

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

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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 (λ_{max}) at 234 nm, which was selected for further analytical studies. The method obeyed Beer–Lambert’s law in the concentration range of 2–20 $\mu\text{g/ml}$, 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 $\mu\text{g/ml}$ and 2.76 $\mu\text{g/ml}$, 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

