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RP-HPLC Method Development and Validation for Simultaneous Estimation of Metformin and Empagliflozin in Pharmaceutical Dosage Formulations

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Abstract: ***Objective:*** *To optimize a solvent system for the efficient resolution and quantification of Metformin and Empagliflozin from tablet matrices and degradation products.*
Methods: *Various solvent systems were evaluated based on the polarities and solubilities of Metformin and Empagliflozin, alongside reported literature data. Initial trials with 100% acetonitrile demonstrated inadequate resolution and peak splitting. Subsequently, combinations of acetonitrile and methanol with 0.05% and 0.1% Ortho Phosphoric Acid were tested across different ratios. Adjustments were made to reduce solvent interference and improve retention times.*
Results: *The optimal solvent system was determined to be acetonitrile: 0.05% Ortho Phosphoric Acid (80:20 v/v), with the pH adjusted to 6.5 using 0.1% triethylamine. This configuration provided excellent peak symmetry and resolution, minimizing solvent interference. The total analysis time was under 6 minutes, with retention times of 5.690 ± 0.02 minutes for Metformin and 3.044 ± 0.022 minutes for Empagliflozin.*
Conclusion: *The optimized solvent system of acetonitrile and 0.05% Ortho Phosphoric Acid, adjusted with triethylamine, is effective for the reliable and accurate quantification of Metformin and Empagliflozin, demonstrating suitability for pharmaceutical analysis*

Keywords: Metformin, Empagliflozin, solvent system optimization, HPLC, pharmaceutical analysis, peak resolution, retention time

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