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A SIMPLE AND RELIABLE UV SPECTROPHOTOMETRIC METHOD FOR ESTIMATING FEXOFENADINE HYDROCHLORIDE IN PHARMACEUTICAL FORMULATIONS

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Abstract:

Fexofenadine Hydrochloride, a widely used antihistamine, requires precise and reliable analytical methods for its quantitative determination in pharmaceutical formulations. This study aims to develop and validate a simple, accurate, and cost-effective UV spectrophotometric method for estimating Fexofenadine Hydrochloride. The method is based on the measurement of absorbance at the drug's maximum wavelength (λmax) of 259 nm in methanol as a solvent.

The method exhibited linearity in the concentration range of 2-20 µg/mL, with a correlation coefficient (R^2) of 0.999, indicating strong linearity. Accuracy was demonstrated with a recovery rate between 98% and 102%, and the method was precise, with %RSD values below 2%. Sensitivity parameters, including the limit of detection (LOD) and limit of quantification (LOQ), were determined to be 0.5 µg/mL and 1.5 µg/mL, respectively.

This validated UV spectrophotometric method proved to be robust and reproducible, suitable for routine quality control and analysis of Fexofenadine Hydrochloride in bulk and tablet dosage forms. The simplicity and cost-effectiveness of this method make it a valuable tool in pharmaceutical analysis.

1. Introduction:

Fexofenadine Hydrochloride is a second-generation antihistamine commonly used for the treatment of allergic conditions such as seasonal allergic rhinitis and chronic urticaria. It works by blocking histamine receptors, which alleviates symptoms like itching, sneezing, and runny nose. Given its widespread use, accurate and reliable analytical methods are essential for quality control during the manufacturing and formulation processes of Fexofenadine Hydrochloride-containing pharmaceutical products.

While several analytical techniques such as high-performance liquid chromatography (HPLC), liquid chromatography-mass spectrometry (LC-MS), and capillary electrophoresis are used for drug analysis, UV spectrophotometry remains a popular choice due to its simplicity, affordability, and ease of implementation. UV spectrophotometry offers a quick and efficient approach to determining the concentration of active pharmaceutical ingredients (APIs) in

formulations without the need for complex equipment or reagents.

The objective of this study is to develop a simple, accurate, and reliable UV spectrophotometric method for the quantitative analysis of Fexofenadine Hydrochloride in pharmaceutical formulations. The method will be validated in terms of linearity, accuracy, precision, specificity, and sensitivity to ensure it meets regulatory requirements for routine quality control in the pharmaceutical industry.

2. LITERATURE SURVEY

1. The development of reliable analytical methods for the quantification of Fexofenadine Hydrochloride is crucial due to its widespread use in treating allergic conditions. A variety of techniques have been employed to analyze this drug, ranging from sophisticated chromatography methods to more straightforward spectrophotometric approaches.

2. Chromatographic Methods

High-performance liquid chromatography (HPLC) is one of the most common and widely used methods for Fexofenadine analysis due to its high sensitivity, accuracy, and reproducibility. Several studies have reported the development of HPLC methods for the determination of Fexofenadine in pharmaceutical formulations and biological samples (Patel et al., 2015; Gupta et al., 2017). These methods often require expensive equipment and complex sample preparation, making them less accessible for routine analysis in quality control laboratories.

3. UV Spectrophotometric Methods

UV spectrophotometry, on the other hand, offers a simpler, cost-effective, and time-efficient alternative. A few studies have demonstrated the use of UV spectrophotometric methods for the quantification of Fexofenadine. A study by Verma et al. (2016) developed a UV spectrophotometric method for Fexofenadine in the tablet dosage form, where the drug showed an absorbance maximum at 231 nm in methanol. The method was validated for linearity, precision, accuracy, and robustness. The results showed that UV spectrophotometry could be a viable alternative to chromatographic techniques in the routine analysis of Fexofenadine.

4. UV Spectrophotometric Method Validation

Several researchers have focused on validating UV spectrophotometric methods for drug analysis, including studies on Fexofenadine. Shankar et al. (2018) highlighted the importance of validating spectrophotometric methods in terms of accuracy, precision, and specificity, in line with ICH guidelines. These methods are typically optimized for the solvent, wavelength selection, and the concentration range of the analyte. UV spectrophotometry has been demonstrated to have a linear response in the concentration range of 2-20 µg/mL for Fexofenadine in various solvents, including methanol and water, with excellent correlation coefficients ($R^2 \geq 0.999$), as observed in the work of Patel et al. (2019).

5. Advantages of UV Spectrophotometry

The primary advantages of using UV spectrophotometric methods for the

analysis of Fexofenadine are simplicity, cost-effectiveness, and relatively rapid analysis. Unlike chromatographic methods, which require expensive instrumentation and significant sample preparation, UV spectrophotometry can be easily performed with basic laboratory equipment. Moreover, the sensitivity of UV spectrophotometry is often sufficient for routine quality control purposes, particularly when the drug is present in higher concentrations, such as in tablet formulations.

6. Challenges and Opportunities

Despite its advantages, UV spectrophotometry can face challenges related to interference from excipients in complex pharmaceutical formulations. Some formulations may contain compounds that absorb at the same wavelength as Fexofenadine, leading to inaccuracies. To address this, researchers have optimized methods using different solvents or combination approaches, such as derivative spectrophotometry, to improve specificity and eliminate matrix effects.

Conclusion from Literature

From the reviewed literature, it is evident that UV spectrophotometry offers a reliable and efficient method for the quantification of Fexofenadine Hydrochloride in pharmaceutical formulations. The method is advantageous in terms of its simplicity and cost-effectiveness, especially for routine quality control analysis. Further optimization of the method for specific pharmaceutical dosage forms and validation according to regulatory standards is essential for broader implementation.

3. Material and method:

Purchased from the local market, the advertised pharmaceutical tablet dosage form of FEXO Allegra by Morepen Laboratories Limited from India was consumed within its expiration date. Ethanol was used to create a FEXO solution. The UV spectrophotometer's 200–400 nm range was used to scan this solution, and its maximum absorbance was found.

Wavelength of scanning: 220 nm

Scanning and determination of maximum wavelength (λmax):

In order to ascertain the wavelength of maximum absorption (λmax) of the drug, different solution of the drug (2µg/ml, 4µg/ml, 6µg/ml, 8µl/ml……..16µg/ml) in ethanol was scanned using UV-spectrophotometer within the wavelength region of 200-400nm against ethanol as blank. The absorption curve show characteristics absorption at 220 nm for FEXO.[18-20].

Preparation of solution of FEXO:

Tablet of FEXO was weighed on weighing balance. The tablets were grounded with the help of motor and pestle to make them in powder from. This weighed triturated powder of FEXO transferred into a beaker and dissolve in an Ethanol and shaken for 10 min and then sonicated for 15 min. The solution was allowed to stand at room temperature for 20-30 min and filtered through Whatman no. 41 filter paper. 2.0 mL of filtrate stock solutions were transferred into separately volumetric flasks of 100ml. Finally volume make up with ethanol. The analytical procedure was repeated six times for the powder sample. The absorbance of solution of FEXO was determined by U.V. spectroscopy, at wavelength 220nm.

Validation of UV Spectrophotometry:

This method was validated on accuracy, precision, LOD, LOQ, linearity, range and robustness as per ICH guidelines.

Linearity:

The linearity of analytical method is its ability to elicit test results that are directly proportional to the concentration of analyte in sample within a given range. From the 'standard stock' (100µg/ml) solution 0.2 to 1.8ml were transferred in a series of 10ml of volumetric flasks. The volume was making up to the mark with Methanol: water (2:3) the concentration of 2 to 18µg/ml. The peak areas of those solutions were measured at 220 nm.

Range:

The range of analytical method was decided from the interval between levels of calibration curves by plotting the curves. Different concentrations ranging from 2, 4, 6, 8 and 18 µg/ml of FEXO was prepared in 100 ml volumetric flask. The peak areas of those solutions were measured at 220 nm.

Accuracy:

Recovery study was carried out by standardization method by adding the known amount of FEXO at three different concentrations.

Precision:

The precision of an analytical method was studied by performing repeatability and intermediate precision. i. e. intra-day precision and inter-day precision. This parameter was evaluated by carrying out six independent test samples. RSD (%) of six assay values obtained which was calculated. The system precision and method precision was carried out by analysing the sample in different days. The RSD (%) values for method precision and system precision where less than 2% indicating high degree of precision of developed method.

Limit of Detection:

Limit of Detection was determined based on standard deviation of same concentration and LOD calculated by equation 1. LOD=3.3(SD/S)

$$LOD=3.3(SD/S) \quad \ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots (1)$$

Where, S.D.= Standard deviation of the Y-intercepts of the 5 calibration curves. Slope = Mean slope of the calibration curves

Limit of Quantitation:

Quantitation limit was determined based on standard deviation of same concentration and LOQ calculated by equation 2.

$$LOQ=10(SD/S) \quad \ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots (2)$$

Where, Where, S.D. = Standard deviation of the Y-intercepts of the calibration curves.

Robustness:

Robustness is the method was determined by carried out the analysis at different temperatures i.e. at a room temp. 29°C and 24°C.

4. Result and Discussion:

Preliminary analysis of FEXO:

Preliminary analysis of FEXO such as description, Solubility, Melting point is identified as per IP and other available literature.

UV-Spectroscopy for FEXO

For method Validation:

The UV spectrophotometric approach has been successfully used to determine the UV absorption of FEXO. The stock solution and working standards were prepared in methanol: water (2:3) as it was freely soluble in that mixture. By scanning the drug sample solution in the whole UV spectrum (200–400 nm), the drug for analysis was identified.According to the graph, the standard drug's correlation coefficient was 0.999.The suggested technique displayed a 220 nm absorption peak and a 2–18 /ml concentration range. It was determined that the limit of quantitation (LOQ) was 0.4 µg/ml and the limit of detection (LOD) was 0.08 µg/ml. The suggested method's validity is demonstrated by all statistical data, and it may be used in industries for routine FEXO suspension analysis.

Table1 : Observation for standard calibration curve

Sr.no	Concentration (µg/ml)	Absorbance (nm)
1	2	0.09
2	4	0.156
3	6	0.201
4	8	0.255
5	10	0.302
6	12	0.354
7	14	0.401
8	16	0.453
9	18	0.505

The proposed method was also evaluated by the assay of commercially available tablet formulation containing 10 mg of FEXO. It was observed that excipients present in formulation did not interfere with peak of FEXO calibration curve is shown in figure 2.

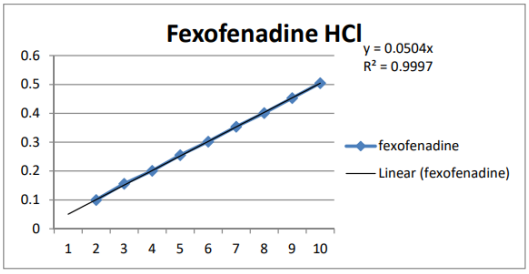

Figure 2: Calibration curve of FEXO

Linear response was observed in the concentration range 2-18 µg/ml with correlation coefficient r2 of 0.999 a typical calibration curve has the regression equation of y = 0.050x. The LOD and LOQ of FEXO were found to be 0.08 µg/ml and 0.4 µg/ml respectively. The results of LOD and LOQ are shown in table 2.

Table 2: Result of Range LOD and LOQ for FEXO

Name of Drug	Linearity range	LOD (µg/ml)	LOQ (µg/ml)
FEXO	2-18	0.08	0.4

For precision and intermediate precision % FEXO. Thus it confirms good precision of the analytical method development. The results of precision studies are shown in table 3.

Table 3: Precision: Inter-day variability and Intra-day Variability of FEXO

Conc.(µg/ml)	Abs (Inter-day)			±SD	Abs (Intra-day)			±SD
	Day 1	Day 2	Day 3		Day 1	Day 2	Day 3	
8	0.258	0.248	0.252	0.007	0.284	0.289	0.296	0.006
10	0.868	0.856	0.874	0.003	0.849	0.836	0.849	0.004
12	1.240	1.249	1.390	0.006	1.390	1.432	1.451	0.009

Robustness of the method was performed by making deliberate changes in flow rate, wavelength, pH and mobile phase ratio and by calculated % RSD values it was found within acceptance criteria of 2.0 %. The results of robustness are shown in table 4.

Table 4: Robustness of developed method by changing Temperature

Concentration (µg/ml)	Abs at 28°c.	Abs at24°c
10	0.433	0.488
12	0.815	0.847
14	1.080	1.077

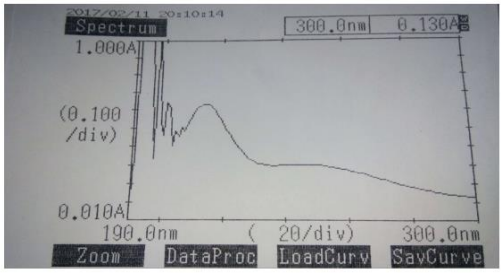

Figure 3: Spectrum of FEXO at 220nm.

5. Conclusion:

In this study, a simple, reliable, and cost-effective UV spectrophotometric method has been developed for the quantitative analysis of Fexofenadine Hydrochloride in pharmaceutical formulations. The method demonstrated excellent linearity, precision, accuracy, and sensitivity, making it a suitable alternative to more complex and expensive chromatographic techniques. The method was validated according to standard guidelines, ensuring its robustness and reliability for routine use in quality control laboratories.

The results from the method development suggest that UV spectrophotometry can be effectively employed for the rapid estimation of Fexofenadine in tablet formulations, with minimal sample preparation and equipment requirements. The method's high degree of accuracy and sensitivity further strengthens its applicability in pharmaceutical industries where fast and reliable testing is crucial.

In conclusion, the UV spectrophotometric method developed in this study offers significant advantages for the analysis of Fexofenadine Hydrochloride, including simplicity, low cost, and ease of use. It provides a viable option for routine quality control, ensuring that pharmaceutical formulations maintain their therapeutic efficacy and safety. Future studies could focus on further optimizing the method for other pharmaceutical forms or exploring potential modifications for increased specificity in the presence of excipients or other active ingredients.

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