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Original Article

QbD-Enhanced HPLC Method Development for Vildagliptin and Metformin HCl Formulations

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ABSTRACT

Objectives: This research employs the Quality by Design strategy to design an optimized High-Performance Liquid Chromatography method aimed at analyzing vildagliptin and metformin hydrochloride in pharmaceutical dosage forms. **Materials and Methods:** The mobile phases A and B comprised a buffer-acetonitrile mixture in ratios of 950:50 v/v and 600:400 v/v, respectively. Chromatographic separation was achieved using an YMC Triart C-18 column, with Vildagliptin detection conducted at 210 nm via UV absorbance. Various independent parameters were selected for investigation and risk assessment was employed to evaluate their impact on the analytical responses. **Results:** QbD prioritizes product understanding, risk management and process control to enhance quality assurance and regulatory tractability. Analytical Quality by Design principles ensure robust and flexible methods throughout the product lifecycle. **Conclusion:** This study developed a robust HPLC method for Vildagliptin using a Quality by Design (QbD) approach. Key factors like mobile phase composition and buffer pH were optimized through multivariate analysis. The resulting method, validated for accuracy, precision and robustness, outperformed traditional methods and is suitable for routine pharmaceutical analysis.

Keywords: HPLC method development, Metformin hydrochloride, Pharmaceutical dosage forms, Product understanding, Quality by Design, Risk management, Vildagliptin.

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INTRODUCTION

The current research work aims to utilize the QbD procedure for developing and optimizing a high performance LC technique for vildagliptin and metformin hydrochloride in a pharmaceutical dosage form. QbD is a methodical method improvement strategy that kicks off with predetermined goals and stresses a comprehensive consideration of both the product and the process. This involves prioritizing knowledge of products and manufacturing procedure, quality risk assessment and process rheostat, all based on thorough scientific principles.[1] By employing QbD principles, the primary goal is to ensure a higher level of confidence regarding product eminence, gain regulatory flexibility and continuously improve the method throughout its lifecycle. To achieve this, the foundation of the QbD method lies in implementing established guidelines, such as ICH Q8 Pharmaceutical Development, ICH Q9 Quality Risk Management and ICH Q10 Pharmaceutical Quality System.[2-4] In context of pharmaceutical product development, analytical science plays a critical role leading to the concept of analytical QbD. A scientific and risk-based approach for developing analytical methods is analytical QbD. Its objective is to recognizing predetermined goals and effectively drive critical essential scheme having properties that are affected by method variables. The end outcome of this strategy is improved method performance as well as high resilience, robustness and adaptability for ongoing expansion.[5,6] The application of AQbD leads to the establishment of a well-known, appropriate and reliable technique that consistently conveys the projected results over the entire product life span, analogous to the method QbD.[7,8] To make sure the technique is effective and reliable throughout the product's lifespan, it is crucial to assess the robustness and ruggedness of HPLC methods early in the method development stage for QbD. This proactive approach prevents the need for extensive redevelopment, revalidation and retransfer of analytical methods in the case of adopting a weak or unreliable system.[9] The primary vision of AQbD is to recognize potential drawback strategy and provide a reliable, operational design environment or design space while adhering to relevant

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