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Stability Indicating RP-HPLC Method for the Estimation of Fexofenadine HCL in Bulk and its Tablet Dosage Form

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ABSTRACT

Stability indicating RP-HPLC method was developed and validated for the quantitative determination of Fexofenadine in tablet dosage form. Separation was achieved using an Inertsil ODS-3V column with flow rate of 1.0ml/min using PDA detector and eluents are observed at 245 nm. The mobile phase consisting of 100% methanol. The drug was reacted with the oxidation, hydrolysis, photolysis and thermal degradation. The method was linear over the concentration range of 10-50µg/ml (r2=0.999) with detection and quantification limit of 0.1 µg/ml and 0.4 µg/ml respectively. The method was accurate, precise and robust for the assay of Fexofenadine in pharmaceutical dosage forms.

Keywords: Fexofenadine hydrochloride, RP-HPLC, Validation and forced degradation.

INTRODUCTION

Fexofenadine hydrochloride is chemically bezeneacetic acid, 4-[1-hydroxy-4-[4-(hydroxydiphenylmethyl)-1-piperidinyl] butyl]-α, α-Dimethyl-hydrochloride [1,2] (Figure 1).

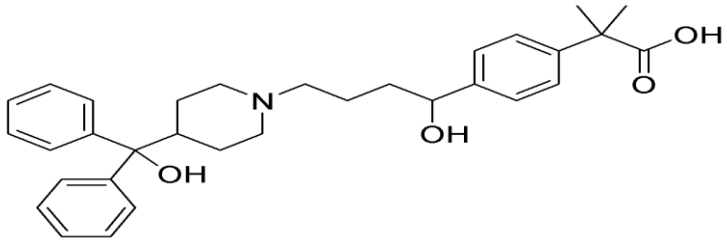

Figure 1: Structure of fexofenadine.

It is second generation long lasting H_1 receptor antagonist. It is an active metabolite of terfenadine and it completes with histamine for H_1 receptor sites on effectors cells in GIT, blood vessels and respiratory tract. Fexofenadine does not cross blood brain barrier, resulting the reduced potential for sedation [3]. Literature survey reveals that several methods have been available for the estimation of Fexofenadine in plasma, stability indicating, impurities and other combination drugs using HPLC-MS [4-10]. The reported methods was found to be more time consuming, solvent consuming as it shows long R_t for drug. The proposed method is more precise, accurate and specific for the quantitative determination of Fexofenadine in pharmaceutical dosage forms.

EXPERIMENTAL PROCEDURE

Fexofenadine pure compound was kindly supplied by Aurobindo Pharma, Hyderabad, India and was used without further purification. Tablet formulation Histafree (Mankind, India) containing labelled amount of 120 mg of fexofenadine were purchase from local market. All the chemicals were used of analytical HPLC grade [11-15].

Preparation of solutions

Diluent

Based on the solubility of drug methanol was selected as diluent.

Preparation of standard stock solution

Accurately weigh 10 mg of fexofenadine, transferred in 10ml volumetric flask. To it add little quantity of diluent and sonicate it for 10 min and make up with diluent (1000 ug/ml).

Preparation of standard working solution

Pipette out 1 ml of the above solution into another 10ml volumetric flask and make up with diluent (100 ug/ml). 1ml of the above solution was transferred into another 10 ml volumetric flask and make up with diluent (10 ug/ml) [16,17].

RESULT AND DISCUSSION

An effort has made to identify simple precise, specific and accurate method for the estimation of fexofenadine in bulk and formulation by using RP-HPLC. After considering all system suitability parameters, 100% Methanol was selected for analysis; 1 ml flow rate was optimized for advanced studies. The retention time of fexofinadine was found to be 3.7 min. The calibration was done by using external calibration method, with the optimum chromatographic conditions standard stock solutions of fexofenadine were prepared by using diluents and various concentrations has been prepared in the range of 10-50 µg/ml of fexofenadine solutions. 20 µl of each solution was injected individually and corresponding chromatogram was recorded at 245 nm. The calibration curve has plotted using concentration against peak area. The procedure has repeated for three times. The R^2 was found to be 0.999 indicates the concentration of fexofenadine has good linearity. The precision of the method was confirmed by repeatable injections of the standard solutions for 6 times. The % RSD value was found to be 0.89. Accuracy was confirmed by recovery studies by adding known amount of pure drug to the previously analyzed formulation was analyzed by proposed method. The % recovery of fexofenadine present in formulation was found between 98-102%. The LOD and LOD were determined from the linearity studies and calculated by using average of slope and standard deviation of intercept. The LOD was found to be 0.15 and LOQ was found to be 0.48. Robustness of the method was done by the deliberate changes in flow rate; column oven temperature and wavelength have been recorded (Figures 2 and 3, Tables 1-5).

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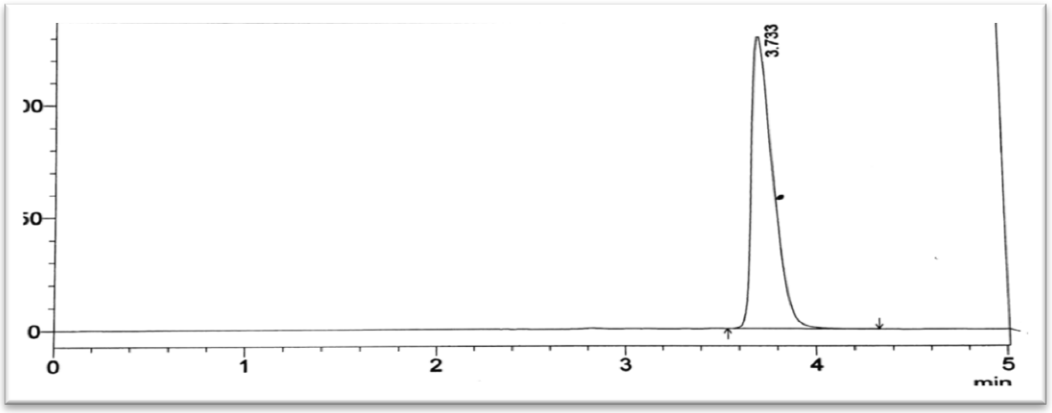

Figure 2: Optimized chromatogram of fexofenadine by proposed method.

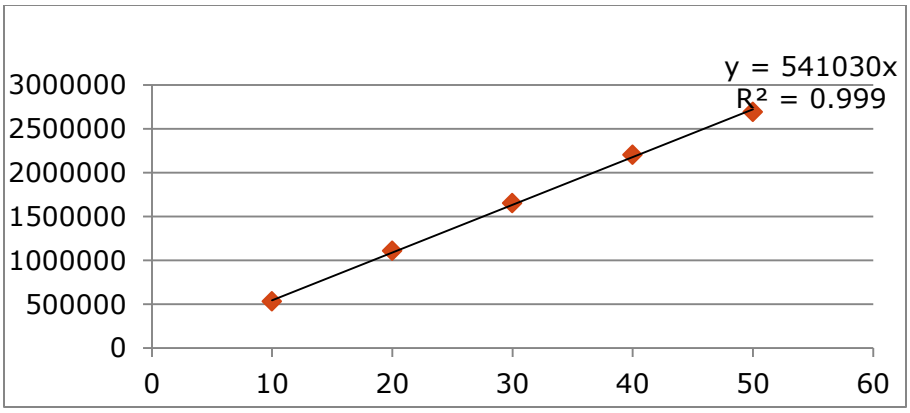

Figure 3: Linearity plot of fexofenadine.

Table 1: Precision results.

S. No	Concentration (µg/ml)	Amount (µg/ml)	% of Amount	Avg	S.D	% RSD
1	30	30.1	100.3	100.2	0.90	0.89
2		30.1	100.3			
3		30	100			
4		30.1	100.3			
5		30.1	100.3			
6		30	100			

Table 2: Accuracy results.

Percentage level	Amount (µg/ml)	Amount added (µg/ml)	Amount found	Amount Recovery	%Recovery	Avg%	S.D	%RSD
50	30	15	44.9	14.9	99.3	100.6	1.1	1.09
			45.2	15.2	101.3			
			45.2	15.2	101.3			
100		30	60.1	30.1	100.3	100.7	0.40	0.41
			60.3	30.3	101			
			60.3	30.3	101			
			74.8	44.8	99.5			

150		45	74.1	44.1	98	99	0.93	0.93
			74.9	44.9	99.7			

Table 3: LOD and LOQ.

S. No	Parameters	Fexofenadine
1	LOD	0.15
2	LOQ	0.48

Table 4: Robustness results.

Parameter	Conditions	Variation	%RSD
Wavelength Variation	245	250	2
		240	0.55
Column oven temperature Variation	30ºC	25ºC	1.3
		35ºC	0.95
Flow rate Variation	1ml/min	0.9ml/min	0.22
		1.1ml/min	0.39

Table 5: Degradation results.

Degradation Mechanism	% of Degradation
Acid Degradation	11.65%
Base Degradation	11.65%
Peroxide Degradation	5%
Hydrolysis Degradation	8%

CONCLUSION

The developed technique was valid as per ICH guidelines. The developed technique was found to be specific, linear, accurate, precise and reproducible. So it was concluded that the developed RP-HPLC method was specific and may be used for routine analysis and stability studies of Fexofenadine.

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