmentally harmless, and safer to handle. In contrast, hydrochloric acid is corrosive and generates hazardous waste requiring special disposal procedures. Despite these differences, both methods provide comparable analytical performance. Therefore, the developed method represents a greener and more sustainable alternative for the routine analysis of Acotiamide tablets.

Table 09: Determination of Accuracy of Acotiamide Tablet

Parameter	Water (Green solvent)	HCL
Toxicity	Non toxic	Corrosive
Environmental impact	Minimal	Generates acidic taste
Cost	Very low	Higher
Safety	Safe to handle	Requires precautions
Disposal	Environmentally friendly	Special disposal required
Green chemistry compliance	Excellent	Limited
Analytical performance	comparable	Comparable

CONCLUSION

The present investigation successfully established a green analytical approach for the estimation of Acotiamide in tablet dosage forms by UV spectrophotometry employing water as the sole solvent. The proposed method demonstrated satisfactory analytical performance during validation studies and fulfilled the acceptance criteria recommended by ICH guidelines. The elimination of organic solvents not only enhances environmental sustainability but also improves the cost-effectiveness and safety of routine analysis. The developed procedure offers a practical alternative for pharmaceutical quality assessment owing to its simplicity, reliability, and ease of implementation. Therefore, the method can be effectively utilized for routine assay and quality control of Acotiamide tablets in academic, research, and industrial laboratories while supporting the principles of green analytical chemistry.

ACKNOWLEDGMENT

The authors express their sincere gratitude to the Management, Principal, and Faculty members of Hindu College of Pharmacy, Amaravathi Road, Guntur, for providing the necessary facilities, infrastructure, and academic support to carry out this research work successfully. The authors also thank the Department of Pharmaceutical Analysis for their valuable guidance and encouragement throughout the study.

FUNDING

Nil

CONFLICT OF INTEREST

Not declared

INFORMED CONSENT AND ETHICAL STATEMENT

Not Applicable

AUTHOR CONTRIBUTIONS

All Authors Are Contributed Equally

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