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Development and Validation of a High-Performance Liquid Chromatographic Method for Analysis of Tacrolimus in Tablet Formulation

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Abstract: *A simple, rapid, and accurate Reverse Phase High-Performance Liquid Chromatography (RP-HPLC) method was developed and validated for the quantitative determination of Tacrolimus (TAC) in tablet formulations. The chromatographic separation was achieved on a C8 (Thermo Hypersil gold) column (4.6 x 250 mm, 5µm particle size) using an isocratic mobile phase consisting of water (0.1% Ortho Phosphoric Acid) and Acetonitrile in a ratio of 50:50 % v/v, at a flow rate of 1 ml/min. The eluent was monitored at a wavelength of 210 nm. The method was validated according to USP guidelines for system suitability, precision, linearity, accuracy, robustness, and specificity. System suitability parameters, including retention time (approximately 5.2 minutes), tailing factor (< 2), and theoretical plates (> 2000), were within acceptable limits. The method demonstrated good linearity over the range of 80-150% of the target concentration (R2=0.999). Accuracy, assessed by recovery studies, was within 99.80-99.86%. Precision, as repeatability (%RSD), was less than 2%. The method was also found to be robust to small changes in chromatographic conditions and specific, with no interference from excipients or placebo. The developed and validated RP-HPLC method is suitable for the routine quality control analysis of TAC in tablet formulations.*

Keywords: Tacrolimus, HPLC, Method Development, Validation, Pharmaceutical Analysis, Quality Control

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