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Development and Validation of New Analytical Methods for the Simultaneous Estimation of Selected Combinations of Drugs in Pharmaceutical Formulations

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Abstract: *This paper proposes a high-performance liquid chromatography (HPLC) method for the simultaneous estimation of nortriptyline and gabapentin. The analytical conditions of the method were selected based on the chemical nature of the two compounds, and the method was validated through various studies including system suitability, specificity, linearity, LOD/LOQ, and recovery studies. The proposed method uses a Zorbax C18 column, a phosphate buffer with an acidic pH, and acetonitrile as the organic constituent of the mobile phase. The system suitability test evaluated the suitability of the chromatographic system for the analysis of the drug combination, and the specificity of the method was evaluated by assessing interference from excipients in the pharmaceutical dosage form prepared as a placebo solution. The linearity of the method was evaluated through linear regression analysis of the standard curve, and the LOD and LOQ values were determined by serial dilutions of nortriptyline and gabapentin stock solutions. The recovery studies were conducted to evaluate the degree of accuracy of the proposed method through known amounts of standard nortriptyline and gabapentin added to preanalyzed samples. Overall, the proposed HPLC method offers a reliable and accurate means for the simultaneous estimation of nortriptyline and gabapentin.*

Keywords: HPLC method, Nortriptyline, Gabapentin, Validation, System suitability, Specificity

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