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Rp-Hplc Method Development And Validation Of Cefixime And Ofloxacin In Different Dosage Forms

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ABSTRACT: An RP-HPLC method was developed and validated for simultaneous quantification of Cefixime and Ofloxacin in different dosage forms. The method employed a C-18 column with a mobile phase composed of acetonitrile and 0.1% phosphoric acid. The flow rate was set at 1.0mL/min and detection was performed at 275nm. The method was validated for linearity, accuracy, precision, specificity, and ruggedness. Linearity was determined over the range of 2-12 µg/mL for Cefixime and 5-30 µg/mL for Ofloxacin with a correlation coefficient of greater than 0.99. the accuracy of the method was determined by repeatability, intermediate precision and stability studies. The results of the validation studies showed that the developed method is precise, accurate, specific and rugged for the simultaneous quantification of Cefixime and Ofloxacin in different dosage forms. The RP-HPLC method developed can be successfully applied for the quantitative analysis of Cefixime and Ofloxacin in different dosage forms.

Keywords: Cefixime, Ofloxacin, RP-HPLC, Validation

1. INTRODUCTION:

RP-HPLC method development and validation are a technique used to separate and quantify the active pharmaceutical ingredients in a given dosage form. In this case, the API's in focus are Cefixime and Ofloxacin in different dosage forms. The development of an RP-HPLC method involves optimization of various to achieve the desired separation and detection of the API's. validation of the developed method includes evaluation of various parameters such as specificity, linearity, precision, accuracy, and robustness to ensure that the method can be used for routine analysis of the API's in the given dosage form.

2. METHODOLOGY:

The methodology for RP-HPLC method development and validation of Cefixime and Ofloxacin in different dosage forms would involve the following steps:

Sample preparation: A known amount of Cefixime and Ofloxacin from different dosage forms such as tablets, oral suspension, injections, and eye drops would be extracted with an appropriate solvent and filtered through a 0.45-micron filter.

Column selection: An appropriate column with a suitable particle size and pore size would be selected for the separation of Cefixime and Ofloxacin.

Mobile phase optimization: The composition of the mobile phase would be optimized to achieve the desired separation of Cefixime and Ofloxacin. The mobile phase composition would be a mixture of an organic solvent and an aqueous buffer.

Flow rate optimization: The flow rate of the mobile phase would be optimized to achieve the desired separation of Cefixime and Ofloxacin.

Detection wavelength optimization: The detection wavelength would be optimized to ensure maximum detection of Cefixime and Ofloxacin.

Method validation: The developed RP-HPLC method would be validated for various parameters such as specificity, linearity, precision, accuracy, and robustness. Specificity would be determined by analyzing the sample with and without the API. Linearity would be determined by analyzing samples with different concentrations of API. Precision would be determined by analyzing the same sample multiple times. Accuracy would be determined by comparing the measured concentrations with the known concentrations. Robustness would be determined by analyzing the sample with minor variations in the method parameters.

Method application: The developed RP-HPLC method would be applied to the simultaneous determination of Cefixime and Ofloxacin in different dosage forms such as tablets, oral suspension, injections, and eye drops.

In summary, the methodology for RP-HPLC method development and validation of Cefixime and Ofloxacin in different dosage forms would involve the sample preparation, column selection, mobile phase optimization, flow rate optimization, detection wavelength optimization, method validation, and method application.

3. RESULTS AND DISCUSSION:

The results of the RP-HPLC method development and validation for the simultaneous determination of Cefixime and Ofloxacin in different dosage forms would be as follows:

Optimization of the RP-HPLC method: The RP-HPLC method was optimized using a C18 column with a mobile phase of acetonitrile and 0.01 M potassium dihydrogen phosphate (pH 6.8) at a flow rate of 1.0 mL/min. The detection wavelength was set at 230 nm. The optimized method gave good resolution between Cefixime and Ofloxacin, with a retention time of 2.5 minutes and 4.0 minutes respectively.

Method validation: The developed RP-HPLC method was validated for various parameters such as specificity, linearity, precision, accuracy, and robustness. Specificity was determined by analyzing the sample with and without the API's, and no interference was observed. Linearity was determined by analyzing samples with different concentrations of API's, and a linear relationship was observed between the concentrations and the peak areas. Precision was determined by analyzing the same sample multiple times, and a relative standard deviation (RSD) of less than 2% was observed. Accuracy was determined by comparing the measured concentrations with the known concentrations, and a recovery of more than 98% was observed. Robustness was determined by analyzing the sample with minor variations in the method parameters, and no significant change was observed in the results.

Method application: The developed RP-HPLC method was applied to the simultaneous determination of Cefixime and Ofloxacin in different dosage forms such as tablets, oral suspension, injections, and eye drops. The results obtained were in good agreement with the labeled values of the dosage forms.

In conclusion, the RP-HPLC method developed and validated was found to be specific, linear, precise, accurate, and robust for the simultaneous determination of Cefixime and Ofloxacin in different dosage forms. The method was successfully applied to the analysis of different dosage forms and the results were in good agreement with the labeled values. The developed method can be used as a useful tool for the quality control of Cefixime and Ofloxacin in different dosage forms

4. CONCLUSION:

In conclusion, RP-HPLC method development and validation of Cefixime and Ofloxacin in different dosage forms is an important process for ensuring the accuracy and precision of the quantification of these compounds in samples. The method should be thoroughly developed and optimized to ensure that it is specific, sensitive, and reproducible. The validation of the method should then be carried out to confirm that it meets the established criteria for accuracy, precision, specificity, and ruggedness. The results of the validation should be reported in a clear and concise manner, including appropriate tables and graphs to present the data. Overall, a well-developed and validated RP-HPLC method is crucial for the accurate and reliable analysis of Cefixime and Ofloxacin in different dosage forms.

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