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UV Spectrophotometric Method Development and Validation for Fexofenadine Hydrochloride in Bulk And Tablet Dosage form

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ABSTRACT

Development of a simple, precise, accurate, specific, and robust UV-visible spectrophotometric method for the quantitative determination of Fexofenadine Hydrochloride in bulk and tablets dosage form.

Method: *The method is developed using 0.1M NaOH as a solvent. The stock solution of Fexofenadine Hydrochloride was prepared in 0.1M NaOH and subsequent dilutions were done in 0.1M NaOH. The standard solution of Fexofenadine Hydrochloride showed absorption maxima at 220 nm. The sample was prepared by simple extraction method. The developed method was validated according to the International Conference on Harmonization (ICH) guidelines with respect to linearity, accuracy, precision, specificity, robustness, ruggedness and solution stability.*

Results: *The drug solutions obeyed Beer–Lambert's law and linearity was studied in the concentration range of 5-40 µg/ml with correlation coefficient 0.9993 at 220 nm. The limit of detection and limit of quantification were found to be 1.577µg/ml and 4.778µg/ml respectively. The accuracy of the method was checked by recovery experiment performed at three different levels i.e., 80%, 100% and 120 %. The % recovery was found to be in the range 98.75-100.52%. The low values of % relative standard deviation (RSD) are indicative of the accuracy and reproducibility of the method. The precision of the method was studied as an intra-day, inter-day variations and repeatability. The % RSD value less than 2 indicate that the method is precise.*

Conclusion: *The above method was a cost-effective quality-control tool for routine analysis of Fexofenadine Hydrochloride in bulk and in tablet dosage form.*

Keywords: *Absorption, Beer–Lambert's law, Percent RSD, Fexofenadine Hydrochloride, UV visible spectrophotometric.*

INTRODUCTION

Spectrophotometric methods are a large group of analytical methods that are based on atomic and molecular spectroscopy. Spectroscopy is a branch of science dealing with the study of interaction of electromagnetic radiation with matter. The kind and amount of radiation absorbed by the molecule depends on the number of molecule interacting with the radiation [1, 2].

Fexofenadine Hydrochloride (FH) is an antihistaminic drug used to treat allergic symptoms. Chemically FH is known as *(RS)* α, α-dimethyl-4-[1-hydroxy-4-[4-(hydroxydiphenylmethyl)-1-piperidinyl] butyl] benzene acetic acid hydrochloride (Figure 1). FH belongs to a class of drugs known as first-generation Histamine (H1) receptor antagonist. FH acts H_1 antagonists have an established and valued place in the symptomatic treatment of various immediate hypersensitivity reactions [3].

The literature survey reveals that various methods for the determination of Fexofenadine Hydrochloride are reported. Among this liquid chromatography, HPLC, RP-HPLC, RP-UPLC methods are for Fexofenadine Hydrochloride. However less suitable visible spectrophotometric method is reported till date for the estimation of Fexofenadine Hydrochloride [4-11].

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So, an attempt was made to develop a simple, precise, accurate, specific, and robust UV-visible spectrophotometric method for the quantitative determination of FH in tablets and bulk form using 0.1M NaOH as a solvent. The current research work deals with development of spectrophotometric method and its validation as per ICH guidelines.[12] The devised method was found to be selective, reliable, faster and more straight forward than other reported methods.

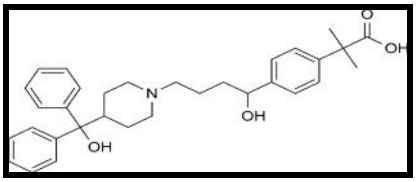

Fig. 1: Structure of Fexofenadine Hydrochloride

MATERIALS AND METHODS

Instruments and Reference standard:

UV-visible double beam spectrophotometer (Shimadzu, 1800, Japan) with matched quartz cells corresponding to 1 cm path length. AUX – 220 single pan electronic balance was used for weighing the materials. Pure sample of Fexofenadine Hydrochloride was obtained from Dolphin Pharma. Ltd. Surat, India. Sodium hydroxide was purchased from Loba Cheime, Mumbai, India.

Marketed tablet preparation:

Trade Name	Company Name	Dose	Batch Number	Manufactured Date	Expiry Date
Allegra 120mg	SANOFI	120mg	0214628	JUL.2014	JUN.2016

Procedure:

Preparation of 0.1M NaOH: [13]

0.1M NaOH was prepared by dissolving 4gm Sodium Hydroxide pellets in 1000 ml volumetric flask using distilled water and then volume was make up by distilled water.

Preparation of standard stock Solution:

Standard stock solution was prepared by dissolving drug equivalent to 10 mg of drug in 0.1M NaOH into 100 ml volumetric flask and then volume was adjusted to 100 ml with 0.1M NaOH.

Scanning of stock solution for determination of λmax:

The stock solution prepared as above procedure then scanned for maximum absorption wavelength (λmax). First in both cuvettes was distilled water added then spectrum was obtained between 400-200 nm. Then baseline correction was carried out. Further the stock solution was added into a cuvette and again spectrum was scanned from 400-200 nm and the wavelength at which maximum absorption observed was noted.

Beer's law range:

The stock solution was suitably diluted with 0.1M NaOH to get concentration range from 5 to 40µg/ml. The solutions were scanned in UV regions between 400 to 200nm then absorption was measured at maximum λmax. Calibration curve was plotted by using absorbance and concentrations.

Analysis of tablet formulations:

Twenty tablets were finely powdered. An accurately weighed quantity of powder equivalent to about 10mg of Fexofenadine Hydrochloride was transferred to a 100ml volumetric flask. The contents of the flask were mixed with 0.1M NaOH and shaken to dissolve the active ingredients and then made up to the volume with the same solvent. The solution was filtered and the filtrate was further diluted with 0.1M NaOH to give a final drug concentration of 5 to 40µg/ml. Absorbance values of sample solution were recorded at 220nm. The proposed method was validated for the following parameters.

Linearity:

Linearity was determined by constructing analytical curve with eight calibration points for drug, with the concentrations 5-40 µg/ml. The absorbance values were plotted against the respective concentrations of drug to get the analytical curve. The results were subjected to regression analysis by the least squares method to calculate the slope (m), intercept (c) and regression coefficient (R^2).

Sensitivity:

The sensitivity of measurements of FH by the use of the proposed method was estimated in terms of the limit of quantification (LOQ) and limit of detection (LOD).

Formula:

$$LOD = 3.3 \times M/S$$
$$LOQ = 10 \times M/S$$

Where, M is the standard deviation of y-intercepts of regression lines and S is the slope of the calibration curve.

Precision:

The precision of an analytical procedure expresses the closeness of agreement (degree of scatter) between a series of measurements obtained from multiple sampling of the same homogeneous sample under the prescribed conditions. Precision of the method was determined in terms of repeatability and intraday and interday precisions.

Repeatability:

Repeatability of the method was determined by analyzing six samples of 5 µg/ml concentrations of drug and the % RSD were calculated.

Intraday and interday precision:

Intraday precision was determined by analyzing the drug at three different concentrations 20, 25 and 30 µg/ml and each concentration for three times, on the same day. Interday precision was determined similarly, but the analysis being carried out daily, for three consecutive days.

Ruggedness:

The solutions were prepared and then analyzed with change in the analytical condition like different analyst.

Robustness:

The robustness of a method is its capacity to remain unaffected by small changes in conditions. To determine the robustness of the method, the experimental conditions were deliberately altered and assay was evaluated. The effect of detection wavelength was studied at ±2 nm. For changes of conditions, the sample was determined in triplicate. When the effect of altering one set of conditions was tested, the other conditions were held constant at the optimum values.

Accuracy (Recovery):

The accuracy of the methods was determined by performing recovery studies on tablet formulation and for prepared solutions containing known amount of drug by standard addition method in which pre-analyzed samples were taken and standard drug was added at three different levels (80%, 100% and 120%) and constant was kept 2µg/ml.

RESULTS AND DISCUSSION

A simple, economic, precise, accurate method for estimation of Fexofenadine Hydrochloride was developed. This developed method was validated according to ICH guidelines.

Table No. 1: Linearity data of FH by UV spectroscopy

Concentration (µg/ml)	Abs 1	Abs 2	Abs 3	Mean (n=3)	±SD	%RSD
5	0.241	0.244	0.238	0.241	0.0028	1.17068
10	0.394	0.392	0.393	0.393	0.0008	0.20191
15	0.539	0.539	0.541	0.540	0.0011	0.20667
20	0.695	0.697	0.694	0.695	0.0012	0.16584
25	0.869	0.869	0.867	0.869	0.0011	0.12185
30	1.043	1.044	1.043	1.043	0.0006	0.05337
35	1.203	1.203	1.202	1.202	0.0008	0.06601
40	1.370	1.370	1.369	1.370	0.0009	0.06238

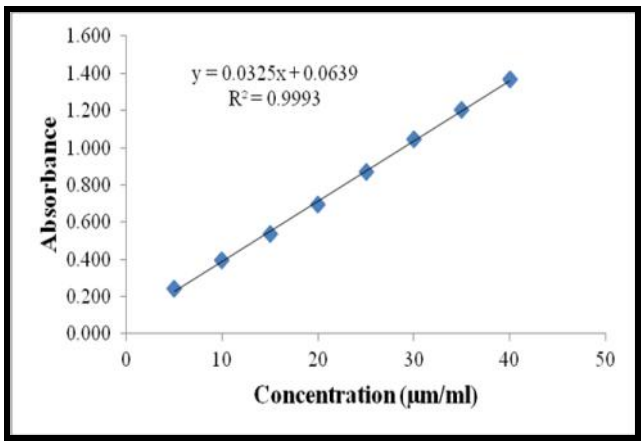

Fig. 2: Calibration curve of FH in 0.1M NaOH

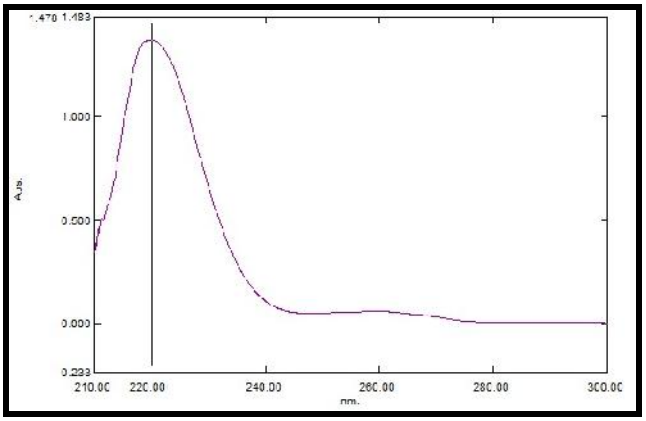

Fig. 3: Spectra Fexofenadine Hydrochloride

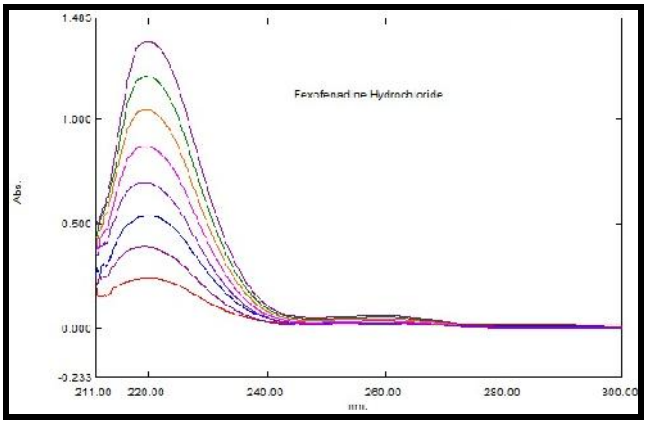

Fig. 4: Overlay Spectra

Table No. 2: Calibration parameters

Sr. no.	Parameters	Method wavelength (nm)
1)	Absorption maxima (nm)	220
2)	Beer's law limit (µg/ml)	5-40
3)	Correlation coefficient	0.9993
4)	Regression equation (y = mx + c)	y = 0.0325x + 0.0639
5)	Slope (m)	0.0325
6)	Intercept (c)	0.0639
7)	S.D. of Slope	0.000376
8)	S.D. of Intercept	0.015530
9)	LOD	1.577
10)	LOQ	4.778

Table No. 3: Observations for intraday and inter-day precision

Condition	Concentration (µg/ml)	Abs 1	Abs 2	Abs 3	Mean (n=3)	±SD	%RSD
Intraday	20	0.6953	0.7015	0.7108	0.7025	0.0078	1.11048
	25	0.8689	0.8812	0.8489	0.8663	0.0163	1.88175
	30	1.0432	1.0725	1.0378	1.0512	0.0187	1.77626
Inter-day	20	0.6953	0.6854	0.6783	0.6863	0.0085	1.24405
	25	0.8689	0.8572	0.8745	0.8669	0.0088	1.01831
	30	1.0432	1.0765	1.0579	1.0592	0.0167	1.57553

Table No. 4: Results of repeatability

conc.(µg/ml)	Absorbance
5	0.2414
5	0.2411
5	0.2411
5	0.2413
5	0.2412
5	0.2414
Mean	0.24125
S.D.	0.00012583
%RSD	0.05215775

Table No. 5: Results of Ruggedness

Conc.	Abs.	
	Analyst 1	Analyst 2
10 µg/ml	0.394	0.396
	0.392	0.395
	0.393	0.395
	0.392	0.397
	0.394	0.396
	0.392	0.395
Mean	0.3928	0.3957
S.D.	0.0008	0.0007

Table No. 6: Results of Ruggedness

Wavelength	218	220
Conc.	10 µg/ml	10 µg/ml
Abs.	0.389	0.383
	0.385	0.382
	0.384	0.381
	0.387	0.382
	0.384	0.384
	0.385	0.382
Mean	0.3857	0.3823
S.D.	0.0018	0.0009

Table No. 7: Data of %recovery

Concentration Level (%)	Amount of tablet powder eq.to(mg)	Amount of standard spiked(mg)	Total Drug Recover (mg)	%Recovery
0	50	0	49.97	
0	50	0		
0	50	0		
80	50	40	89.85	99.7
80	50	40	89.92	99.875
80	50	40	90.05	100.2
100	50	50	99.68	99.42
100	50	50	100.23	100.52
100	50	50	99.97	100
120	50	60	109.79	99.7
120	50	60	109.89	99.86667
120	50	60	110.09	100.2

Table No. 8: Results of analysis of tablet formulation *(n=3)

Drugs	Label claim(mg)	Amount of drug estimated (mg)	% label claim* ± S.D.	% Recovery
Allegra	120	119.24	98.33 ± 1.66	99.36

CONCLUSION

From the above results it can be concluded that the new visible spectrophotometric method for fexofenadine hydrochloride is simple, rapid, accurate, precise and economical. Hence the method can be applied for quantitative analysis of fexofenadine hydrochloride in bulk and pharmaceutical tablet dosage forms.

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