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A SIMPLE, RAPID UV-SPECTROPHOTOMETRIC METHOD DEVELOPMENT AND VALIDATION FOR THE DETERMINATION OF THE FENOFIBRATE

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ABSTRACT
UV-Visible spectroscopy is a widely used analytical technique in various fields such as pharmaceuticals, environmental science, food industry, and materials science. It explores the methodologies employed in the development and validation of UV-Visible spectroscopic methods. The focus is on discussing the key steps involved in method development, including selection of appropriate solvent, determination of suitable wavelength, optimization of instrumental parameters, and validation of the developed method according to regulatory guidelines. A significant portion of the review is dedicated to method validation, focusing on parameters such as accuracy, precision, linearity, robustness, etc. In addition to method development and validation, the review explores various estimation techniques utilizing UV-Visible spectroscopy. To develop and validate a UV-spectrophotometric approach for estimating the formulation of the anti-hyperlipidaemic drug- Fenofibrate. An effective, accurate, precise, and reproducible UV-spectrophotometric method in ethanol was developed for the validation of drug. ethanol was used as the medium for the UV-spectrophotometric measurement, which was carried out with a UV-Vis spectrophotometer. LOD and LOQ, selectivity and specificity, linearity and range, and accuracy, and precision were performed as validation parameters.

KEYWORDS: LOD: Limit of determination; LOQ: Limit of Quantification.

INTRODUCTION

Spectroscopy involves observing and understanding the electromagnetic radiation absorbed or emitted by molecules, atoms, or ions as they transition between different energy levels. These transitions occur from ground state to excited state or vice versa. The energy of a molecule in its ground state comprises rotational, vibrational, and electronic energies. Therefore, spectroscopy examines the alterations in these energy levels, providing valuable insights into the properties Lowering cholesterol is achieved using an antilipemic drug. antilipidemic drug rise High-density lipoproteins whereas low-density lipoproteins decline. Hyperlipidaemia is the greatest hazard factor of coronary heart disease Anti-hyperlipidaemic agent- Fenofibrate is a safe and efficient way to raise HDL levels and lower TGL. As a result of UV spectrophotometry's ease of use, accuracy, reliability, minimal solvent usage, and short analysis times, it is commonly used to determine the number of drugs present in pharmaceutical products. Therefore, the objective of this work was to verify the preciseness, accuracy, linearity, range, limit of detection, limit of quantification, and system suitability of the UV spectroscopic method for transdermal formulation.[1]

METHODOLOGY

1. Preparations of Standard Stock Solutions

The standard stock solution stock -1 of Fenofibrate was made by precisely weighing 10 mg of Fenofibrate into a volumetric flask that held 10 mL, then diluting with ethanol until the required strength was achieved. To achieve a 100 µg/mL concentration, Stock-1 was diluted using ethanol of Stock-2 and additional stock-2 was properly diluted to get the final concentration of 100 µg/mL of Stock-3.

2. Determination of wavelength of maximum absorbance (λmax)

Full output mode and medium scanning speed were used to scan the Standard Stock Solution using a variety of UV/VIS Spectrophotometers. The resulting solution was scanned using a solvent system in the UV region as a blank. The spectrum was obtained, and λmax was found. The above method was repeated thrice. The maximum absorbance of Fenofibrate in the spectrum was at 240 nm.

3. Linearity and range

Stock-3 was used to create the five-diverse calibration standard representing 2,4, 6,8, 10, and 12 µg/mL strength, and it was utilized to prepare the calibration curve. Each calibration standard's absorbance was calculated with a fixed wavelength measuring mode to a maximum of 230 nm. Using Microsoft Excel 2019, the calibration curves representing concentration vs. absorbance were plotted.[2]

4. Method Validation

In terms of parameters like linearity, range, precision, robustness, ruggedness, accuracy, the limit of quantification and the limit of detection the developed UV technique for the estimation of Fenofibrate was examined.

5. Accuracy/recovery study

This study was carried out using the % Recovery method by adding the known amounts/concentration of standard to the sample. In order to achieve the three concentrations, three different levels were made in triplicate at levels of 80%, 100%, and 120% of its predetermined concentration.

6. Specificity in the presence of excipients

Excipients were the only substances used to test the specificity. Comparing the spectra of a drug, a blank, and a formulation sample. In order to verify that none of the degradation products interfered with the quantification of the drug, the sample solution was subjected to accelerate degradation by heat (60° C temperature) for 72 hours in order to determine the specificity.[4,5]

7. Assay of content

The drug content in the sample was successfully estimated using a newly developed and pre validated UV-Vis method. Formulations were developed for the study, calculate the required amount of the sample was weighed and the appropriate dilutions were prepared with ethanol solvent. Preparation samples were evaluated using a UV method that has been previously validated, and results were reported as an average percent assay.[6,7]

8. Ruggedness

In accordance with the circumstances in which the procedure is to be used, intermediate precision should be achieved at a specific level. The applicant should explain that random events influence the analytical procedure's accuracy. Days, analysts, and equipment are examples of typical variations to be evaluated.[8,9]

9. Robustness

An analytical procedure's robustness is a measure of its ability to remain unaffected by small, deliberate changes in method parameters and provides an indication as to its reliability under typical conditions.[10]

RESULTS AND DISCUSSION

1. Method development and optimization

Fenofibrate drug is easily soluble in organic solvents like ethanol but practically insoluble in an aqueous medium. A few ml of ethanol used as the diluent during the development phase produced a more favourable UV analysis result. The maximum absorption wavelength (λmax), which was predetermined, was 240 nm.

2. Linearity and range

The calibration curve obtained was evaluated by its correlation coefficient. The absorbance of the samples in the range of 2-10 µg /mLwas linear with a correlation coefficient (R2) greater than 0.9783. According to the Results, a good correlation exists between the concentration of the sample and its absorbance.

3. Specificity in the presence of excipients

The specificity of the analytical method was proved by comparing the spectra of drug, formulation, and placebo formulation of sample solution with that of the accuracy sample. No interference was observed at 230 nm indicating that the method is specific.

4. Estimation of drug content

The developed UV method was successfully applied for the estimation of drug content in the sample. This solution was filtered through the Whatman filter paper. The proposed method was used to analyze the filtered sample spectrophotometrically at 230 nm after it had been suitably diluted with ethanol. The sample average percent assay was found to be 97%.

5. Robustness

The ability of an analytical method to withstand the change in its performance despite a slight, deliberate change in the method parameters is known as robustness. robustness study's determined % RSD value of less than 1% revealed that the approach is reliable.

6. Reproducibility/Ruggedness

Reproducibility was studied in order to determine whether the proposed UV technique was reliable. The method's reproducibility was examined, and the results were compared. The low % RSD (<1%) indicated that the method is precise.

7. Limit of Quantitation and Limit of Detection

LOQ represents the lowermost concentration that can be analyzed with acceptable accuracy and precision. Generally, LOQ is the first calibration standard. LOD and LOQ of the proposed UV method were found to be 0.38 and 1.16 µg/ml respectively. A lower LOQ value indicated that the proposed method would be suitable for analyzing the samples containing even small quantities of a drug.

CONCLUSION

The method was validated according to ICH guidelines with respect to Linearity, accuracy, precision, accuracy, ruggedness, the limit of detection, the limit of quantitation, robustness, and assay. The calibration curve for the methods was linear over the concentration range of 2-10 µg/ml for Fenofibrate at 240nm. The determination of coefficient was 0.9993. The methods were found to be precision and the % RSD value for repeatability and Intermediate day were found to be less than ±1 %. The accepted limits of accuracy were found to be 80%-120% and all observed data are within the required range which indicates good recovery value.

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