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Development and Validation of Reverse Phase High-Performance Liquid Chromatographic Method for Analysis of Flupirtine Maleate in Tablet Formulation

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Abstract: *A simple, rapid, and reliable Reverse Phase High-Performance Liquid Chromatographic (RP-HPLC) method was developed and validated for the quantitative determination of Flupirtine Maleate (FLU) in tablet formulations. The chromatographic separation was achieved on a C18 column (Thermo Hypersil gold, 4.6 x 250 mm, 5 µm) using an isocratic mobile phase consisting of 10 mM Phosphate buffer (pH 3.5) and Acetonitrile (60:40 % v/v) at a flow rate of 1.0 ml/min. The eluent was monitored at 250 nm. The method was validated according to ICH guidelines for system suitability, linearity, range, accuracy, precision, ruggedness, robustness, and specificity. The retention time of Flupirtine Maleate was approximately 4.6 minutes. The method exhibited excellent linearity over the concentration range of 80-180 µg/ml (R2=0.9997). Accuracy, determined by the standard addition method, showed mean recoveries ranging from 99.90% to 99.98%. The method demonstrated good precision with a system precision of 0.39% RSD and a method precision of 0.03% RSD. Ruggedness and robustness studies confirmed the reliability of the method under varied conditions. The method was specific, with no interference from placebo components. The developed and validated RP-HPLC method is suitable for routine quality control analysis of Flupirtine Maleate in tablet formulations.*

Keywords: Flupirtine Maleate, HPLC, Method Development, Validation, Pharmaceutical Analysis, Quality Control

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