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Analytical Method Development and Validation of Alogliptin and Dapagliflozin in Tablet Dosage Form by RP HPLC

Bagnawar Ashabai Maruti, Deshpande Poonam Suresh, Dr. Rajurkar Vikas
Dr. Vedprakash Patil Pharmacy College, Chh. Sambhajinagar, Maharashtra, India

Abstract: *The development and validation of a reverse-phase high-performance liquid chromatography (RP-HPLC) method for the simultaneous quantification of Alogliptin and Dapagliflozin in tablet dosage forms are presented in this study. Methanol was selected as the optimal solvent due to its superior solubility for both drugs. The wavelength for detection was set at 286 nm, as determined by the overlay PDA-spectrum, ensuring accurate quantification. The method was optimized using an HPLC C18 column (150 mm × 4.6 mm, 2.5 µm particle size) with a mobile phase comprising acetonitrile and 0.05% ortho phosphoric acid (80:20 % v/v), adjusted to pH 6.5 with 0.1% triethylamine. The chromatographic conditions were fine-tuned to achieve excellent resolution and symmetrical peak shapes for both drugs, with retention times of 5.690 ± 0.02 min for Alogliptin and 3.044 ± 0.022 min for Dapagliflozin. The method was validated as per ICH guidelines, demonstrating linearity, accuracy, precision, sensitivity, robustness, and specificity. Linearity was confirmed for Alogliptin (5–25 µg/mL) and Dapagliflozin (40–200 µg/mL) with correlation coefficients (r^2) of 0.9999 and 0.9996, respectively. The method exhibited satisfactory accuracy with recovery rates within 99-101% and precision with %RSD less than 2%. Sensitivity analysis revealed limits of detection (LOD) and quantification (LOQ) appropriate for routine analysis. The method was successfully applied to the analysis of both bulk samples and marketed tablet formulations, proving its utility for quality control and routine analytical purposes in the pharmaceutical industry.*

Keywords: RP-HPLC, Alogliptin, Dapagliflozin, analytical method, validation, tablet dosage, linearity, accuracy.