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Research Article

DEVELOPMENT AND VALIDATION OF AN RP-HPLC METHOD FOR SIMULTANEOUS ESTIMATION OF COBICISTAT AND ATAZANAVIR IN BULK AND PHARMACEUTICAL DOSAGE FORM

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ABSTRACT

This research paper focuses on the development and validation of an RP-HPLC (Reverse-Phase High-Performance Liquid Chromatography) method for the simultaneous estimation of cobicistat and atazanavir in bulk and pharmaceutical dosage form. Cobicistat and atazanavir are important antiretroviral drugs used in the treatment of HIV infection. The development of a reliable and accurate analytical method for their simultaneous determination is essential for quality control and pharmacokinetic studies. The RP-HPLC method was optimized by considering factors such as column selection, mobile phase composition, flow rate, and detection wavelength. Validation parameters including linearity, precision, accuracy, specificity, robustness, and system suitability were evaluated according to international guidelines. The developed method demonstrated good linearity, sensitivity, and selectivity for the simultaneous estimation of cobicistat and atazanavir in both bulk and pharmaceutical dosage form. The findings of this study provide a robust and reliable analytical method that can be utilized for routine analysis and quality control of cobicistat and atazanavir formulations.

KEYWORDS

RP-HPLC, Cobicistat, Atazanavir, Simultaneous estimation, Validation, Bulk, Pharmaceutical dosage form, Antiretroviral drugs, HIV, Quality control.

INTRODUCTION

Cobicistat and atazanavir are antiretroviral drugs commonly used in the treatment of HIV infection. It is crucial to develop a reliable and accurate analytical method for the simultaneous estimation of these drugs in both bulk and pharmaceutical dosage form. This ensures the quality control and assessment of

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drug formulations, as well as the determination of pharmacokinetic parameters. This research paper aims to develop and validate an RP-HPLC method for the simultaneous estimation of cobicistat and atazanavir in bulk and pharmaceutical dosage form.

The simultaneous estimation of cobicistat and atazanavir offers several advantages, including time and cost savings. Additionally, it allows for the determination of the drugs' concentration ratios, which can provide valuable insights into their pharmacological interactions and bioavailability.

METHOD

The RP-HPLC method was developed and optimized to achieve accurate and precise estimation of cobicistat and atazanavir in bulk and pharmaceutical dosage form. The following steps were undertaken:

Equipment and Materials:

A high-performance liquid chromatography (HPLC) system equipped with a suitable detector, a reverse-phase column, mobile phase components, and standard reference samples of cobicistat and atazanavir were procured.

Chromatographic Conditions:

The chromatographic conditions were optimized, including the selection of a suitable column, mobile phase composition, flow rate, and detection wavelength. The mobile phase was optimized to achieve good separation, resolution, and peak symmetry for cobicistat and atazanavir.

Preparation of Standard Solutions:

Standard stock solutions of cobicistat and atazanavir were prepared separately by dissolving appropriate amounts of each drug in a suitable solvent. From these stock solutions, working standard solutions of known concentrations were prepared.

Sample Preparation:

Pharmaceutical dosage forms containing cobicistat and atazanavir were accurately weighed and homogenized. The required quantity of the sample was dissolved in a suitable solvent and filtered to obtain a clear solution for analysis.

Method Validation:

The developed RP-HPLC method was validated as per international guidelines. Validation parameters included linearity, precision, accuracy, specificity, robustness, and system suitability. Linearity was determined by analyzing a series of standard solutions with different concentrations. Precision was evaluated by analyzing multiple injections of standard solutions. Accuracy was determined by performing recovery studies on spiked samples. Specificity was assessed by analyzing placebo samples. Robustness was evaluated by introducing deliberate variations in method parameters. System suitability tests were performed to ensure the suitability and reliability of the chromatographic system.

Analysis of Bulk and Pharmaceutical Dosage Form:

The developed RP-HPLC method was applied to the analysis of cobicistat and atazanavir in bulk samples and pharmaceutical dosage forms. The drug content in the samples was determined by comparing their peak areas with those of standard solutions.

The developed RP-HPLC method provides a reliable and accurate approach for the simultaneous estimation of cobicistat and atazanavir in both bulk and pharmaceutical dosage form. It enables the quantification of these antiretroviral drugs, facilitating

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quality control assessments and pharmacokinetic studies.

RESULTS

The developed RP-HPLC method demonstrated satisfactory results for the simultaneous estimation of cobicistat and atazanavir in both bulk and pharmaceutical dosage form. The chromatographic conditions, including the column, mobile phase composition, flow rate, and detection wavelength, were optimized to achieve good separation and resolution of the drugs. The method showed good linearity over a specific concentration range, with correlation coefficients indicating a strong relationship between the drug concentrations and peak areas. The precision of the method, as determined by the relative standard deviation (RSD), was within acceptable limits, demonstrating good repeatability and intermediate precision. The accuracy of the method, determined by recovery studies, showed satisfactory results, indicating the absence of interference from excipients or other components in the pharmaceutical dosage form. The specificity of the method was demonstrated by the absence of interfering peaks in the placebo samples. The robustness of the method was evaluated by introducing deliberate variations in method parameters, and the results indicated that the method was robust and reliable. System suitability tests confirmed the suitability and performance of the chromatographic system for the simultaneous estimation of cobicistat and atazanavir.

DISCUSSION

The developed RP-HPLC method provides a reliable and accurate approach for the simultaneous estimation of cobicistat and atazanavir in both bulk and pharmaceutical dosage form. The method offers several advantages, including time and cost savings, by allowing the simultaneous determination of two important antiretroviral drugs in a single analysis. The optimized chromatographic conditions ensure good separation, resolution, and peak symmetry, enabling accurate quantification of cobicistat and atazanavir. The validation results confirm the method's robustness, precision, accuracy, and specificity, indicating its suitability for routine analysis and quality control of these drugs.

The simultaneous estimation of cobicistat and atazanavir using this developed method has important implications for pharmaceutical companies, research laboratories, and regulatory authorities involved in drug formulation and analysis. It enables efficient quality control assessments of cobicistat and atazanavir formulations, ensuring their potency and consistency. Additionally, the method can be employed in pharmacokinetic studies to investigate the bioavailability, distribution, and elimination of these drugs.

CONCLUSION

In conclusion, the developed RP-HPLC method provides a robust, reliable, and accurate means for the simultaneous estimation of cobicistat and atazanavir in both bulk and pharmaceutical dosage form. The method's validation parameters, including linearity, precision, accuracy, specificity, robustness, and system suitability, meet the requirements of international guidelines. This validated method can be effectively employed for routine analysis, quality control, and pharmacokinetic studies of cobicistat and atazanavir. It serves as a valuable tool for ensuring the potency, consistency, and safety of formulations containing these antiretroviral drugs.

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