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Stability Indicating Method Development and Validation for the Simultaneous Estimation of Dutasteride and Latanoprost in a Synthetic Mixture Using RP-HPLC Method

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Abstract: ***This review article discusses the development and validation of a stability-indicating reverse-phase high-performance liquid chromatographic (RP-HPLC) method for the simultaneous estimation of Dutasteride and Latanoprost in a synthetic mixture. The main objective of such methods is to ensure accurate, precise, and specific quantification of active pharmaceutical ingredients (APIs) even in the presence of degradation products. Stability-indicating methods are critical for establishing the stability profile of drugs and ensuring quality control in accordance with ICH guidelines. The review focuses on various chromatographic parameters, validation criteria, and forced degradation studies, emphasizing their importance in developing robust, reproducible, and regulatory-compliant analytical procedures.***
Keywords: RP-HPLC, Stability indicating method, Dutasteride, Latanoprost, Validation, ICH Guidelines.

I. INTRODUCTION

Analytical method development and validation are essential aspects of pharmaceutical research and quality control. Reverse-phase high-performance liquid chromatography (RP-HPLC) is one of the most widely used analytical techniques due to its versatility, accuracy, and reproducibility. The development of a stability-indicating method ensures that the method can distinguish the analyte from its degradation products, thereby confirming the stability and purity of pharmaceutical formulations.

Dutasteride is a dual 5α-reductase inhibitor used in the treatment of benign prostatic hyperplasia, while Latanoprost is a prostaglandin F2α analog used in glaucoma management. Simultaneous estimation of these drugs in a synthetic mixture presents analytical challenges due to differences in polarity, stability, and UV absorption characteristics. Therefore, a validated RP-HPLC method that meets ICH Q2(R1) requirements is necessary to ensure consistent and accurate results.

II. LITERATURE REVIEW

A number of analytical techniques have been reported for individual estimation of Dutasteride and Latanoprost, including UV spectrophotometry, HPLC, LC-MS, and UPLC. However, simultaneous estimation using a single stability-indicating RP-HPLC method has not been extensively explored. The review of existing literature reveals that most studies focus on either method optimization or validation independently, but not on their combined stability performance. This review integrates findings from previous studies and highlights gaps in method robustness and forced degradation analysis.

III. METHODOLOGY

Method development begins with selection of suitable mobile phase, column type, detection wavelength, and flow rate. A C18 column (250 mm × 4.6 mm, 5 µm) is typically preferred for separation. Various mobile phase compositions, such as methanol:acetonitrile:buffer mixtures, are tested to achieve optimal resolution. The synthetic mixture of Dutasteride and Latanoprost is prepared at known concentrations for calibration curve generation. Forced degradation studies under acidic, alkaline, oxidative, photolytic, and thermal conditions are performed to demonstrate method specificity.

IV. VALIDATION PARAMETERS

The developed method is validated as per ICH Q2(R1) guidelines, including parameters such as specificity, linearity, accuracy, precision, LOD, LOQ, robustness, and system suitability. Specificity ensures the method distinguishes analytes from degradation products. Linearity is assessed over a defined range, with correlation coefficients (r^2) typically >0.999. Accuracy is determined by recovery studies at 80%, 100%, and 120% levels. Precision includes repeatability and intermediate precision, expressed as %RSD less than 2%. Robustness examines the impact of small variations in flow rate, pH, or mobile phase ratio.

V. RESULTS AND DISCUSSION

Results from optimization and validation indicate that the RP-HPLC method provides well-resolved, symmetrical peaks for both analytes. Retention times for Dutasteride and Latanoprost are approximately 4.2 and 6.1 minutes, respectively, depending on mobile phase composition. Forced degradation studies confirm the method's stability-indicating nature, with degradation peaks adequately separated from drug peaks. Statistical validation parameters, including low %RSD and high recovery, confirm the reliability of the developed method.

VI. CONCLUSION

The developed RP-HPLC method for simultaneous estimation of Dutasteride and Latanoprost is precise, accurate, specific, and robust. It meets the requirements of a stability-indicating method as per ICH Q2(R1) guidelines. The method can be successfully applied for routine quality control of combined formulations, ensuring consistency and compliance with pharmaceutical standards.

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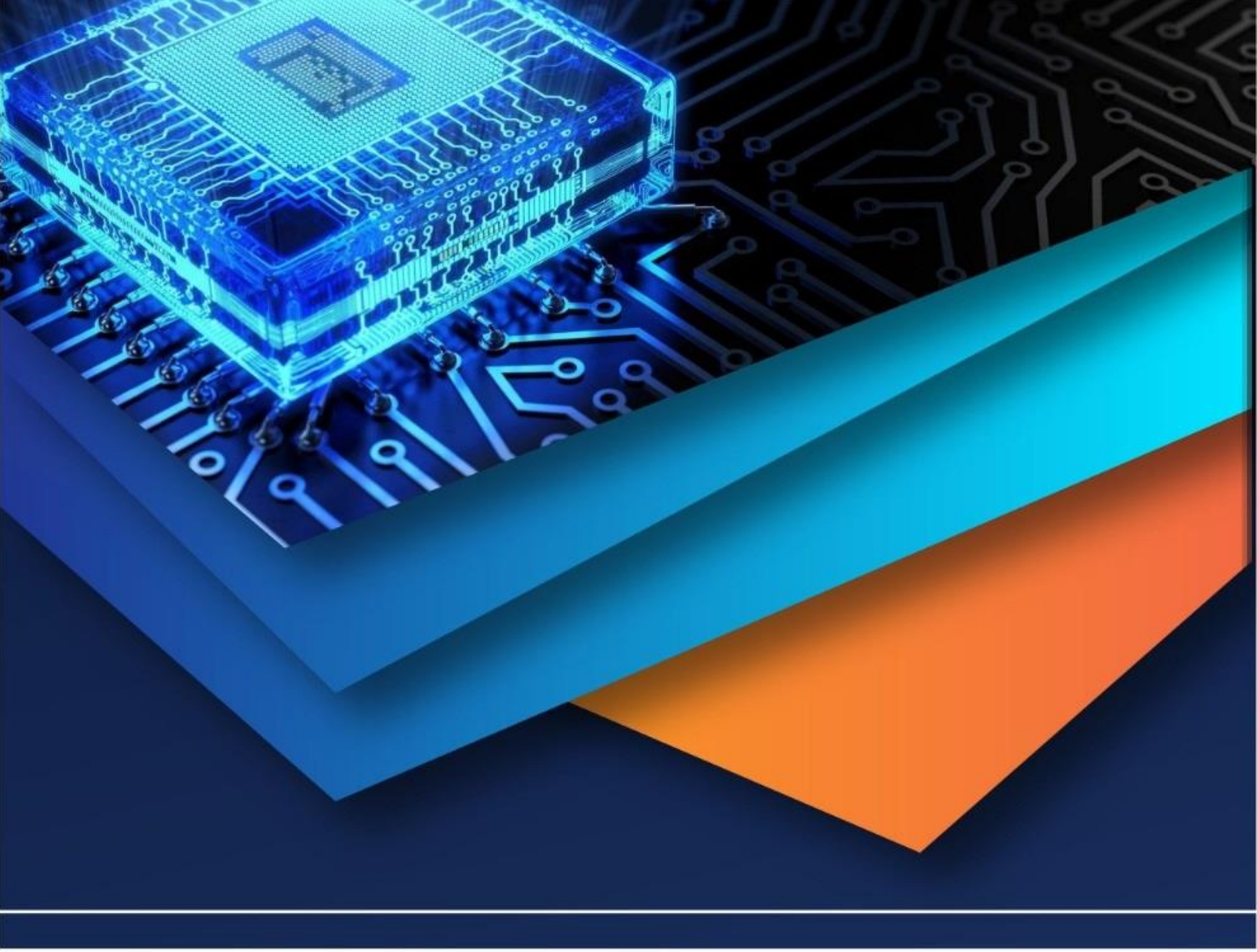

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