

Development and Validation of RP-HPLC Method for the Estimation of Linagliptin, Dapagliflozin and Metformine Hydrochloride in Combined Dosage Form

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Abstract: To develop and validate a simple, accurate, precise, and robust Reverse-Phase High-Performance Liquid Chromatography (RP-HPLC) method for the simultaneous quantification of Metformin (METF), Linagliptin (LINA), and Dapagliflozin (DAPA) in their combined oral dosage form. Chromatographic separation was achieved on an ODS Hypersil C18 column (250 mm × 4.6 mm, 5 μm). The mobile phase consisted of 20 mM phosphate buffer (pH 3.5) and Methanol in a ratio of 80:20 (v/v), delivered isocratically at a flow rate of 1.0 mL/min. Detection was performed at 217 nm. The method was validated according to ICH guidelines for linearity, accuracy, precision, specificity, LOD, LOQ, and robustness. The method successfully resolved all three drugs with good peak symmetry. The linearity was excellent across the established ranges (e.g., METF: 50–500 μg/mL) with high correlation coefficients ($r^2 > 0.991$). The assay of the marketed formulation, 'Dapaglyn LM', showed high accuracy, with average drug recovery percentages of 100.57% (METF), 100.73% (LINA), and 101.70% (DAPA). Precision studies yielded low %RSD values (e.g., Method Precision RSD < 0.9810), confirming reliability. The validated RP-HPLC method is efficient, sensitive, and meets all regulatory requirements for the simultaneous estimation of Metformin, Linagliptin, and Dapagliflozin. It is highly suitable for routine quality control and stability analysis in pharmaceutical manufacturing.

Keywords: RP-HPLC, Pharmacokinetics, Bioavailability, Chromatography, Analytical Validation

