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 5, Issue 4, May 2025
Impact Factor: 7.67

Development and Validation of High-Performance Liquid Chromatographic Method for Analysis of Zolpidem in Marketed Sublingual Spray

Mr.Suchisht Bhakare, Dr. Anil P. Dewani, Prof. (Dr) A.V. Chandewar
Department of Quality Assurance
Pataldhamal Wadhwani College of Pharmacy, Yavatmal, India

Abstract: *A rapid, sensitive, and reliable High-Performance Liquid Chromatographic (HPLC) method was developed and validated for the quantitative determination of Zolpidem tartrate (ZOL), a widely used sedative and hypnotic. The chromatographic separation was achieved on a reversed-phase C18 column using an isocratic mobile phase consisting of 0.1% OPA and Methanol (50:50 v/v) at a flow rate of 1.0 mL/min. UV detection was carried out at 293 nm. The method was validated according to USP guidelines for linearity, range, accuracy, precision (repeatability and intermediate precision), specificity (placebo interference), and robustness. The method exhibited good linearity over the concentration range of 1.2-2.7 µg/mL with a correlation coefficient (R^2) of 0.999. Accuracy, determined by recovery studies, was within the acceptable limits of 98-102%. Precision, expressed as the relative standard deviation (%RSD), was less than 2.0% for both repeatability (0.45%) and intermediate precision (0.82%). The method was specific, with no interference from placebo. Robustness was demonstrated by evaluating the effect of small deliberate changes in flow rate, organic phase composition, and wavelength. The developed and validated HPLC method is suitable for routine quality control analysis of Zolpidem in pharmaceutical sublingual spray formulations.*

Keywords: Zolpidem tartrate, HPLC, Method Development, Validation, Pharmaceutical Analysis, Quality Control