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Analytical method development and validation for the simultaneous estimation of valsartan and hydrochlorothiazide in bulk and pharmaceutical dosage forms by using rp-hplc method

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The aim of this study was to develop and validate a novel Ultra-High Performance Liquid Chromatography (UHPLC) method for the quantitative analysis of Dapagliflozin in bulk drug and formulated dosage forms.The objective was to establish an efficient and precise UHPLC method for the rapid quantification of Dapagliflozin, ensuring its suitability for routine quality control in both bulk and pharmaceutical formulations.The UHPLC method was developed using a Waters Acquity UPLC system with a C18 column (100 mm × 2.1 mm, 1.7 µm). The mobile phase was optimized to a mixture of water (containing 0.1% formic acid) and acetonitrile in a 60:40 (v/v) ratio, with a flow rate of 0.5 mL/min. Detection was performed at 235 nm. The method was validated according to ICH guidelines, assessing parameters such as linearity, accuracy, precision, specificity and robustness.The method demonstrated excellent linearity in the concentration range of 0.1–10 µg/mL for Dapagliflozin with a correlation coefficient (R^2) greater than 0.999. The accuracy was confirmed with recovery values between 98% and 102%, and precision results showed RSD values of less than 2% for both intra-day and inter-day variations. The method was highly specific, with no interference from excipients or degradation products. Robustness studies confirmed the method's reliability under slight variations in chromatographic conditions.The developed UHPLC method provides a rapid, accurate, and precise approach for the quantitative analysis of Dapagliflozin in bulk drug and formulated dosage forms. The method meets the requirements for routine quality control and is suitable for regulatory compliance in pharmaceutical industries.

Biography

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. .

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