Selection of buffer for the HPLC estimation of Posaconazole 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.

1 The selection of an appropriate buffer is critical for achieving optimal separation and analysis of target compounds in HPLC. The choice of buffer depends on various factors such as the pKa of

the compound, the pH range of the buffer, and the compatibility with the stationary phase. For acidic compounds, a buffer with low pH is preferred to suppress the ionization of organic acids. In contrast, a buffer with high pH is preferred for basic compounds to promote their ionization.

2 In HPLC, a buffer with a pH range of 2 to 8 is generally used to prevent the stationary phase from losing its bonded phase due to hydrolysis or solubility issues. Phosphate and acetate buffers are popular choices due to their buffering capacity within this pH range. Phosphate buffers have three pKa values that buffer at different pH ranges, while acetate buffers fill the gap between pH 3.1 and 6.2. Citrate buffers can buffer over a pH range of 2.1 to 6.4 but have a higher cut-off than acetate and phosphate buffers.

3 In the current study, based on the pKa values of Posaconazole, a buffer with pH 6.8 was selected, and phosphate buffer was chosen as it was compatible with the stationary phase and within the desired pH range.

4 Overall, the selection of an appropriate buffer is crucial for achieving accurate and reproducible results in HPLC analysis. By considering the pKa values of the compounds and the pH range of the buffer, an optimal buffer can be selected for successful separation and quantification of the target compound.

5 Preparation of Phosphate Buffer : 0.869g of Sodium dihydrogen phosphate monohydrate , 0.511g of Disodium hydrogen phosphate in 1L of water will give a 10mM Phosphate buffer of pH 6.8