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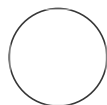
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Selection of Stationary Phase of HPLC for Posaconazole Estimation V.1

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ABSTRACT

Introduction: Posaconazole is a widely used antifungal drug, and its accurate quantification is essential for quality control and assessment of its pharmaceutical products. This study aimed to develop and validate a reverse-phase high-performance liquid chromatography (HPLC) analytical method for quantifying Posaconazole in bulk and dosage form.

Methods: The HPLC method was developed and validated based on International Conference on Harmonisation (ICH) guidelines. The developed method was then applied to quantify Posaconazole in a marketed tablet formulation. The method's specificity, linearity, precision, accuracy, robustness, and stability were evaluated.

Results: The developed HPLC method showed good linearity over a 2-20 µg/mL concentration range. The percentage recovery of Posaconazole from the bulk and marketed formulations was found to be 99.01% and 99.05%, respectively. The intra-day and inter-day precisions were less than 1%, and the method was stable under different conditions. The HPLC method was successfully applied to quantify Posaconazole in the marketed formulation.

Conclusion: The developed and validated HPLC method is reliable and efficient for analyzing Posaconazole in bulk and dosage forms. The method's accuracy, precision, specificity, linearity, robustness, and stability demonstrate its effectiveness. The method can be used for the quality control and assessment of Posaconazole-containing pharmaceutical products.

Selection of Stationary Phase

- 1 To determine the appropriate stationary phase for the HPLC method, a total of 60 trials were conducted using various columns, including Phenomenex Luna C18, Phenomenex Kinetex C18, Phenomenex Hyperclone C18, and Agilent Eclipse XDB C18.
- 2 The selection criteria included cost-effectiveness, sensitivity, retention time, peak area, tailing factor, and K factor.
- 3 After a thorough evaluation, the Phenomenex Hyperclone C18 column was chosen as the optimal stationary phase due to its superior performance and cost-effectiveness.
- 4 The results of this selection process ensured that the HPLC method was optimized to deliver accurate and reliable results for the quantification of Posaconazole in bulk and dosage form.