IJARSCT
International Journal of Advanced Research in Science, Communication and Technology
International Open-Access, Double-Blind, Peer-Reviewed, Refereed, Multidisciplinary Online Journal
ISSN: 2581-9429
Volume 6, Issue 3, March 2026
Impact Factor: 8.2

Development and Validation of a UV–Visible Spectrophotometric Method for the Quantitative Estimation of Zonisamide in Tablet Dosage Form

Ms. Rutuja Ganpat Dhakne[1*] and Dr. K Sarvanan[2]
Research Scholar, Bhagwant Global University, Kotdwar, Uttarakhand[1]
Research Guide, Bhagwant Global University, Kotdwar, Uttarakhand[2]

Abstract: *A simple, rapid, and reliable UV–visible spectrophotometric method was developed and validated for the quantitative estimation of Zonisamide in tablet dosage form. The analysis was carried out using a solvent system consisting of acetonitrile and 0.1 N hydrochloric acid. The drug exhibited maximum absorbance (λmax) at 234 nm, which was selected for further analytical studies. The method obeyed Beer–Lambert's law in the concentration range of 2–20 µg/ml, demonstrating excellent linearity with a correlation coefficient (R^2 = 0.9986). The developed method was validated in accordance with the guidelines of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use with respect to linearity, accuracy, precision, repeatability, limit of detection (LOD), limit of quantification (LOQ), and robustness. The percentage assay of the tablet formulation was found to be 98.7%, indicating good agreement with the labeled claim. Recovery studies were performed at three concentration levels (50%, 100%, and 150%), and the percentage recovery ranged from 98.0% to 99.2%, confirming the accuracy of the method. Precision studies showed low %RSD values, demonstrating good reproducibility and reliability of the method. The limit of detection and limit of quantification were found to be 0.91 µg/ml and 2.76 µg/ml, respectively, indicating the sensitivity of the developed method. The proposed UV spectrophotometric method was found to be simple, accurate, precise, and cost-effective, making it suitable for routine quality control analysis of Zonisamide in bulk and pharmaceutical dosage forms.*

Keywords: Zonisamide, UV–Visible Spectrophotometry, Method Development, Method Validation, Tablet Dosage Form, Pharmaceutical Analysis, ICH Guidelines

I. INTRODUCTION

Zonisamide is a broad-spectrum antiepileptic drug widely used in the management of partial seizures and other seizure disorders. Chemically, it is a benzisoxazole derivative containing a sulfonamide group and is known as **1,2-benzisoxazole-3-methanesulfonamide**. Zonisamide exerts its antiepileptic activity through multiple mechanisms, including the inhibition of voltage-gated sodium channels and T-type calcium channels, which reduces neuronal hyperexcitability and stabilizes neuronal membranes. Additionally, the drug has been reported to enhance gamma-aminobutyric acid (GABA) mediated inhibitory neurotransmission and exhibit neuroprotective and antioxidant properties. Due to these pharmacological actions, Zonisamide is commonly prescribed for the treatment of epilepsy and is sometimes used as adjunct therapy in neurological disorders.

Reliable analytical methods are essential for the **quality control, formulation development, and routine analysis of pharmaceutical dosage forms** containing Zonisamide. Several analytical techniques such as high-performance liquid chromatography (HPLC), liquid chromatography–mass spectrometry (LC–MS), and capillary electrophoresis have been reported for its determination in biological fluids and pharmaceutical formulations. Although these techniques provide high sensitivity and selectivity, they often require expensive instrumentation, complex sample preparation, and

DOI: 10.48175/IJARSCT-31605

IJARSCT
International Journal of Advanced Research in Science, Communication and Technology
International Open-Access, Double-Blind, Peer-Reviewed, Refereed, Multidisciplinary Online Journal
ISSN: 2581-9429
Volume 6, Issue 3, March 2026
Impact Factor: 8.2

longer analysis time. In contrast, UV–visible spectrophotometry offers a **simple, rapid, and cost-effective analytical approach**, making it highly suitable for routine laboratory analysis and quality control applications.

Spectrophotometric methods are widely employed in pharmaceutical analysis due to their simplicity, reproducibility, and minimal operational requirements. However, the development and validation of a reliable UV spectrophotometric method for Zonisamide estimation in tablet dosage forms are necessary to ensure accurate quantification and compliance with regulatory standards. Method validation is an important step in analytical method development and is performed to demonstrate that the method is suitable for its intended purpose. According to the guidelines of the **International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use**, parameters such as linearity, accuracy, precision, repeatability, limit of detection, and limit of quantification must be evaluated to establish the reliability of the analytical method.

Therefore, the present study aims to develop a **simple and validated UV–visible spectrophotometric method for the quantitative estimation of Zonisamide in tablet dosage form** using a suitable solvent system. The developed method was validated according to ICH guidelines and applied for the routine analysis of Zonisamide in pharmaceutical formulations to ensure accuracy, precision, and reproducibility.

II. MATERIALS AND METHOD

The analytical method for the estimation of **Zonisamide** in tablet dosage form was developed using UV–Visible spectrophotometry. A pure sample of Zonisamide was obtained as a reference standard, while commercially available Zonisamide tablets were purchased from a local pharmacy and used for analysis. Analytical grade **acetonitrile (ACN)** and **0.1 N hydrochloric acid (HCl)** were used as solvents for the preparation of stock and working solutions, and double-distilled water was used throughout the study. The spectrophotometric measurements were performed using a UV–Visible double beam spectrophotometer equipped with matched quartz cells of 1 cm path length. For preparation of the standard stock solution, accurately weighed 10 mg of Zonisamide was transferred into a 100 ml volumetric flask, dissolved in a small quantity of solvent mixture consisting of acetonitrile and 0.1 N HCl, sonicated to ensure complete dissolution, and the volume was made up to the mark with the same solvent mixture to obtain a stock solution of 100 µg/ml. Appropriate dilutions of this stock solution were prepared to obtain working concentrations within the range of 2–20 µg/ml. The absorption maximum (λmax) of the drug was determined by scanning a suitable diluted solution in the wavelength range of 200–400 nm against the solvent blank, and the maximum absorbance was observed at 234 nm, which was selected for further analysis. A calibration curve was constructed by measuring the absorbance of different concentrations (2–20 µg/ml) at 234 nm and plotting concentration versus absorbance to evaluate the linearity of the method. For tablet analysis, twenty tablets were weighed, finely powdered, and a quantity equivalent to 10 mg of Zonisamide was transferred into a 100 ml volumetric flask. The powder was dissolved in the solvent mixture with sonication for about 10–15 minutes, filtered through Whatman filter paper No. 41 to remove insoluble excipients, and diluted appropriately to obtain the required concentration for analysis. The developed method was validated according to the guidelines of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) by evaluating parameters such as linearity, accuracy, precision, repeatability, limit of detection (LOD), limit of quantification (LOQ), robustness, and recovery studies using the standard addition method at 50%, 100%, and 150% levels to confirm the reliability and suitability of the method for routine quantitative estimation of Zonisamide in pharmaceutical formulations.

III. RESULTS AND DISCUSSION

Linearity

The linearity of the developed UV spectrophotometric method for **Zonisamide** was evaluated over the concentration range of **2–20 µg/ml** using a solvent mixture of **acetonitrile and 0.1 N HCl**. The absorbance values showed a direct proportional relationship with concentration within this range. The calibration curve demonstrated excellent linearity with a **correlation coefficient (R^2) of 0.9986**, indicating strong agreement between concentration and absorbance. The

IJARSCT
International Journal of Advanced Research in Science, Communication and Technology
International Open-Access, Double-Blind, Peer-Reviewed, Refereed, Multidisciplinary Online Journal
ISSN: 2581-9429
Volume 6, Issue 3, March 2026
Impact Factor: 8.2

regression equation obtained was **y = 0.0804x + 0.0982**, confirming that the method follows Beer–Lambert's law over the studied concentration range. This indicates the suitability of the developed method for quantitative estimation of the drug in pharmaceutical formulations.

Accuracy (Assay of Tablets)

The accuracy of the developed method was assessed by determining the assay of the marketed tablet formulation. The absorbance values obtained for the sample solution were **0.873 and 0.875**, with an average absorbance of **0.874**. The standard solution exhibited an absorbance of **0.885**. Based on the comparison of sample and standard absorbance values, the percentage assay of the tablet formulation was found to be **98.7%**, which falls within the acceptable limits for pharmaceutical analysis. These results indicate that the developed method is accurate and suitable for routine quality control analysis of Zonisamide tablets.

Recovery Studies

The accuracy of the analytical method was further confirmed through recovery studies using the **standard addition method**. Known quantities of standard drug were added to the pre-analyzed sample at three concentration levels: **50%, 100%, and 150%**. The resulting solutions were analyzed and the percentage recovery was calculated.

The recovery values were found to be within the range of **98.0% to 99.2%**, indicating excellent accuracy and minimal interference from tablet excipients. These results confirm that the proposed analytical method is reliable and capable of accurately determining Zonisamide in pharmaceutical dosage forms.

Precision (Inter-Day Precision)

Precision of the method was evaluated by analyzing three different concentrations (**4, 14, and 18 µg/ml**) on three consecutive days. The absorbance values obtained on Day 1, Day 2, and Day 3 were found to be very close to each other, indicating minimal variation in results.

The small differences observed between measurements demonstrate the **high reproducibility and precision** of the developed method. This confirms that the analytical procedure provides consistent results when performed on different days under similar experimental conditions.

Repeatability (System Precision)

Repeatability of the system was assessed by measuring the absorbance of a **10 µg/ml solution** of Zonisamide at **234 nm** six times under identical conditions. The mean absorbance obtained was **0.891**, with a **standard deviation of 0.0005** and **%RSD of 0.06%**.

The very low %RSD value indicates excellent repeatability of the method and confirms that the instrument response and analytical procedure are highly consistent and reliable.

Method Validation

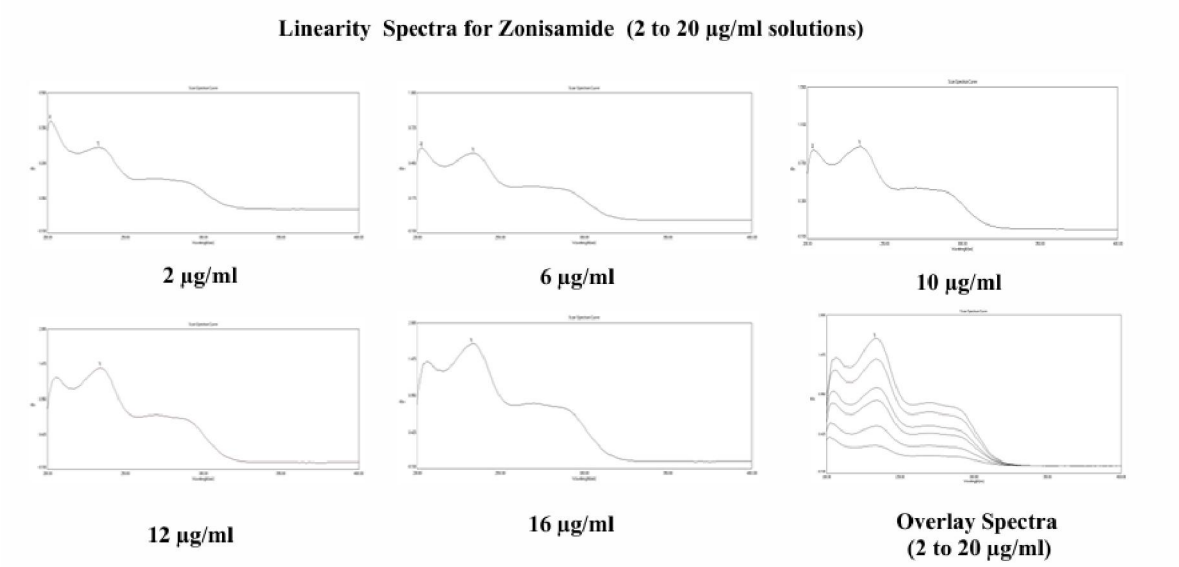
The developed UV spectrophotometric method was validated according to **International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) guidelines. The absorption maximum (λmax) of Zonisamide was found at **234 nm**. The method exhibited good linearity within the range of **2–20 µg/ml**.

The calculated **molar absorptivity (0.0881 L/mol/cm)** indicates adequate sensitivity of the method. The **limit of detection (LOD)** and **limit of quantification (LOQ)** were determined to be **0.91 µg/ml** and **2.76 µg/ml**, respectively, demonstrating the sensitivity of the analytical procedure.

Furthermore, the method was found to be **robust**, as small variations in experimental conditions did not significantly affect the analytical results. Overall, the validation parameters confirm that the developed method is **accurate, precise, sensitive, and reliable** for the routine analysis of Zonisamide in bulk and tablet dosage forms.

IJARSCT
International Journal of Advanced Research in Science, Communication and Technology
International Open-Access, Double-Blind, Peer-Reviewed, Refereed, Multidisciplinary Online Journal
ISSN: 2581-9429
Volume 6, Issue 3, March 2026
Impact Factor: 8.2

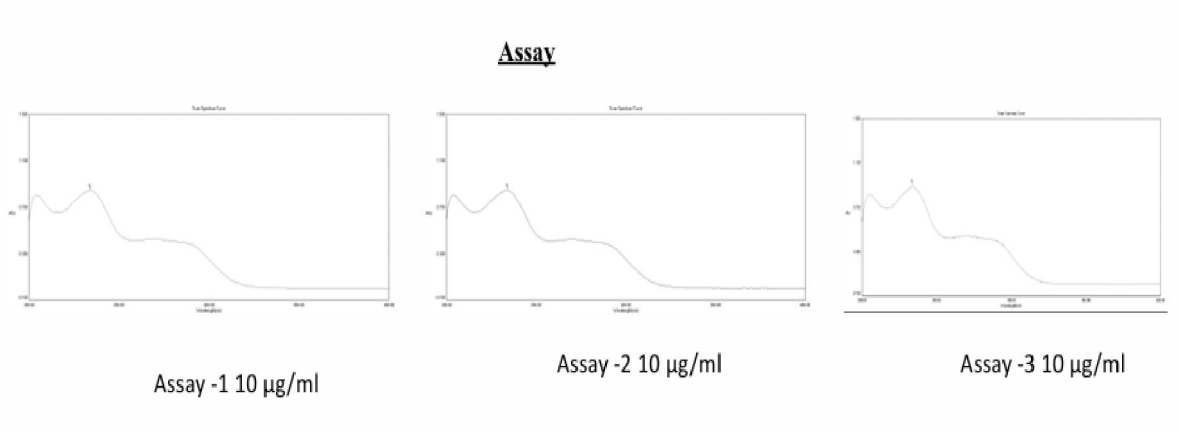
Linearity: Zonisamide



Accuracy

Table 1: Assayof Zonisamide Tablets

No.	ID	Mode	A	Assay(%)
			nm	
1	Sample	Absorbance	0.873	
			0.875	
			Avg. 0.874	98.7%
1	Standard	Absorbance	0.885	



Recovery Studies

In this parameter, Accuracy was conducted by analyzing sample solution spiked with known amounts of the bulk drug or standard at three kinds of concentration levels of 50, 100 and 150% of each at a specified limit.For all three levels,

IJARSCT
International Journal of Advanced Research in Science, Communication and Technology
International Open-Access, Double-Blind, Peer-Reviewed, Refereed, Multidisciplinary Online Journal
ISSN: 2581-9429
Volume 6, Issue 3, March 2026
Impact Factor: 8.2

percentage recoveries were measured and found to be within the limit. The accuracy and reliability of the developed method were established. Solutions prepared by using stock solution-

Table 2: Recovery Studies

Level	Standard Stock solution taken	Tablet Stock Solution taken	Diluted with Solvent mixture	Zonisamide (inµg/ml)
I(50%)	0.05 ml	0.1 ml	10 ml	15
II(100%)	0.10 ml	0.1 ml	10 ml	20
III(150%)	0.15 ml	0.1 ml	10 ml	25

Recovery Studies

In this parameter, Accuracy was conducted by analyzing sample solution spiked with known amounts of the bulk drug or standard at three kinds of concentration levels of 50, 100 and 150% of each at a specified limit.For all three levels, percentage recoveries were measured and found to be within the limit. The accuracy and reliability of the developed method were established. Solutions prepared by using stock solution-

Table 3: Recovery Studies

Level	Standard Stock solution taken	Tablet Stock Solution taken	Diluted with Solvent mixture	Zonisamide (inµg/ml)
I(50%)	0.05 ml	0.1 ml	10 ml	15
II(100%)	0.10 ml	0.1 ml	10 ml	20
III(150%)	0.15 ml	0.1 ml	10 ml	25

Table 4: Inter–Day Precision

No.	Concentration in µg/ml	Absorbance
Day 1	4	0.420
	14	1.229
	18	1.569
Day 2	4	0.422
	14	1.231
	18	1.563
Day 3	4	0.421
	14	1.230
	18	1.565

Repeatability

Table 5: System precision– Zonisamide (10 µg/ml solution)-

Sr. No.	Wavelength	Absorbance
1	234 nm	0.891
2		0.891
3		0.892
4		0.892
5		0.891
Mean	-----	0.891
SD	-----	0.0005
%RSD	-----	0.06%

DOI: 10.48175/IJARSCT-31605

IJARSCT
International Journal of Advanced Research in Science, Communication and Technology
International Open-Access, Double-Blind, Peer-Reviewed, Refereed, Multidisciplinary Online Journal
ISSN: 2581-9429
Volume 6, Issue 3, March 2026
Impact Factor: 8.2

Method validation:

Table 6: Method validation

Sr. No.	Parameters	InACN:0.1NHCl
1.	Absorbance maximum(λ max) in nm	234 nm
2.	Beer's law limit(µg/ml)	2-20µg/ml
3.	Molar Absorptivity(L/mol/cm)	0.0881
4.	Slope	0.0804 x
5.	Intercept	0.0982
6.	Correlation coefficient	0.9986
7.	LOD(µg/ml)	0.91
8.	LOQ(µg/ml)	2.76
9.	Robustness	Robust
10.	Recovery	98.0 to 99.2%

IV. CONCLUSION

A simple and sensitive UV–visible spectrophotometric method was successfully developed for the quantitative estimation of Zonisamide in tablet dosage form. The developed method showed good linearity within the concentration range of 2–20 µg/ml with a high correlation coefficient, confirming adherence to Beer–Lambert's law. Validation studies demonstrated that the method is accurate, precise, reproducible, and robust, with percentage recovery values close to 100% and very low %RSD values. The limits of detection and quantification indicated adequate sensitivity of the method for pharmaceutical analysis. The assay results of the tablet formulation were within acceptable limits, indicating the suitability of the method for routine quality control. Therefore, the proposed analytical procedure can be effectively applied for the quantitative determination of Zonisamide in bulk drug and pharmaceutical formulations in research laboratories and pharmaceutical industries.

REFERENCES

[1]. Vancha, H., Tewari, D., Kumar, R., Govindaiah, P., Mohd, S., Singh, S. K., & Gulati, M. (2023). Analytical Quality by Design Driven Development and Validation of UV-Visible Spectrophotometric Method for Quantification of Xanthohumol in Bulk and Solid Lipid Nanoparticles. *Turkish journal of pharmaceutical sciences*, *20*(3), 165–175. https://doi.org/10.4274/tjps.galenos.2022.05335

[2]. Sulistiawati, Enggi, C. K., Isa, H. T., Wijaya, S., Ardika, K. A. R., Asri, R. M., Donnelly, R. F., &Permana, A. D. (2022). Validation of spectrophotometric method to quantify cabotegravir in simulated vaginal fluid and porcine vaginal tissue in ex vivo permeation and retention studies from thermosensitive and mucoadhesive gels. *Spectrochimica acta. Part A, Molecular and biomolecular spectroscopy*, *267*(Pt 2), 120600. https://doi.org/10.1016/j.saa.2021.120600

[3]. Sharma, S., Sharma, J. B., Bhatt, S., & Kumar, M. (2020). Method Development and Validation of UV Spectrophotometric Method for the Quantitative Estimation of Curcumin in Simulated Nasal Fluid. *Drug research*, *70*(8), 356–359. https://doi.org/10.1055/a-1193-4655

[4]. Aljaber, K. A., Darwish, I. A., & Al-Hossaini, A. M. (2023). Spectrophotometric Study of Charge-Transfer Complexes of Ruxolitinib with Chloranilic Acid and 2,3-Dichloro-5,6-dicyano-1,4-benzoquinone: An Application to the Development of a Green and High-Throughput Microwell Method for Quantification of Ruxolitinib in Its Pharmaceutical Formulations. *Molecules (Basel, Switzerland)*, *28*(23), 7877. https://doi.org/10.3390/molecules28237877

[5]. Alzeer, H. S., Alzaid, S. F., Aldawsari, F. S., & Alshehri, Y. M. (2023). Development and validation of a simple method for the determination of triamcinolone acetonide in nasal spray. *Saudi pharmaceutical journal*

IJARSCT
International Journal of Advanced Research in Science, Communication and Technology
International Open-Access, Double-Blind, Peer-Reviewed, Refereed, Multidisciplinary Online Journal
ISSN: 2581-9429
Volume 6, Issue 3, March 2026
Impact Factor: 8.2

:SPJ : the official publication of the Saudi Pharmaceutical Society, *31*(10), 101793. https://doi.org/10.1016/j.jsps.2023.101793

[6]. Schmitz, C., Kuhn, D., Schwingel Henn, G., Mfoutou Massouangui, G. P., Marquetto, V. D. S., Zannata, G. S., Schlabitz, C., Weber, A. C., Cordeiro, S. G., Altenhofen, G., Hoehne, L., Lehn, D. N., & Volken de Souza, C. F. (2025). An Alternative UV-Vis Spectrophotometric Method for Accurate Quantification of Total Selenium in Se-Enriched Microbial Biomass. *ACS omega*, *10*(46), 55750–55758. https://doi.org/10.1021/acsomega.5c07107

[7]. Sharma, H., Sapkota, H. P., Paudel, K., Raila, A., Kandel, S., Chaudhary, P., & Bhattarai, K. (2023). Green Spectrophotometric Determination of Organophosphate in Selected Fruits and Vegetables. *International journal of analytical chemistry*, *2023*, 6691659. https://doi.org/10.1155/2023/6691659

[8]. Biswas, B. K., Biswas, N., Saha, S., Rahaman, A., Mandal, D. P., Bhattacharjee, S., Sepay, N., Zangrando, E., Garribba, E., & Roy Choudhury, C. (2022). Interaction with bioligands and in vitro cytotoxicity of a new dinucleardioxido vanadium(V) complex. *Journal of inorganic biochemistry*, *237*, 111980. https://doi.org/10.1016/j.jinorgbio.2022.111980

[9]. Baldera-Aguayo, P. A., Lee, A., & Cornish, V. W. (2022). High-Titer Production of the Fungal Anhydrotetracycline, TAN-1612, in Engineered Yeasts. *ACS synthetic biology*, *11*(7), 2429–2444. https://doi.org/10.1021/acssynbio.2c00116

[10]. Singh, S. K., Srinivasan, A., Mitra, S., &GoohPattader, P. S. (2022). Carbon dots and Methylene blue facilitated photometric quantification of Hemoglobin. *Spectrochimica acta. Part A, Molecular and biomolecular spectroscopy*, *271*, 120906. https://doi.org/10.1016/j.saa.2022.120906

[11]. Cardoso-Avila, P. E., Patakfalvi, R., Rodríguez-Pedroza, C., Aparicio-Fernández, X., Loza-Cornejo, S., Villa-Cruz, V., & Martínez-Cano, E. (2021). One-pot green synthesis of gold and silver nanoparticles using *Rosa canina* L. extract. *RSC advances*, *11*(24), 14624–14631. https://doi.org/10.1039/d1ra01448j

[12]. Varpe, A. S., Deshpande, M. D., Tope, D. R., &Borhade, A. V. (2023). Enhanced photocatalytic performance of $CdFe_2O_4/Al_2O_3$ nanocomposite for dye degradation. *Environmental science and pollution research international*, *30*(18), 52549–52560. https://doi.org/10.1007/s11356-022-24834-4