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Development and Validation RP-HPLC Method for Estimation of Antidiabetic Drugs in Pharmaceutical Dosage Form

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Abstract: *This study details the development and validation of an RP-HPLC method for estimating Canagliflozin and Metformin in pharmaceutical dosage forms. Canagliflozin, an SGLT2 inhibitor, and Metformin, an antihyperglycemic agent, were obtained from Arti Drug Pvt. Ltd. Marketed formulation Invokamet was sourced locally. Chromatographic separation was achieved on a C18 column (250 x 4.6 mm, 5 µm) using a mobile phase of Methanol: Water (80:20) with 0.1% ortho phosphoric acid at a 1.0 ml/min flow rate and detection at 254 nm. The retention times for Canagliflozin and Metformin were 8.183 min and 3.633 min, respectively. Method validation parameters included system suitability, accuracy, precision, and robustness. System suitability tests confirmed adequate resolution and repeatability. Accuracy was evaluated through recovery studies at 80%, 100%, and 120% concentration levels, yielding satisfactory results. Precision was demonstrated with intra-day and inter-day % RSD values below 2. Robustness was assessed by varying mobile phase composition and flow rate, showing consistent retention times and tailing factors. The method proved selective, accurate, precise, and robust, with a short run time, facilitating rapid quantification of samples. It is suitable for routine quality control analysis of Canagliflozin and Metformin in pharmaceutical formulations*

Keywords: RP-HPLC, Canagliflozin, Metformin, pharmaceutical dosage forms, method validation, accuracy, precision, robustness.