

Analytical Method Development and Validation of Antihypertensive Drug by RP-HPLC

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Abstract: A robust reverse-phase high-performance liquid chromatography (RP-HPLC) method was developed and validated for the quantitative analysis of Felodipine (FLD) in tablet formulations. Chromatographic separation was achieved using a Shimadzu Mode.0001 CBM-20A/20 Alite HPLC system with an SPD M20A prominence photodiode array detector and a C18 Zorbax column. The mobile phase consisted of phosphate buffer (pH 7.0) and acetonitrile (20:80, v/v), with a flow rate of 1.2 mL/min and detection at 234 nm. The method exhibited excellent linearity (0.1-150 µg/mL), high precision (RSD < 2%), and accurate recovery (97.16%-98.80%). Robustness was confirmed by varying key parameters, and the LOD and LOQ were determined to be 0.0279 µg/mL and 0.0852 µg/mL, respectively. Stability studies confirmed the method's capability to separate FLD from its degradation products under various stress conditions. The method successfully quantified FLD in commercial tablets with near-100% recovery, indicating its suitability for routine quality control in pharmaceutical laboratories.

Keywords: Felodipine, RP-HPLC, Method Validation, Quantitative Analysis, Pharmaceutical Formulations, Linearity, Precision, Accuracy, Robustness, Stability Studies.