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Optimization and Validation of a UV Spectrophotometric Assay for Empagliflozin: A Cost-Effective Approach for Pharmaceutical Quality Control

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Empagliflozin, a selective sodium-glucose co-transporter 2 (SGLT2) inhibitor, is widely used for the management of type 2 diabetes mellitus (T2DM). Ensuring the quality and consistency of empagliflozin-containing pharmaceutical products requires validated analytical methods that are simple, accurate, and cost-effective. This study aimed to develop and validate a UV spectrophotometric method for the quantitative estimation of empagliflozin in bulk drug and tablet formulations, following ICH Q2(R1) guidelines. A UV spectrophotometric method was developed using a 50:50 methanol-deionised water solvent system. The λmax (223 nm) was identified from the absorption spectrum, and calibration curves were prepared within the 2–20 μg/mL range. Validation parameters—including linearity, specificity, accuracy, precision, limits of detection and quantification (LOD/LOQ), and solution stability—were evaluated per ICH Q2(R1). Commercial empagliflozin 10 mg tablets were assayed using both the developed UV method (200–400 nm range) and a validated HPLC method to confirm method accuracy. Empagliflozin exhibited optimal solubility and spectral stability in the selected solvent system, with a prominent λmax at 223 nm. Calibration data demonstrated excellent linearity (R = 0.9994). Method validation confirmed excellent specificity, with no interference from excipients. Accuracy studies demonstrated recovery values ranging from 97.1% to 99.8%, while intra-day and inter-day precision yielded %RSD values of 0.57% and 0.53%, respectively. The LOD and LOQ were 0.34 μg/mL and 1.03 μg/mL, respectively. Analytical solutions remained stable for up to 24 hours at room temperature with less than 1% change in absorbance. API content obtained using UV spectrophotometry (97.8%) closely matched that obtained by HPLC (98.2%), supporting the reliability of the developed method. Overall, the developed UV spectrophotometric method is simple, rapid, environmentally friendly, and cost-effective, meeting all regulatory validation requirements. It is suitable for routine quality control of empagliflozin formulations and provides an accessible alternative to chromatographic techniques, particularly in laboratories with limited resources.

Keywords: Empagliflozin, UV spectrophotometry, Method validation, Quality control