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DEVELOPMENT OF UV-SPECTROPHOTOMETRIC METHOD FOR FEXOFENADINE IN PURE AND DOSAGE FORM

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ABSTRACT

This study primarily focuses on developing a novel UV method for the assay of Fexofenadine in both pure form and pharmaceutical dosage forms. The process involves preparing standard and working solutions of Fexofenadine, followed by the analysis of different concentrations of the working solution. The established method is then subjected to validation as per ICH guidelines. The results indicate that the developed method is sensitive and accurate, particularly within the concentration range of 10-80 µg/ml. The correlation coefficient (R2) was determined to be 0.999. Notably, there was no interference observed with the excipients present in the formulation. The proposed method holds potential for the analysis of Fexofenadine in bulk and formulation, making it suitable for routine analysis

Keywords: Ultraviolet Spectroscopy, validation, Fexofenadine, method development, assay

INTRODUCTION:

Fexofenadine (FXD) is a selective H1-antagonist utilized for the managing symptoms related to allergic rhinitis and idiopathic urticarial effectively. Its mode of

action involves blocking the effects of histamine, a chemical in the body responsible for producing symptoms. FXD, depicted in **Figure 1**, has a chemical name of (±)-4-[1-Hydroxy-4-[4-(hydroxydiphenylmethyl)-1-piperidinyl]-butyl]-α,α-dimethyl benzeneacetic acid. It exists as a white crystalline powder with 501.68 g/mol. This compound is soluble in methanol (when sonicated and slightly heated) and completely insoluble in hexane. It exhibits easy solubility in alcohol, and moderate solubility in chloroform and water, with a melting point ranging between 218-220 °C. FXD functions as an antiallergic agent, and its pKa value is 4.43 **[1]**. Through a comprehensive examination of existing literature, it has been observed that only a small amount of research has been recorded on this topic regarding the assessment of FXD using HPLC **[2-7]**. Additionally, there is a investigation focused on the quantitative determination of FXD in human plasma through HPLC-MS **[8]**. There are few spectrophotometric methods reported for analysis of FXD **[8-10]**.

This investigation aimed to analyze FXD in both its pure form and pharmaceutical formulation, specifically tablets. Buffers with a pH of 6.68 were chosen as the preferred solvent. Following the development of the UV method, all optimization parameters were taken into account. The validated method proved successful, affirming its appropriateness for determining the overall drug content in commercially accessible FXD formulations. Consequently, the development and validation processes adhered to ICH guidelines **[9-10]**.

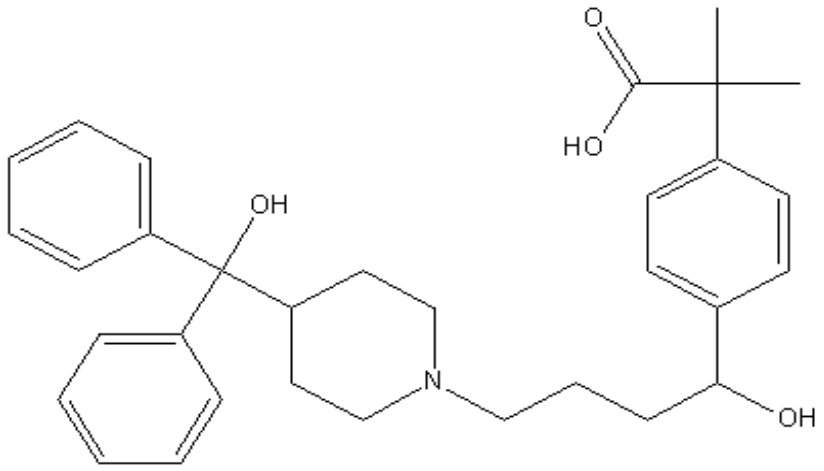

Figure 1: Chemical structure of FXD

MATERIALS AND METHODS:

Instruments and Reagents:

A complimentary sample of FXD with a purity level of 99.98% was obtained from a manufacturing facility located in Visakhapatnam. The instruments employed in the study included UV/Visible spectrophotometer, Lab india, model T60 and analytical balance, shimadzu, japan. The investigation utilized analytical-grade chemicals and reagents. Allegrwyn-branded FXD tablets, each containing 400 mg, were obtained for the formulation.

Standard stock solution (1000µg/ml):

A quantity of 100 mg of the drug was introduced into a 100 ml calibrated flask, where it was dissolved and topped up to the calibration mark with acetonitrile, resulting in 1000 µg/ml. This establishes the standard stock solution of FXD.

Working standard solution (100µg/ml):

A quantity of 2.5 ml was extracted from the standard stock solution mentioned earlier and transferred into a 25 ml calibrated flask. Acetonitrile was added to the flask to achieve a concentration of 100 µg/ml, and the solution was adjusted to the mark.

Calibration curve:

Following that, it was subjected to scanning using a UV Spectrophotometer covering the 200-400 nm range, with acetonitrile employed as the blank. The peak absorbance was pinpointed at a wavelength of 218 nm. To generate different concentrations spanning from 10 to 80 µg/ml, portions were formulated using distilled water as the solvent. These samples were then assessed at the specified wavelength of 218 nm to ascertain their respective absorbance values. The collected data was subsequently used to construct a calibration curve.

RESULTS AND DISCUSSION

Method Validation:

Linearity:

Various samples of FXD were created within the 10-80 µg/ml range using the working standard solution (50 µg/ml). These solutions underwent scanning on a UV-spectrophotometer spanning the 200-400 nm range, with acetonitrile serving as the reference. The spectrum was captured at 218 nm **(Figure 2)**. The data illustrated the relationship between concentration and absorbance, is depicted in **Table 1**. The results indicate a high degree of linearity in the established relationship.

Precision:

The method's precision was showcased through assessments of intra-day and inter-day variations. In the intra-day analysis, six separate solutions with 50 µg/ml were created and assessed twice daily. For the

inter-day study, solutions of 50 µg/ml were formulated and was tested six times over two successive days, and the absorbance was noted (refer to **Table 2**). The calculated percentage of relative standard deviations was found to be below 2%.

Accuracy:

The method's accuracy was assessed using the standard addition method, wherein the percent recovery of FXD was computed. Pre-quantified sample solutions of FXD were supplemented with known quantities of standard solutions at 80%, 100%, and 120% levels. These solutions were prepared in triplicate, and the accuracy, as indicated by the %recovery, was calculated and presented in **Table 3**. The %recovery was determined to be satisfactory.

Robustness:

The method's reliability was evaluated through the examination of a sample with a concentration of 50 µg/ml at three distinct wavelengths, including one at λmax, and recording the corresponding absorbance values. The outcomes presented in **Table 4** suggest that the method demonstrated robustness.

Ruggedness:

To assess the ruggedness of the method, the sample was analyzed by two different analysts using the identical apparatus, and by the same examiner using two different cuvettes, with the respective absorbance values recorded. The results from the first analyst revealed a %RSD of 0.1672, while the second analyst showed a %RSD of 0.2184. These results indicate that the utilized methodology was robust, as no notable distinction is evident among various operators.

Sensitivity:

The drug's LOD and LOQ were determined from the standard curve and found to be 0.5017 µg/ml and 1.5068 µg/ml, respectively.

Assay of formulation*:*

The analysis of the obtained formulation involved assaying an equivalent weight of 25 mg of FXD formulation in a 25 ml calibrated flask, utilizing acetonitrile as the diluent. The final concentration was adjusted to 50 µg/ml using distilled water. The assessment was conducted at a UV wavelength of 218 nm, revealing an assay result of 99.72%.

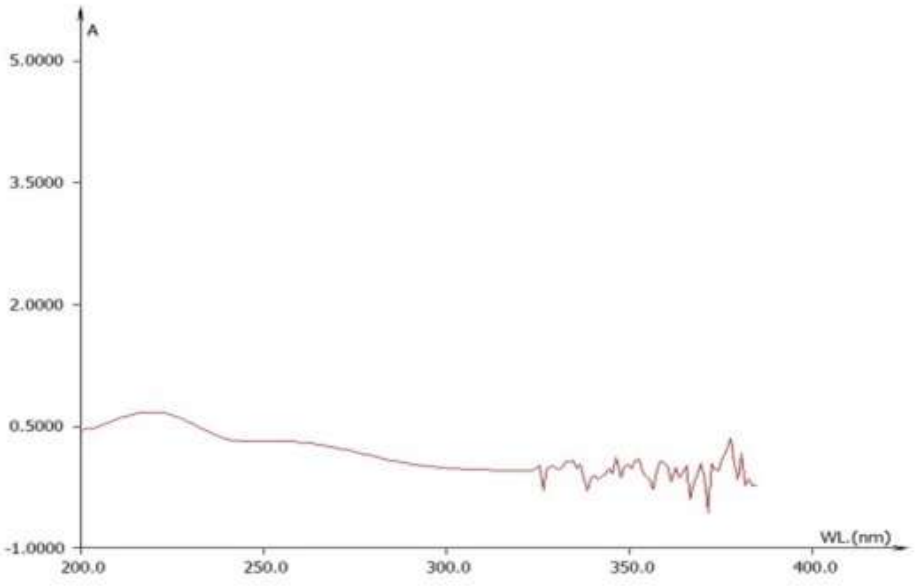

Figure 2: Spectrum obtained for pure drug

Table 1: Linearity

Concentration (µg/ml)	Absorbance
10	0.1504
20	0.2357
30	0.3299
40	0.4234
50	0.5229
60	0.6012
70	0.7222
80	0.8125
Regression equation	Y=0.009x+0.047
Correlation coefficient(R^2)	0.998

Table 2: Intermediate Precision

Conc. [µg/ml]	Absorbance	
	Examiner-1/Day-1	Examiner-2/Day-2
50	0.5611	0.5125
50	0.5614	0.5126
50	0.5467	0.5205
50	0.5467	0.5212
50	0.5616	0.5226
50	0.5432	0.5232
Mean	0.55275	0.51875
S.D	0.00949	0.00490
%RSD	1.71	0.94

Table 3: Accuracy of method

Addition Level	Amount of formulation	Quantity added	Hypothetical quantity.	Experimental amount	% recovery
80%	40	32	56	55.82	99.6
100%	40	40	40	40.16	100.4
120%	40	48	68	67.91	99.86

Table 4: Robustness Study

Conc. (µg/ml)	Absorbance		
	217nm	218nm	219nm
50	0.5124	0.5226	0.5128
50	0.5126	0.5124	0.5136
50	0.5012	0.5136	0.5132
50	0.5206	0.5224	0.5132
50	0.5224	0.5205	0.5210
50	0.5136	0.5206	0.5204
AVG	0.50380	0.518683	0.51707
SD	0.00748	0.004504	0.00424
%RSD	1.45	0.86	0.82

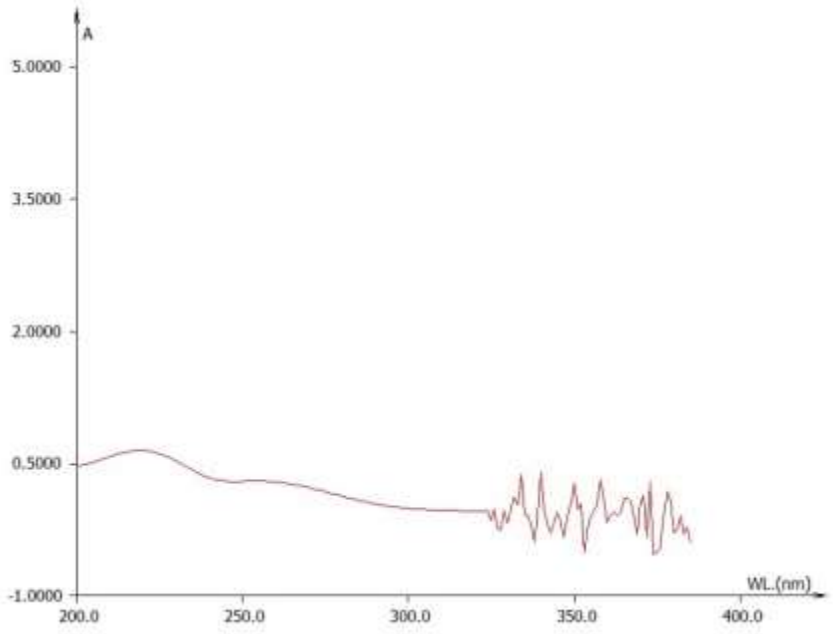

Figure 3: Spectrum obtained for formulation

CONCLUSION:

The proposed method proved to be simple, exhibiting accuracy, precision, and robustness while being easily implementable. The calibration plot covered a broad range, and the recoveries of samples were consistent. The equipment and reagents utilized are likely to be accessible, even in basic laboratory setups. Therefore, the established method is recommended for regular use in quality control analysis of FXD. Additionally, it is deemed suitable for analyzing samples in accelerated stability studies, routine formulation analyses, and the assessment of drug substance.

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