RP-HPLC Method Development For Determination of Loratadine

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Summary

A simple, rapid and precise reversed-phase HPLC method has been developed for the quantitation of loratadine on a Zorbax SB-C8 150 X 4.6 mm, 5µ Column (P/N: 883975-906) column using a mobile phase consisting acetonitrile- Buffer (Di sodium hydrogen phosphate, pH-3.7) (55:45 % v/v) using a flow rate of 1.0 mL/min at 225 nm as detector wavelength. The retention time of loratadine have been found to be 7.2 minutes and recoveries were between 99.27-100.71 %. Validation of the proposed method has also been done.

Keywords: Loratadine (Lora), HPLC, acetonitrile, phosphate buffer.

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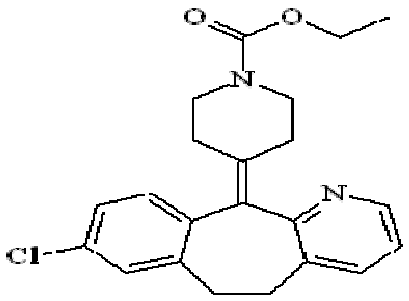
Introduction

Loratadine is a new generation antihistamine drug. Loratadine is a tricyclic antihistaminic drug, which selectively antagonizes peripheral histamine H_1-receptors. It is used to treat allergies such as hay fever (allergic rhinitis), urticaria (hives), and other skin allergies, and marketed for its non-sedating properties. The chromatographic separation was obtained within 10 min and was found to be linear in the concentration range of 1-200 µg/mL. The method was validated for all the parameters as per the ICH guidelines and was found to be within the acceptance range.[1,2]



Material and Methods:

All chemicals/ solvents used were of AR/HPLC grade. Standard loratadine was provided by I.S.P Hongkong. A Schimadzu HPLC system was used for the analysis. The method was carried out at Zorbax SB-C8, 150 X 4.6 mm, 5µ Column as a stationary phase and acetonitrile- Buffer (55:45 % v/v) solution as a mobile phase at flow rate of 1.0 mL/min at 225 nm. The mobile phase was filtered through a 0.45 µ membrane filter and degassed. The analysis was carried out at room temperature.

Accurately about 10 mg of Loratadine working standard was weighed and quantitatively transferred to a 100 ml clean, dry standard volumetric flask. To this about 20 ml of the diluent was added and kept in an ultrasonic bath to dissolve. The volume was made up to the mark with the diluent and mixed well. This yielded a standard Loratadine stock solution of 1000 ppm concentration. Buffer and Acetonitrile were mixed in the ratio 45:55 and used as the diluent

The 1000 ppm stock solution prepared above was used to make the solutions for the calibration graph. One mL of the above stock solution was diluted to 10 mL with the diluent to get a standard solution concentration of about 100 ppm. Similarly 200 ppm, 150 ppm and 50 ppm solutions were also prepared by pipeting 2.0, 1.5, 0.5 mL respectively into 10 mL volumetric flask and diluted to volume with diluent.

From the 100 ppm solution 1, 5 and 10 ppm solutions were prepared by pipeting out 0.1, 0.5 and 1.0 mL, respectively into corresponding 10 mL volumetric flask and making up to the volume using the diluent. Each concentration was injected in triplicate. The linear regression analysis data is given in Table 3. (Figure 1). The retention time of loratadine was found to be 7.2 minute concentrations of loratadine in sample solution were obtained by comparing with the standard solution.[10,11]

Results and Discussion

The average recovery of the drug was determined. Accuracy was investigated in the concentration range of 80-120% of the standard concentration for Loratadine. The percentage recovery values obtained was found to lie within the standard limit of 95 % to 105%.Precision of the method was demonstrated by reproducibility studies. This was done analyzing six samples prepared from a homogenous sample. Linearity and range of the method was determined analyzing standard solution containing 1-20 mcg/ml. the calibration curve was plotted using area under curve Vs concentration of the standard solution. Ruggedness of the method was evaluated by carrying out the experiment by different conditions. Stability of the standard and sample solution was ascertained by analyzing it periodically. Robustness of the method was demonstrated by variation in composition of mobile phase (±2%), PH of the mobile phase and temperature.

The chromatographic parameters were validated by system suitability studies and peak asymmetry and column efficiency were determined (Table 1). The precision data shows that reproducibility of the assay procedure is satisfactory and % RSD was found to be 0.08 and 0.23 (Table 1). Accuracy studies indicated that the mean percent recovery of the standard drug values obtained was found to lie within the standard limit of 95 % to 105 %.(Table 2). A linear relationship was obtained in the concentration range of 1-200 ppm with the equation y = 20,748.752X+ 3,711.174 and correlation coefficient 1. Ruggedness study signified the reproducibility of the method for different stress conditions. The method was found to be robust with respect to theoritical plates and retention time. Limit of detection and limit of quantification was found to be 0.1 and 0.4 ppm, respectively(Table 3). Robustness was established by varying the flow rate, pH, Column temperature and mobile phase composition (Table 4).

Accuracy of the method was studied by recovery experiments. The proposed HPLC method was found to be simple, accurate, precise, linear, rugged and rapid. Hence this method can be applied for the routine analysis of different formulations.

Table 1: System suitability studies[12,13]

S.No	Sample details	RT(min)	Area
1	Loratadine WS	7.22	2044221
2		7.21	2045530
3		7.21	2039345
4		7.21	2047564
5		7.22	2037887
6		7.22	2049831
	Average	7.22	2044063
	STDEV	0.01	4649.87
	%RSD	0.08	0.23
	USP Tailing		1.01
	USP Plate count		9666

Table 2 : Accuracy

Concentration (in %)	Average Area	Recovery (in %)
80	1623518.83	99.27
100	2055644.83	100.56
120	2470480.50	100.71

Table 3: LOD and LOQ

Concentration in ppm	S/N ratio
0.1	3.5 (LOD)
0.4	11.5 (LOQ)

Table 4: Robustness

Parameter	Altered parameter	Retention Time(min)	Area counts
Flow (in ml/min) (As per method 1 ml/min.)	0.9ml	8.04	2286388
	1.1ml	6.57	1853961
Column Temperature(^{0}C) (As per method 30°C)	28°C	7.12	2087555
	32°C	7.15	2164761
Mobile Phase composition Buffer:Acetonitrile (45:55)	43:57	6.49	2042867
	47:53	8.13	2074696
pH (As per method 3.7)	3.5	8.15	2056518
	3.9	6.68	2013191

Figure 1: Representative chromatogram for Blank

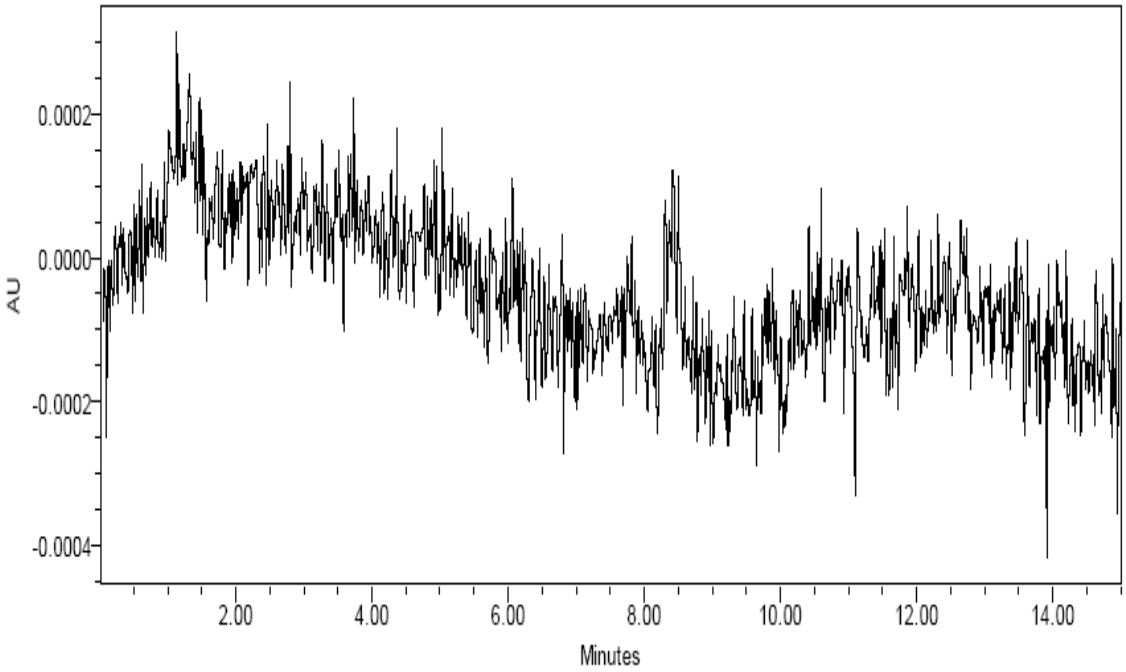
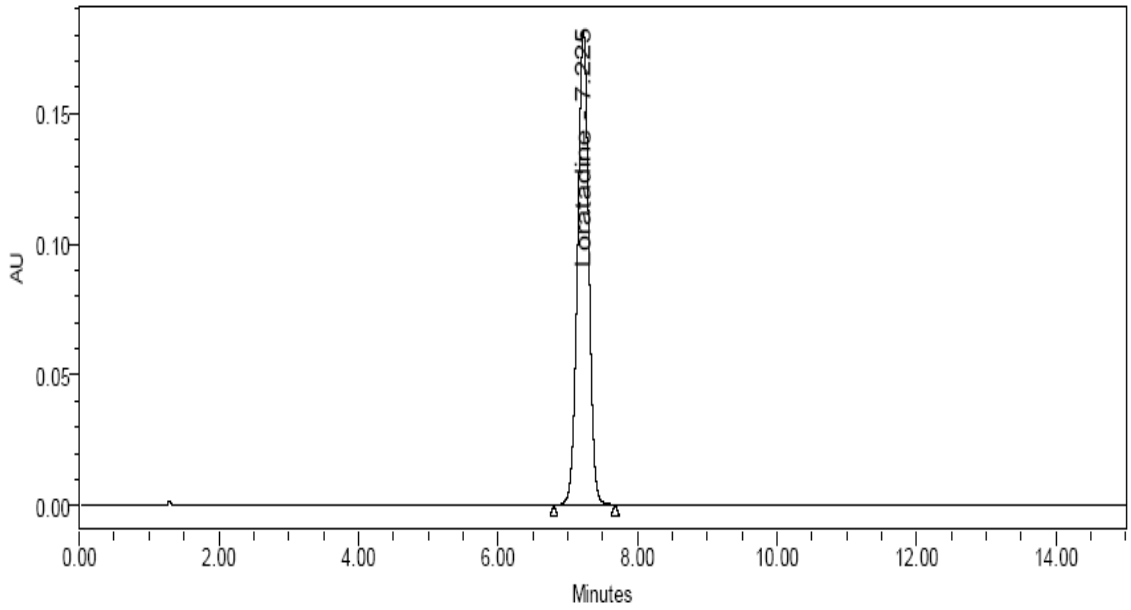


Figure 2: Representative chromatogram for Loratidine Standard



Conclusion

The method is accurate and precise for the reliable evaluation of Loratidine in pharmaceutical formulation with good accuracy and precision. The method was validated for all the parameters and was found that all the validation parameters were within the acceptance range as per the ICH guidelines. Therefore, the proposed method can be successfully applied for the quantitative analysis of Loratadine in pharmaceutical dosage forms of the drug and was found to be a stability indicating.

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