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 1, May 2025
Impact Factor: 7.67

Development and Validation of a High-Performance Liquid Chromatography Method for the Analysis of Amlodipine and Telmisartan in a Fixed-Dose Drug Combination

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Abstract: *A sensitive and reliable Reversed-Phase High-Performance Liquid Chromatography (RP-HPLC) method was developed and validated for the simultaneous estimation [1] of Amlodipine (AML) and Telmisartan (TEL) in a fixed-dose combination tablet. The chromatographic separation was achieved on a C18 column (4.6 x 250 mm) using an isocratic mobile phase consisting of 0.2% Ortho Phosphoric Acid in water and Acetonitrile in the ratio of 70:30 (v/v) at a flow rate of 1.0 ml/min. UV detection was performed at 258 nm. The method was validated according to USP guidelines for system suitability, precision, accuracy, linearity, robustness, and specificity. System suitability parameters were within acceptable limits. The method demonstrated good precision with %RSD values for system and method precision below 2.0%. Accuracy was confirmed by recovery studies, yielding mean recoveries between 98-102% for both analytes. Linearity was established with a correlation coefficient (R^2) of 0.998 for both AML and TEL over the concentration range of 50-150%. The method was found to be robust to small deliberate changes in chromatographic conditions and specific as no interference was observed from the placebo. The developed and validated RP-HPLC method is simple, rapid, and suitable for routine quality control analysis of Amlodipine and Telmisartan in pharmaceutical formulations.*

Keywords: RP-HPLC, Method Development, Method Validation, Simultaneous Estimation, Amlodipine, Telmisartan, Fixed-Dose Combination, Pharmaceutical Analysis

DOI: 10.48175/IJARSCT-26174