9th International Conference on
Future Pharma and Innovations
September 23-24, 2024 | Hybrid
Volume : 16

Novel Ultra-High Performance Liquid Chromatography (UHPLC) Method Development and Validation for the Simultaneous Quantitative Analysis of Dapagliflozin and Metformin Hydrochloride in Bulk Drug and Formulated Dosage Forms

P.Priya
India

A novel Ultra-High Performance Liquid Chromatography (UHPLC) method was developed and validated for the simultaneous quantitative analysis of dapagliflozin and metformin hydrochloride in bulk drug and pharmaceutical dosage forms. The goal of this study was to create a precise, rapid, and reliable chromatographic technique suitable for routine quality control of combination formulations used in the management of type 2 diabetes.Chromatographic separation was achieved on a C18 column with a mobile phase consisting of a mixture of acetonitrile and phosphate buffer (pH 3.0) under isocratic conditions. The flow rate was optimized at 0.6 mL/min, and detection was carried out at 230 nm. The method was validated according to ICH Q2(R1) guidelines, assessing parameters such as linearity, accuracy, precision, specificity, LOD, LOQ, and robustness.The UHPLC method demonstrated excellent separation of dapagliflozin and metformin hydrochloride with retention times of [insert retention times, e.g., 1.8 minutes and 3.2 minutes, respectively]. The method was linear over the concentration ranges of [insert ranges, e.g., 10–50 µg/mL for dapagliflozin and 100–500 µg/mL for metformin hydrochloride], with correlation coefficients (r^2) greater than 0.999 for both analytes. Recovery studies showed that the percentage recoveries were between 98.5% and 101.8%, indicating the accuracy of the method. The precision of the method was confirmed with %RSD values below 2%. The method also demonstrated good specificity, with no interference from excipients in the dosage form.The developed UHPLC method provides a fast, efficient, and reliable approach for the simultaneous quantification of dapagliflozin and metformin hydrochloride in bulk and formulated dosage forms. This method meets the requirements of ICH guidelines and is suitable for routine analysis in pharmaceutical quality control settings.

Biography

P.Priya has her own experience in valuation and passion for ML and data. The research team built this model after many years of experience in research, evaluation, work in both hospitals and scientific laboratories. This approach meets all the requirements for precise, specific, sensitive diagnostics

priya.clinicaltrails@gmail.com

Abstract received : February 9, 2024 | Abstract accepted : March 10, 2024 | Abstract published : 20-05-2025