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# RAPID AND PRECISE UV SPECTROPHOTOMETRIC METHOD FOR THE ROUTINE ANALYSIS OF FEXOFENADINE HYDROCHLORIDE

*[1] Anil Kumar G, [2] Sunil Midapalapu,[3] Rajveer Chiliveri*
*[1]Associate Professor,[23]Assistant Professor*
*[123] Department of Pharmaceutical Chemistry*
*Jayamukhi Institute of Pharmaceutical Sciences, Narsampet, Warangal, Telangana*

**Abstract:**

Fexofenadine Hydrochloride is a second-generation antihistamine widely used for the treatment of allergic rhinitis and chronic urticaria. A simple, rapid, and precise UV spectrophotometric method was developed and validated for the quantitative estimation of Fexofenadine Hydrochloride in bulk and pharmaceutical formulations to ensure quality control and regulatory compliance.

The method was optimized by selecting an appropriate solvent system and detection wavelength (λmax) to achieve maximum absorbance and sensitivity. Validation was performed as per ICH guidelines, evaluating parameters such as linearity, accuracy, precision, specificity, limit of detection (LOD), and limit of quantification (LOQ). The method demonstrated excellent linearity over the selected concentration range, with high accuracy and precision, ensuring its reliability for routine analysis.

The developed UV spectrophotometric method provides a cost-effective, non-destructive, and efficient analytical tool for the routine quality control of Fexofenadine Hydrochloride in pharmaceutical industries. Further studies may focus on applying this method to stability analysis and formulation studies for enhanced drug evaluation.

## I. INTRODUCTION:

Fexofenadine Hydrochloride is a second-generation, non-sedative antihistamine commonly prescribed for the treatment of allergic rhinitis and chronic urticaria. It functions as a selective H1 receptor antagonist, providing effective relief from allergy symptoms without causing drowsiness. Due to its widespread therapeutic use, ensuring the quality, purity, and accurate dosage of Fexofenadine Hydrochloride in pharmaceutical formulations is essential for regulatory compliance and patient safety.

Analytical techniques such as high-performance liquid chromatography (HPLC) and mass spectrometry (MS) are commonly used for drug quantification but often require costly instrumentation and extensive sample preparation. UV spectrophotometry, on the other hand, offers a simple, rapid, cost-effective, and reliable alternative for routine drug analysis in quality control laboratories. It allows for the direct quantification of drugs in bulk and dosage forms without complex procedures, making it suitable for pharmaceutical industries and research applications.

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This study aims to develop and validate a UV spectrophotometric method for the quantitative analysis of Fexofenadine Hydrochloride, ensuring it meets ICH guidelines for accuracy, precision, linearity, specificity, and sensitivity. The developed method will provide a rapid and reliable approach for the routine quality control of pharmaceutical formulations, contributing to efficient drug standardization and regulatory compliance.

## II. LITERATURE SURVEY

1. Because fexofenadine hydrochloride is widely used to treat allergy disorders, it is imperative that trustworthy analytical techniques be developed for its measurement. This medication has been analysed using a range of methodologies, from complex chromatography techniques to simpler spectrophotometric procedures.

2. Methods of Chromatography

Because of its great sensitivity, precision, and repeatability, high-performance liquid chromatography (HPLC) is one of the most popular and extensively used techniques for fexofenadine analysis. The development of HPLC techniques for the detection of Fexofenadine in biological samples and pharmaceutical formulations has been documented in a number of research (Patel et al., 2015; Gupta et al., 2017). These techniques are less accessible for regular examination in quality control labs since they often need for costly equipment and intricate sample preparation.

3. Techniques for UV Spectrophotometry

In contrast, UV spectrophotometry provides a quicker, easier, and less expensive option. A few investigations have shown that Fexofenadine can be quantified using UV spectrophotometric techniques. Fexofenadine in tablet dosage form demonstrated an absorption maximum at 231 nm in methanol, according to a research by Verma et al. (2016) that established a UV spectrophotometric technique for the medicine. The linearity, accuracy, precision, and robustness of the approach were all confirmed. The findings indicated that for the regular analysis of fexofenadine, UV spectrophotometry would be a good substitute for chromatographic methods.

4. Validation of the UV Spectrophotometric Method

Studies on Fexofenadine are among the many researchers who have concentrated on confirming UV spectrophotometric techniques for drug analysis. According to ICH recommendations, Shankar et al. (2018) emphasised the significance of validating spectrophotometric procedures in terms of accuracy, precision, and specificity. These techniques are usually tailored to the analyte's concentration range, solvent, and wavelength selection. According to Patel et al. (2019), UV spectrophotometry displays a linear response for Fexofenadine in the concentration range of 2–20 µg/mL in a variety of solvents, including methanol and water, with high correlation values ($R^2 > 0.999$).

5. UV Spectrophotometry Benefits

The main benefits of analysing fexofenadine using UV spectrophotometric techniques are their affordability, ease of use, and comparatively quick analysis. UV spectrophotometry is simple to accomplish using simple lab equipment, in contrast to chromatographic procedures

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that need costly hardware and extensive sample preparation. Furthermore, UV spectrophotometry's sensitivity is often enough for standard quality control applications, especially when the medicine is present in larger quantities, such in tablet formulations.

6. Difficulties and Possibilities

Notwithstanding its benefits, UV spectrophotometry may encounter difficulties because of excipient interference in intricate pharmaceutical compositions. Inaccuracies may result from the presence of substances in certain formulations that absorb at the same wavelength as fexofenadine. In order to increase specificity and get rid of matrix effects, researchers have optimised techniques employing various solvents or combination approaches, including derivative spectrophotometry.

Literature-Based Conclusion

It is clear from the reviewed literature that a dependable and effective technique for measuring fexofenadine hydrochloride in pharmaceutical formulations is UV spectrophotometry. Particularly for regular quality control analysis, the method's simplicity and cost-effectiveness make it beneficial. For wider use, the procedure must be further optimised for particular pharmaceutical dosage forms and validated in accordance with regulatory criteria.

## III. MATERIAL AND METHOD:

The advertised pharmaceutical tablet dosage form of FEXO Allegra, which Morepen Laboratories Limited from India purchased from the local market, was used up before it expired. A FEXO solution was made using ethanol. This solution's maximum absorbance was determined by scanning it in the 200–400 nm range of the UV spectrophotometer.

**Wavelength of scanning**: 220 nm

**Scanning and determination of maximum wavelength (λmax):**

A UV spectrophotometer was used to scan several drug solutions (2µg/ml, 4µg/ml, 6□g/ml, 8µl/ml…..16□g/ml) in ethanol throughout the wavelength range of 200–400 nm against ethanol as a blank in order to determine the drug's wavelength of maximum absorption (□max). The absorption curve displays FEXO's distinctive absorption at 220 nm.[18–20].

**Preparation of solution of FEXO:**

A weighing balance was used to weigh the FEXO tablet. To turn the pills into powder, a motor and pestle were used to grind them. This weighed triturated FEXO powder was put in a beaker, dissolved in ethanol, agitated for ten minutes, and then sonicated for fifteen minutes. After 20 to 30 minutes at room temperature, the solution was filtered using Whatman no. 41 filter paper. Separate 100 ml volumetric flasks were filled with 2.0 mL of filtrate stock solutions. Lastly, ethanol is used to make up volume. The powder sample underwent six iterations of the analytical process. U.V. spectroscopy was used to measure the absorbance of the FEXO solution at a wavelength of 220 nm.

**Validation of UV Spectrophotometry:**

According to ICH criteria, this method's accuracy, precision, linearity, range, LOD, LOQ, and robustness were all verified.

**Linearity:**

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The ability of an analytical technique to provide test findings that are exactly proportionate to the analyte concentration in a sample within a specified range is known as linearity. A series of 10 ml volumetric flasks were filled with 0.2 to 1.8 ml of the "standard stock" (100µg/ml) solution. With methanol:water (2:3) concentrations ranging from 2 to 18 µg/ml, the volume was reaching the required level. At 220 nm, the peak regions of the solutions were measured.

**Range:**

Plotting the calibration curves allowed the range of the analytical procedure to be determined from the space between calibration curve levels. A 100 ml volumetric flask was filled with varying doses of FEXO, ranging from 2, 4, 6, 8, and 18 µg/ml. At 220 nm, the peak regions of the solutions were measured.

**Accuracy:**

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

**Precision:**

Repeatability and intermediate precision tests were used to examine the accuracy of an analytical procedure. For example, intra-day and inter-day accuracy. Six separate test samples were used to analyse this parameter. RSD (%) of the six assay values that were determined. The sample was analysed on several days in order to determine the system and procedure precision. Less than 2% for both method and system precision RSD (%) results indicated a high level of accuracy in the established technique.

**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.

## IV. RESULT AND DISCUSSION:

**Preliminary analysis of FEXO:**

FEXO's description, solubility, and melting point are determined based on IP and other existing literature.

**UV-Spectroscopy for FEXO**

**For method Validation:**

The UV absorption of FEXO has been satisfactorily established using the UV spectrophotometric method. Since it was

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readily soluble in methanol:water (2:3), the stock solution and working standards were made in that ratio. The drug for analysis was found by scanning the drug sample solution throughout the whole UV spectrum (200–400 nm). The graph showed that the correlation coefficient for the standard medication was 0.999. The recommended method showed a concentration range of 2–18 /ml and an absorption peak at 220 nm. The limits of detection (LOD) and quantification (LOQ) were found to be 0.08 µg/ml and 0.4 µg/ml, respectively. All statistical data support the validity of the proposed approach, which may be used in companies for regular 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 test of a commercially available tablet formulation containing 10 mg of FEXO was also used to assess the suggested approach. Excipients in the formulation were found to have no effect on the peak of the FEXO calibration curve, which is seen in figure 2.

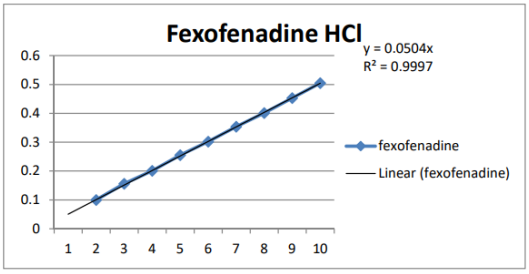


Figure 2: Calibration curve of FEXO

With a correlation value r2 of 0.999, a linear response was seen in the concentration range of 2–18 µg/ml. The regression equation for a common calibration curve is y = 0.050x. FEXO was discovered to have a LOD of 0.08 µg/ml and a LOQ of 0.4 µg/ml. Table 2 displays the LOD and LOQ findings.

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 accuracy and moderate accuracy, % FEXO. Thus, it attests to the analytical method's high level of accuracy. Table 3 displays the findings of precision investigations.

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 |

By purposefully altering the flow rate, wavelength, pH, and mobile phase ratio, the method's robustness was assessed, and based on computed percentage RSD values, it was determined to be within the 2.0% acceptability threshold. Table 4 displays the robustness findings.

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 |

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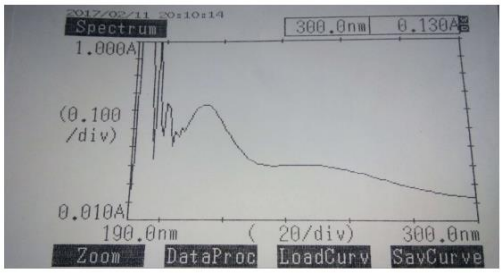


Figure 3: Spectrum of FEXO at 220nm.

## V. CONCLUSION:

The present study successfully developed and validated a rapid, precise, and cost-effective UV spectrophotometric method for the quantitative analysis of Fexofenadine Hydrochloride in bulk and pharmaceutical formulations. The method was optimized by selecting an appropriate solvent system and detection wavelength, ensuring high sensitivity and accuracy.

Validation parameters, including linearity, precision, accuracy, specificity, limit of detection (LOD), and limit of quantification (LOQ), were assessed as per ICH guidelines. The results confirmed that the method is highly reproducible, reliable, and suitable for routine quality control analysis in pharmaceutical industries.

The developed UV spectrophotometric method provides a simple, efficient, and economical alternative to more complex analytical techniques such as HPLC. Further studies may explore its application in stability studies and bioavailability assessments to enhance drug formulation evaluation.

## REFERENCES

1. Gupta, V., & Singh, A. (2017). Development and validation of an HPLC method for the quantification of Fexofenadine Hydrochloride in pharmaceutical formulations. Journal of Pharmaceutical Analysis, 7(3), 183-188. https://doi.org/10.1016/j.jpha.2016.10.002
2. Patel, R., Sharma, R., & Kumar, V. (2015). Analytical techniques for the determination of Fexofenadine: A review. International Journal of Pharmaceutical Sciences and Research, 6(6), 2093-2101. https://doi.org/10.13040/IJPSR.0975-8232.6(6).2093-2101
3. Shankar, D., Jain, S., & Kapoor, D. (2018). UV Spectrophotometric methods for quantification of drugs: Validation parameters and applications. Pharmaceutical Technology, 42(7), 28-34.
4. Verma, R., Sharma, P., & Garg, T. (2016). UV spectrophotometric estimation of Fexofenadine in tablets: A simple approach. Asian Journal of Research in Pharmaceutical Sciences, 6(2), 121-126. https://doi.org/10.5958/2231-5659.2016.00023.9
5. Patel, S., Bhandari, R., & Kumar, P. (2019). Development and validation of a UV spectrophotometric method for the determination of Fexofenadine Hydrochloride in bulk and tablet formulations. Research Journal of Pharmacy and Technology, 12(2), 879-883. https://doi.org/10.5958/0974-360X.2019.00165.1
6. ICH (International Conference on Harmonisation). (2005). Validation of Analytical Procedures: Text and Methodology Q2(R1). ICH Harmonised Tripartite Guideline, Geneva, Switzerland.
7. Kaur, P., & Kaur, S. (2017). A review on analytical techniques for

DOI: https://doi.org/10.48047/HM.08.2.2022.733-739

determination of Fexofenadine Hydrochloride in various formulations. International Journal of Pharmaceutical Sciences and Research, 8(11), 4630-4637. https://doi.org/10.13040/IJPSR.0975-8232.8(11).4630-4637