EUROPEAN JOURNAL OF BIOMEDICAL AND PHARMACEUTICAL SCIENCES
http://www.ejbps.com

ISSN 2349-8870
Coden USA: EJBPBO
Volume: 13
Issue: 6
Year: 2026

A GREEN ANALYTICAL STABILITY INDICATING RP HPLC METHOD FOR THE QUANTIFICATION OF CLOBAZAM RELATED IMPURITIES IN ORAL SUSPENSION DOSAGE FORM

Ravi Kiran Kaja[1], Prasanna Ravi Kanth Konduri[2], Giridhar Kunamaneni[3], Pranitha Sambu[4], Anjaneyulu Vinukonda*[5]

[1]USP Rockville, MD 20852, USA, [2,5]Strides Pharma Inc. 1 Ram Ridge, Chestnut Ridge, Newyork, 10977, USA, [3]Northeastern University 360 Huntington avenue Boston MA 0215, USA, [4]Aurex Laboratories LLC, East Windsor, NJ 08520, USA.

***Corresponding Author: Anjaneyulu Vinukonda**

Strides Pharma Inc. 1 Ram Ridge, Chestnut Ridge, Newyork, 10977, USA.

Email ID: anjaneyulu.vinukonda@hotmail.com **DOI:** https://doi.org/10.5281/zenodo.20523683

How to cite this Article: Ravi Kiran Kaja[1], Prasanna Ravi kanth Konduri[2], Giridhar Kunamaneni[3], Pranitha Sambu[4], Anjaneyulu Vinukonda*[5] (2026). A Green Analytical Stability Indicating Rp Hplc Method For The Quantification Of Clobazam Related Impurities In Oral Suspension Dosage Form. European Journal of Biomedical and Pharmaceutical Sciences, 13(6), 296–304.

Article Received on 05/05/2026 **Article Revised on 25/05/2026** **Article Published on 03/06/2026**

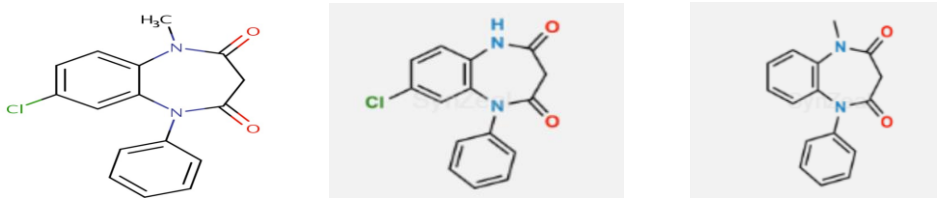
ABSTRACT

A green and eco-friendly high-resolution HPLC method was developed for the quantification of impurities in Clobazam oral suspension dosage forms. The stability-indicating method achieved effective separation and quantification of degradation-related impurities with acceptable peak resolution while reducing organic solvent consumption. Chromatographic separation was achieved on a Zorbax SB-C8 column (250 × 4.6 mm, 5.0 µm) using 10 mM sodium phosphate buffer (pH 7.0) and acetonitrile under gradient elution conditions. The flow rate was maintained at 1.2 mL/min, column temperature at 30 °C, and UV detection was carried out at 230 nm. The developed method provided adequate resolution between Clobazam and its related impurities with excellent specificity. Linearity was established over the concentration range of 0.2000–2.000 µg/mL with correlation coefficients (R^2) greater than 0.999. The method demonstrated acceptable accuracy, with recoveries exceeding 97%, and satisfactory precision in accordance with ICH guidelines. The LOD and LOQ values confirmed the sensitivity of the method for trace-level impurity quantification. Robustness studies indicated that minor deliberate variations in chromatographic conditions did not significantly affect method performance. Forced degradation studies under acidic and basic stress conditions confirmed the stability-indicating capability of the method. Green analytical assessment using Analytical Eco-Scale and GAPI tools indicated(0.82&86)good environmental sustainability and reduced solvent consumption, supporting its application for routine quality control and stability testing.

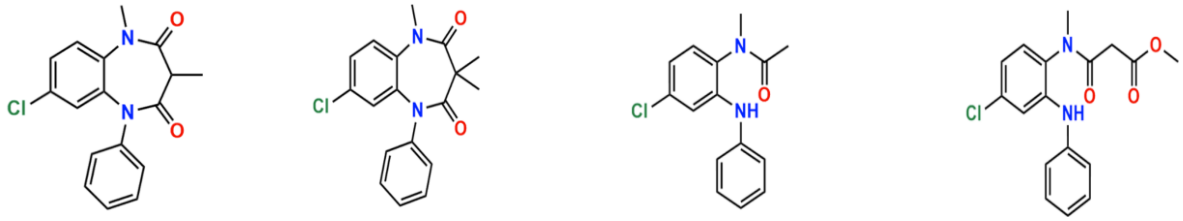
KEYWORDS: Clobazam, HPLC, method development, Validation.

1. INTRODUCTION

Clobazam ($C_{16}H_{13}ClN_2O_2$), chemically known as 7-Chloro-1H-1,5-benzodiazepine-2,4(3H,5H)-dione. It is used in the treatment of epilepsy in association with other antiepileptics. It is also used in the short-term treatment of acute anxiety. The chemical structure of Clobazam and related to various impurities that may arise during its synthesis(Fig. 1).



Clobazam **EP Impurity-A** **EP Impurity-B**



EP Impurity-C **EP Impurity-D** **EP Impurity- E** **EP Impurity- F**

Fig .1 The chemical structure of Clobazam and its organic impurities.

Clobazam bulk powder is a white crystal with molecular weight of 300.7. The drug is slightly soluble in water and soluble in alcoholic solvents. The estimation of impurities in the drug product is critical for understanding its behavior and ensuring its safety and efficacy. Accurate impurity profiling is essential in the regulated pharmaceutical industry. To date, several analytical methods have been developed, primarily for the estimation of impurities in Clobazam oral suspension using various analytical techniques. HPLC and LC-MS/MS analytical methods.[1-6] However, none of the reported methods successfully separate all the peaks of Clobazam and impurities, and excipients. The present study describes a green, validated, stability-indicating RP-HPLC method developed using a systematic determination of Clobazam-related impurities in finished dosage forms. The proposed method offers improved environmental sustainability through reduced solvent consumption, minimized analytical waste, and enhanced method robustness while complying with ICH validation requirements. The present work aims to develop and validate a robust, green, and regulatory-compliant RP-HPLC method for impurities determination in Clobazam finished dosage forms. The method also demonstrates excellent specificity, with no interference observed from excipients and known impurities present in the Clobazam oral suspension dosage form.

MATERIALS AND METHODS

2.1. Chemicals

The AR grade Sodium phosphate monohydrate and Sodium hydroxide were procured from Ankit Raj organo chemicals LTD, India. The HPLC grade of Acetonitrile (J.T. beaker) with certified purity of 99.9% were purchased from Avantor performance materials, Mumbaei. High quality In-House purity water was used for the experiments (TOC <500ppb, pH about 7.0, Conductivity < 1.0 µs/cm, finally exposed to UV radiation and followed filtered through 0.2 µm filter). Clobazam and impurities were procured from MSN-pharma private limited, Hyderabad, India.

2.2. Instruments

Waters HPLC system Alliance e2695 separation module with auto injector, temperature controller for sample storage, and column were used for current analysis. The signal output was observed through Empower 3. The LC column Zorbax SB C8 column (250 × 4.6 mm, 5.0 µm particle size, is manufactured by Agilent. Analytical balance model AX205 (make: Mettler Toledo), sonicator (make: ENERTECH), Rotary shaker (make: REMI; model: RS – 24BL) were employed in this work.

2.3. Preparation of diluent

Mixed 70% of water and 30% acetonitrile in the ratio of (70:30)(v/v)as a diluent.

2.4. Preparation of Clobazam standard stock solution

Weighed and transferred about 10mg of Clobazam working standard/reference standard into 100mL volumetric flask and add 60mL of diluent. Sonicate to dissolve the material completely and dilute up the volume with diluent, Clobazam concentration was about 100µg/mL.

2.5. Preparation of Clobazam standard solution

Transferred 1.0mL of Clobazam standard stock solution into 100mL volumetric flask and diluted the volume with diluent and mixed well. The concentration was about 1µg/mL.

2.6. Preparation of Placebo solution

Accurately weighed and transferred Clobazam placebo equivalent to 10g(10mL) of placebo oral solution into 20mL volumetric flask, added about 5mL of diluent and sonicated for 30 minutes with intermittent shaking and dilute to volume with diluent, and mixed well and centrifuge some portion of solution at 3500 rpm for 10 minutes.

2.7. Preparation of sample solution (About 500 ppm)

Weighed accurately and transferred about 10g(10mL) of Clobazam oral suspension into a clean, dry 20-mL volumetric flask. Added 5 mL of diluent and sonicated

for about 30 minutes with intermittent shaking. Then, dilute to volume with diluent and mixed well. Centrifuged the solution at 5000 RPM for 10 minutes and filtered it through a 0.45 µm glass fiber filter, discarding the initial 5 mL of filtrate. The final concentration was approximately 500µg/mL of Clobazam.

3. RESULTS AND DISCUSSIONS

3.1. Method Development and Optimization

The main objective of the current method was to separate the forms of Clobazam and its impurities-Impurity A, Impurity B, Impurity C, Impurity D, and Impurity-E, Impurity-F Benzoimidazolon, Malonyl amide as well as from the placebo in Clobazam oral suspension. As per DMF impurity-E was degradant, remaining all impurities were process related impurities. The experiment initially employed an isocratic method using a mobile phase consisting of water and acetonitrile in the ratio of 70:30 (v/v). A Nucleosil C18 , (250mmx4.6mm), 5µm column was selected, with a flow rate of 1.0 mL/min, a column temperature of 30°C, and an HPLC system equipped with a photodiode array (PDA) detector.

A spiked sample was prepared and injected into the HPLC. However, all impurity peaks eluted at the same retention time. To achieve better separation of all peaks, a modified mobile phase of 0.02 M potassium dihydrogen phosphate (adjusted to pH 3.0) and acetonitrile in the ratio of 70:30 (v/v), and column ZorbaxC18 , (250mmx4.6mm), 5µm while other chromatographic conditions remained unchanged. Broad peak shapes were observed. To get separated all peaks and better resolution with less running time an attempt was made with gradient program and mobile phase. By using 0.02M potassium dihydrogen phosphate and adjusted pH 3.0 with orthophosphoric acid solution as buffer and 100% buffer used as mobile phase -A and 100% Acetonitrile as mobile phase-B. But peaks were not eluted. For peaks separation and less runtime to introduce the C8 column. All Impurity peaks were separated but peak shape was not satisfied. Hence to modify the buffer salt. By using 0.01M Sodium di hydrogen phosphate pH 7.0 with 2N NaOH solution as buffer. For mobile phase-A used 100% buffer, and mobile phase-B mixed 30% buffer and 70% acetonitrile in the ratio of 30:70(v/v). but impurity peaks resolution were not satisfied. To get peak shape and better resolution with less run time an attempt was made with mobile phase-B, mixed 0.01M buffer and acetonitrile in the ratio of (25:75) (v/v) and flow rate 1.2mL/min and column temperature 30℃. Hence all peaks, i.e. Impurity-B, Impurity-A,

Clobazam, Impurity-C, Impurity-G, Benzoimidazolon, Malonyl amide, impurity-D and impurity-E and impurity-F eluted. To separate for better resolution with less run time an attempt was made with gradient was changed. To separate all peaks, the Known impurities were separated and resolution between all peaks were satisfied.Based on these experiments and optimized conditions. Zorbax SB C8(250mmx4.6mm), 5µm was used as the stationary phase. The column temperature was maintained at 30°C and sample cooler-maintained at 25°C detection was monitored at 230nm. The flowrate was 1.2mL/min and the injection volume were 20µL.

A series of aqueous and organic modifiers used as a diluent, finally decided to 70% of water and 30% Acetonitrile as a diluent. The typical retention time of Impurity-B, Impurity-A, Clobazam, Impurity-C, Impurity-G, Benzoimidazolon, Malonyl amide, impurity-D and impurity-E and impurity-F were eluted about 8.68, 9.96, 16.49, 24.46, 29.73, 32.28, 34.70, 36.24, 39.25, 42.84 min respectively. The impurities of Clobazam, blank and placebo interference were not observed at any retention time of Clobazam and impurities. So, the method was found specifically for determination of impurities. See Table 1 for individual impurity all peaks retention time.

Table 1: individual impurities Retention time.

S.No	Name of the peak	RT from Spike Sample (Minutes)	USP Resolution	RRT with respect to Clobazam
1	EP Impurity-B	8.681	NA`	0.53
2	EP Impurity-A	9.964	2.31	0.60
3	Clobazam	16.493	8.85	1.00
3	EP Impurity-C	24.467	8.00	1.48
4	EP Impurity-G	29.737	3.83	1.80
5	Benzoimidazolon	32.288	1.56	1.96
6	Malonyl amide	34.708	1.80	2.10
7	EP Impurity-D	36.243	1.37	2.20
8	EP Impurity-E	39.252	2.51	2.38
9	EP Impurity-F	42.841	3.27	2.60

3.2. Chromatographic conditions

The chromatographic separation was performed using a gradient program with 0.01 M Sodium phosphate buffer (pH 7.0), adjusted with 2N sodium hydroxide(NaOH) solution as buffer and 100% buffer as a mobile phase-A and mixed 250ml of buffer and 750ml of Acetonitrile in the ratio of (25:75) (v/v) as mobile phase B.The flow rate, column temperature, and sample cooler were set to

1.2 mL/min, 30℃, and 25℃, respectively. ZorbaxC8 column (250 mm × 4.6 mm, 5.0 µm particle size) column was used. Gradient elution was employed, with an injection volume of 20 µL, and component detection was carried out at 230nm.

3.3. Method Validation

The method was validated based on International Conference on Harmonization (ICH) Q2(R2) Guidelines.Validation parameters included linearity, precision, accuracy, specificity and forced degradation[7-12]

3.4. System suitability

System suitability parameters (tailing factor, number of theoretical plates) were assessed by injecting a blank diluent followed by Clobazam solution (1.0µg/ml). See Table 2 for system suitability results.

Table 2: System suitability results.

Name of the parameter	Observed Value
USP tailing factor for Clobazam peak from standard solution	1.1
USP Plate count for Clobazam peak from standard solution	11345
% RSD of Clobazam peak areas for three replicate injections of standard solution	0.1

3.5. Specificity

Prepared blank, known impurities spec level and placebo as per the optimized test procedure and verified the interference of peaks at retention time of active. The results showed no interference at the active peak. All chromatograms showed no interference at retention time of as with known impurities (Fig. 2-5).

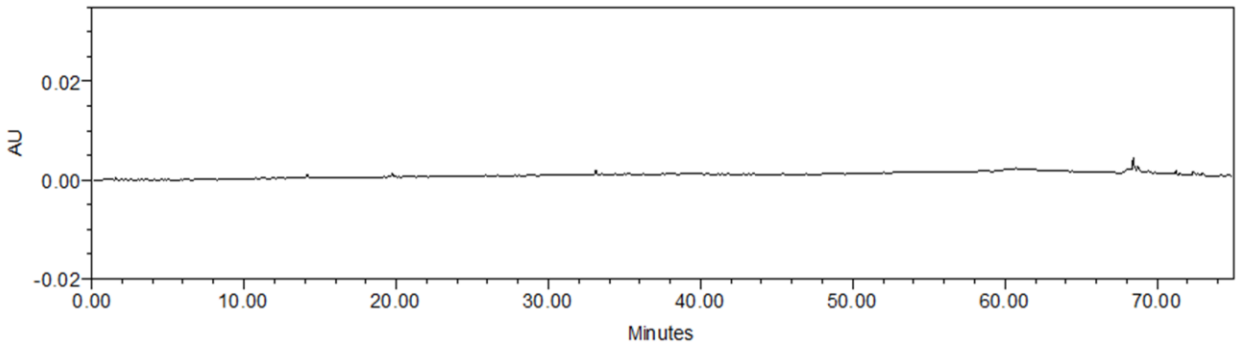


Fig . 2: Typical Chromatogram of Blank.

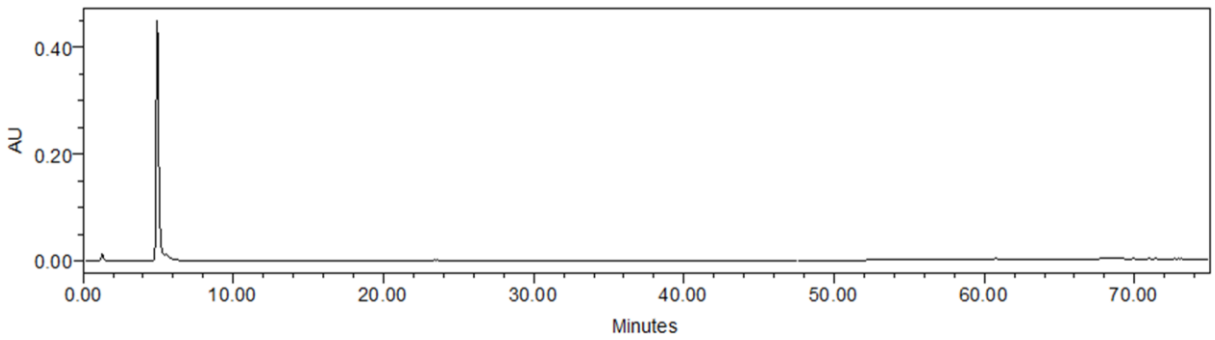


Fig . 3: Typical Chromatogram of Placebo.

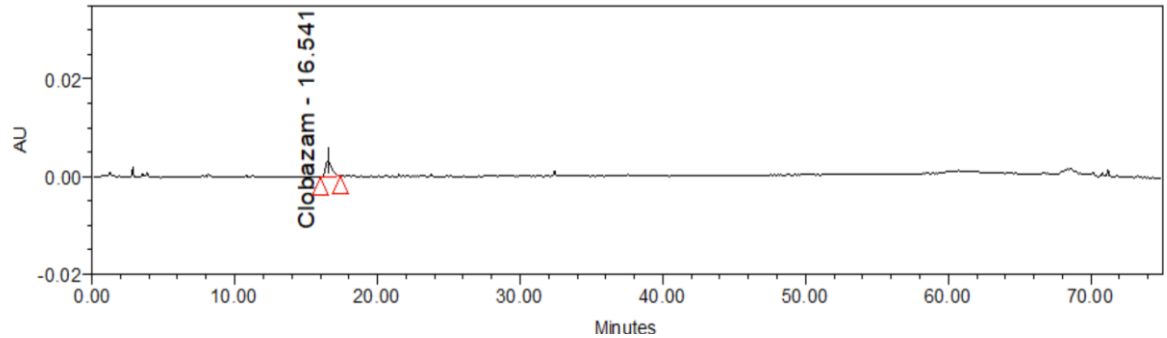


Fig . 4: Typical Chromatogram of Standard.

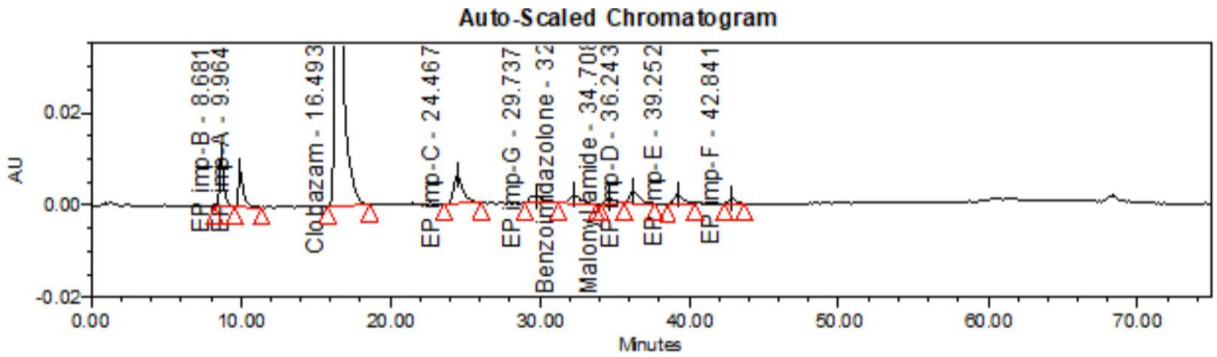


Fig . 5: Typical Chromatogram of Spiked sample.

3.6. Linearity

To prove the linearity of the optimized method a sequence of concentrations was made for Clobazam (0.2509µg/mL to 2.0079µg/mL), impurity-E(0.2551µg/mL to 2.0414µg/mL), from the concentration range (0.05% to 1.0%) by using suitable amounts of the mixture of stock solutions. A curve was created by mapping the peak response and concentration. The components showed correlation coefficient > 0.999. The results are shown in Table 3.

3.7. Sensitivity

The limit of detection (LOD) and Limit of quantification (LOQ) values for EP impurity-E was established by signal to noise ratio(S/N) method. The LOD and LOQ results were shown in Table 3.

3.8. Precision

Precision provides a degree of agreement between the individual test results by applying the procedure or method to the homogeneous sample. Typically, it is expressed as variance, SD. In normal conditions, it is a measure of the degree of repeatability or reproducibility.

Six individual samples were taken from a homogenous mixture of samples and were spiked with them at the 100% level to check the reproducibility. The precision of the analysis was calculated on the RSD values of the six impurity-spiked samples results. To check the ruggedness (intermediate precision) of the method, the analysis was repeated on different days. The precisions for the analysis of each individual impurity at 100% concentration level were <2.0%. The results were shown in Table 3.

3.9. Accuracy

They prove the accuracy of optimized method prepared four levels (LOQ,50%, 100% & 200%). Prepared each sample in triplicate preparation range from 50% level and 200% level and the concentration of Clobazam was 0.5501µg/mL(50%) and 2.0078µg/mL(200%), concentration of EP impurity-E was 0.5513µg/mL(50%) and 2.0091µg/mL(200%), these six-sample preparation ranges from LOQ and 100% level and concentration of Clobazam was 0.2552µg/mL(LOQ) and 1.1032µg/mL (100%),concentration of impurity-E was 0.2564µg/mL(LOQ) and 1.1063µg/mL(100%). The recovery was calculated in terms of the amount estimated to the amount spiked. According to the acceptance criteria, the mean recovery should be within the range of 85.0 % -115.0 % found to be within the range. The results were shown in Table 3.

Table 3: Validation summary results.

Validation parameters	Clobazam	EP Impurity-E
RRT w.r.to Clobazam	1.000	0.469
Linearity range(µg/ml)	0.5501-2.0078	0.5513-2.0091
Coefficient(r^2)	0.999924	0.999936
Slope	98858.255503	95412.182870
(%) Y-intercept	-604.577289	-187.516003
Bias	-0.6	-0.2
Residual sum of squares	1628929.217213	1315560.249378
RRF	1.00	0.97
LOQ concentration(ppm)	0.2550	0.2509
LOD concentration(ppm)	0.1000	0.1020
ACC-LOQ mean %RSD(n=6)	101.4,1.8	102.6,1.2
ACC-50% mean, %RSD(n=3)	99.1,0.7	101.4, 1.2
ACC-100% mean %RSD(n=3)	101.2,1.2	100.8 ,1.9
ACC-200% mean RSD(n=3)	102.3,0.5	101.8,1.5
Method precision %RSD(n=6)	1.2	1.6
Intermediate precision % RSD(n=6)	1.6	1.2

3.10. Robustness

The robustness of the proposed RP-HPLC method was carried out by altering the experimental conditions such as analytical column, column temperature, flow rate. Making a deliberate change in wavelength was taken place and RSD found to be less than 5, specify that the method was robust. The results were shown in table 4.

Table 4: Robustness study results.

Name of the parameter	Flow variation			Temperature Variation		
	1.0mL/min	As such 1.2mL/min	1.4mL/min	25 °C	As such 30 °C	35 °C
USP Tailing of Clobazam peak from standard solution	1.0	1.0	1.0	1.0	1.0	1.0
USP Plate count of Clobazam peak from standard solution	22345	22752	22456	22765	22752	22434
% RSD of Clobazam peak areas for three replicate injections of standard	0.2	0.2	0.2	0.1	0.2	0.1
RRT of EP Impurity-B	0.53	0.53	0.52	0.52	0.53	0.53
RRT of EP Impurity-A	0.59	0.60	0.60	0.59	0.60	0.61
Clobazam	1.00	1.00	1.00	1.00	1.00	1.00
RRT of EP Impurity-C	1.47	1.48	1.48	1.49	1.48	1.50
RRT of EP Impurity-G	1.80	1.80	1.81	1.79	1.80	1.79
RRT of Benzoimidazolon	1.97	1.96	1.96	1.97	1.96	1.98
RRT of Malonyl amide	2.10	2.10	2.11	2.09	2.10	2.11
RRT of EP Impurity-D	2.19	2.20	2.21	2.21	2.20	2.19
RRT of EP Impurity-E	2.37	2.38	2.39	2.39	2.38	2.39
RRT of EP Impurity-F	2.59	2.60	2.61	2.59	2.60	2.59

3.11. Degradation studies

Degradation studies were conducted to determine the specificity and stability-indicating properties of the proposed method. The stress conditions applied included acidic, alkaline, oxidative, and aqueous environments.

An amount equivalent to 10g(10mL) of clobazam solution was weighed and transferred into a 20 mL volumetric flask. Then, 1mL of 1N HCl or 1N NaOH was added, the mixture was thoroughly mixed, and the flask was placed in a water bath at 60°C for approximately 3 hour. Afterward, the solution was neutralized with 1mL of 1N NaOH or 1N HCl. Following neutralization, about 10mL of diluent was added, and the sample was sonicated for 30 minutes. Finally, the volume was made up to 20mL with diluent and mixed well.

For the peroxide degradation sample, an amount equivalent to 10g(10mL) of Clobazam solution was weighed and transferred into a 20mL volumetric flask. Then, 1mL of 3% hydrogen peroxide solution was added, the mixture was thoroughly mixed, and the flask was placed in a water bath at 60°C for approximately 1 hour. Afterward, about 10mL of diluent was added, and the sample was sonicated for 30 minutes. Finally, the volume was made up to 20mL with diluent and mixed well.

weighed and transferred into a 20mL volumetric flask. Then, 1mL of water was added, the mixture was thoroughly mixed, and the flask was placed in a water bath at 60°C approximately for 1 hour. Afterward, about 10mL of diluent was added, and the sample was sonicated for 30 minutes. Finally, the volume was made up to 20mL with diluent and mixed well.

Centrifuged above all degradation solutions at 3500 rpm in 10 minutes. Supernatant solution was injected into HPLC system. The results were shown in table 5.

Table 5: Forced degradation conditions results.

Nature of Stress	% of Total impurities	% Assay of stressed Clobazam	Mass Balance	Purity angle	Purity threshold	Purity flag
Unstressed	0.02	100.4	NA	5.099	7.053	NO
1N HCl@60°C, for 3hrs	0.8	97.5	97.9	0.069	0.262	NO
1 N NaOH@60°C for 1hrs	6.5	91.3	97.2	0.098	0.309	NO
3%Peroxide@60°C for 1hrs	0.5	99.1	99.2	0.180	0.368	NO
1mL water@60°C for 1hrs	0.04	100.0	99.6	0.413	0.664	NO

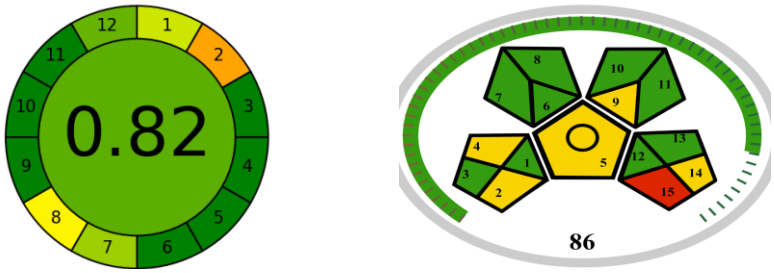
3.9. Stability of Mobile Phase and Sample Solutions

The solution and mobile phase stability was established for control sample solution, spiked sample solution, and dilute standard solutions for impurity determination level at room temperature condition. The solution stability is evaluated using freshly diluted standard solution, and %

recoveries are compared from the initial (T_0) to T_t (h) as stable for 72 hours at room temperature storage conditions.

Assessment of GREEnness

The greenness of the proposed method was assessed using the AGREE and GAPI tools in accordance with the 12 principles of Green Analytical Chemistry. The corresponding pictograms are shown in Fig. 6, while the detailed evaluation data were summarized in Tables 6 and 7. The method achieved AGREE and GAPI scores of 0.82and 86, respectively, indicating a high level of environmental sustainability and strong adherence to Green Analytical Chemistry principles. Key analytical attributes, including reduced sample consumption, simplified sample preparation, automation, avoidance of derivatization, efficient waste management, and low energy consumption, were predominantly classified within the green category, confirming the method as an eco-friendly, sustainable, and efficient analytical approach.



(a) **(b)**

Fig. 6: Greenness evaluation (a) AGREE- Analytical GREEnness Metric Approach (b) GAPI-Green Analytical Procedure Index.

Table 6: Points of the AGREE 12 principles.

Category	Result
1. Select the sampling procedure	In-line
2.The amount of sample in g	10g
3.position of analytical device	In-line
4.How many major distincts are there in the sample procedure	Sonication
5.Degree of automation	Not miniaturized
6.Select derivatization agent	No
7.Amount of waste in g	1g
8.Number of analytes determine in single run	9
9.Select the most energy used in technique used in the method	LC
10.Select the type of reagent	No
11.Does the method involve toxic reagent	No
12.Select the threats which are not avoided	Corrosive

Table 7: Points system of the proposed MoGAPI.

Category	Green	Yellow	Red
Sample preparation 1.Collection	In-line	On-line or at-line	Off-line
2.Preservation	None	Chemical or physical	Physiochemical
3.Transport	None	Required	None
4.Storage	None	Under normal	Special
5.Type of method	No sample preparation	Filtration	Extraction
6.Scale of extraction	Nano extraction	Microextraction	Microextraction
7.Solvents or reagents used	Solvent free methods	Green solvents	Nongreen solvents
8.Additional treatments	None	Special treatment	Advanced treatment
Reagents used 9.amount used	<10mL(<10g)	10-100ml(10-100g)	>100ml(>100g)
10.Health hazard	Slightly toxic NFPA score 0 or 1	Moderately toxic NFPA score 2or 3	Serious injury on short NFPA score 4
11.Safety hazard	Highest NFPA score 0 or 1	NFPA score 2 or 3	NFPA score 4
Instrumentation 12.Energy	≤0.1 kWh per sample	≤0.15 kWh per sample	>0.15 kWh per sample
13.Occupational hazard	Hermetic sealing of	NA	Emission of vapors to the

	analytical process		atmosphere
14.Waste	< 1 mL (< 1 g)	1–10 mL (1–10 g)	> 10 mL (> 10 g)
15.waste treatment	Recycling	Degradation,passivation	No treatment

4. CONCLUSION

Green analytical stability-indicating RP-HPLC method was successfully developed and validated for the quantification of Clobazam impurities in oral suspension dosage forms.The method demonstrated excellent specificity, linearity (R^2 > 0.999), accuracy (>97%), precision, robustness, and effective separation of degradation products. Green metric assessment confirmed the environmental sustainability of the proposed method while maintaining analytical performance. Although sensitivity is comparatively lower than LC–MS based methods, the developed RP-HPLC method is simple, reliable, and cost-effective for routine quality control and stability studies. The findings provide valuable guidance for analysts in identifying chromatographic risks and implementing suitable corrective measures during Clobazam impurity analysis.

Ethical approval

This work did not contain any studies with human participants performed by any of the authors.

Conflict of interest

The authors declare no conflict of interest.

ACKNOWLEDGEMENTS

There was no funding received from any agency.

Data availability statement

The datasets generated during the current study are not publicly available ,but are available from the corresponding author on reasonable request.

Author contributions

Ravi kiran Kaja and Prasanna Ravi kanth Konduri conceptualized and collected the necessary data from literature, designed, developed the analytical methodology, Giridhar Kunamaneni performed the designed, wrote the main manuscript draft ,Pranitha Sambu and Anjaneyulu Vinukonda performed the validation studies. All authors have read and agreed to the published version of the manuscript.

Funding

The present research project was not funded by any external grant.

Consent for publication

The author declare no conflict of interest.

Competing interests

The author declare no conflict of interest regarding this publication.

REFERENCES

1. Kumar N, Devineni SR, Dubey SK, Kumar P. Potential impurities of anxiolytic drug, clobazam: Identification, synthesis and characterization using HPLC, LC-ESI/MSn and NMR. J. Pharm. Biomed. Anal, 2017; 137: 268–278. DOI: 10.1016/j.jpba.2017.01.051.
2. Gopalakrishnan S, Jeyashree B, Backialakshmi S, Chenthilnathan A. A new validated RP-HPLC method for the estimation of clobazam in tablet dosage form. Asian J. Res. Chem, 2011; 4(6): 882–886.
3. Souri E, Farahani AD, Ahmadkhaniha R, Amini M. A stability indicating HPLC method for the determination of clobazam and its basic degradation product characterization. Daru, 2014; 22(1): 49. DOI: 10.1186/2008-2231-22-49.
4. Kumar S, Mahadik DP. Method development and validation of clobazam in bulk and pharmaceutical dosage forms by using high performance thin layer chromatographic method. 2020. DOI: 10.14419/IJAC.V8I1.30498.
5. Christian S, Patel R, Shivprakash. A rapid and sensitive LC-MS/MS assay for the determination of clobazam in human plasma using electro spray ionization technology. Int. J. Pharm. Sci. Res, 2018; 9(6): 2369–2377. DOI: 10.13040/IJPSR.0975-8232.9(6).2369-77.
6. R, Chaithra & GP, Senthil & P., Poojashree & DN, Vidya & DR, Bhadresh & S., Manojkumar. (2020). Method development and validation of clobazam in bulk and pharmaceutical dosage forms by using high performance thin layer chromatographic method. International Journal of Advanced Chemistry, 8: 89. 10.14419/ijac.v8i1.30498
7. Myneni RK, Divadari H, Kasa S, Kamireddy T, Sambu P, Lankalapalli PK, Chollety V. Stability-indicating RP-HPLC method development and validation for the quantification of fluphenazine tablets in solid oral dosage form. Biomed. Chromatogr, 2025; 39(3): e6088. DOI: 10.1002/bmc.6088.
8. Kamireddy T, Sambu P, Lankalapalli PK, Myneni RK, Divadari H. Stability-indicating RP-HPLC method development and validation for the quantification of amlodipine besylate and valsartan tablets in solid oral dosage form. Biomed. Chromatogr, 2024; e6017. DOI: 10.1002/bmc.6017.
9. Divadari H, Kamireddy T, Myneni RK, Chollety V, Sambu P, Kasa S, Morsu A, Lankalapalli PK. Stability-indicating HPLC method development and validation for quantification of salicylic acid impurity in acetaminophen, aspirin, caffeine oral solid dosage forms. Int. J. Pharm. Res, 2024; 9(6): 747–758.

10. Maddukuri N, Morsu A, Kamireddy T, et al. Stability-indicating RP-HPLC method development and validation for the quantification of ketorolac tromethamine tablets in solid oral dosage forms. Chem. Res. J., 2025; 10(1): 21–28.
11. Lankalapalli PK, Kamireddy T, Sambu P. A simple and rapid HPLC method development for quantification of sodium benzoate content in chlorzoxazone oral solid dosage forms. Biomed. Chromatogr, 2024; e6048. DOI: 10.1002/bmc.6048.
12. Lankalapalli, P., Kasa, S., Sambu, P., Myneni, R., Kamireddy, T., chollety, V. and Divadari, H. Stability-Indicating RP-HPLC Method Development and Validation for Quantification of Butylated Hydroxyanisole Content in Loperamide Oral Solid Dosage Form. Biomed. Chromatogr, 2025; 39: e70103. https://doi.org/10.1002/bmc.70103