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Spectrophotometric Determination of Loratadine in Bulk and Pharmaceutical Formulations

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The present work described the development of a UV spectrophotometric method for estimation of loratadine. A simple, accurate, cost effective and reproducible spectrophotometric method has been developed for the estimation of loratadine in bulk and pharmaceutical dosage form. An absorption maximum was found to be at 275 nm. The percentage recovery of loratadine ranged from 99.982 to 101.4908 % in pharmaceutical dosage form. The developed method was validated with respect to linearity, accuracy (recovery), precision, limit of detection (LOD), limit of quantitation (LOQ), Sandell's sensitivity, molar absorbtivity, molar extinction coefficient and specificity. Beer's law was obeyed in the concentration range of 4-40 µg/mL having line equation y = 0.0389x + 0.1011 with correlation coefficient of 0.9999.

Key Words: UV spectrophotometry, Loratadine.

INTRODUCTION

Loratadine, 4-(8-chloro-5,6-dihydro-11*H*-benzo[5,6]-cyclohepta[1,2-b]pyridine-11-ylidine)-1-piperidinecarboxylic acid ethyl ester is a long acting nonsedating antihistaminic agent that was developed for the treatment of seasonal allergic rhinitis[1]. loratadine is a white powder not soluble in water, but very soluble in organic solvents. The structural formula for loratadine is as shown in Fig. 1.

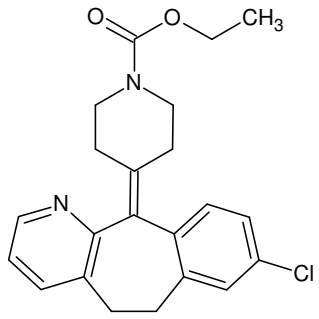

Fig. 1. Chemical structure of loratadine

The estimation of loratadine by ultraviolet spectrophotometry[2], atomic absorption spectrometry (AAS)[3], polarography[4], gas liquid chromatography (GLC)[5] and gas chromatographic mass spectrometry (GC-MS)[6,7], high performance/pressure thin layer chromatography (HPTLC)[8], reversed phase HPLC[9] as well as fluorimetry and thin layer chromatographic (TLC) densitometry[10] is reported in literature. But estimation of this single drug with a different dissolution media with economy and accuracy has not been reported till date in bulk and pharmaceutical formulation. Thus the present study was undertaken to develop and validate a simple, sensitive, accurate, precise and reproducible UV estimation method for loratadine.

In the literature, several methods have been described for determination of loratadine in pharmaceutical preparations including UV spectrophotometry[11-17], colorimetry[12,18-22], spectrofluorometry[12], densitometry[13,23] and capillary electrophoresis [24-27]. The simultaneous determination of loratadine and desloratadine in pharmaceutical preparations adopting liquid chromatography with UV detection was reported by Qi *et al.*[28].

EXPERIMENTAL

Instruments used were JASCO V-630 double beam UV/Visible spectrophotometer and analytical balance Shimadzu AX200. Loratadine was obtain from Shreya Pharma Ltd., Aurangabad as gift sample with 99.98 % w/w assay value and was used without further purification. All chemicals and reagents used were of analytical grade.

General procedure

Preparation of standard stock solution: Standard drug solution of loratadine was prepared by dissolving 10 mg loratadine in 20 mL of 0.1N HCl and was transfered to 100 mL volumetric flask and volume was made upto mark with 0.1 N HCl to obtain stock solution of 100 µg/mL concentration.

TABLE-1
DETERMINATION ACTIVE INGREDIENTS IN TABLET AND ACCURACY BY PERCENTAGE RECOVERY METHOD

Ingredient	Tablet amount (µg/mL)	Level of addition (%)	Amount added (mg)	Drug found (µg/mL)	Recovery (%)	Average recovery (%)
Loratadine	20	80	16	35.4712	101.4908	100.93± 0.824
	20	100	20	40.0072	99.982	
	20	120	24	43. 430	101.3125	

*Lorfast Meltab (10 mg)

Preparation of sample solution: Ten tablets were weighed and powdered. The amount of tablet powder equivalent to 10 mg of loratadine was weighed accurately and transferred to 20 mL 0.1N HCl and kept for 15 min with frequent shaking and volume was made up to 100 mL mark with 0.1N HCl. The solution was then filtered through Whatmann filter paper # 41. This filtrate was diluted suitably with solvent (0.1N HCl) to get the solution of 20 µg/mL concentration. The absorbance was measured against blank. The drug content of the preparation was calculated using standard calibration curve (Table-1).

Detection method

Preparation of calibration curve: Calibration curve was prepared in 0.1N HCl at λ_{max} 275 nm (Figs. 2 and 3) using UV/Visible spectrophotometer for stock solution of 100 mg/mL. Serial dilution of 4, 8, 12, 16, 20, 24, 28, 32, 36 and 40 µg/mL were prepared and absorbance was taken at λ_{max} 275 nm. Average of such 8 sets of values was taken for standard calibration curve and solutions were scanned in the range of 200-400 nm against blank. The calibration curve was plotted. The optical characteristics are summarized in Table-2.

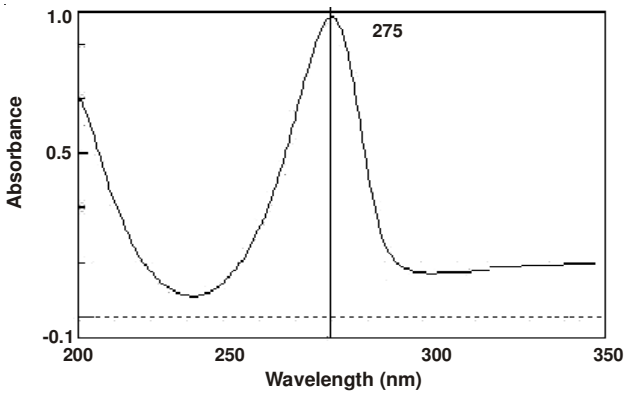

Fig. 2. Determination of λ_{max} of loratadine by UV scanning

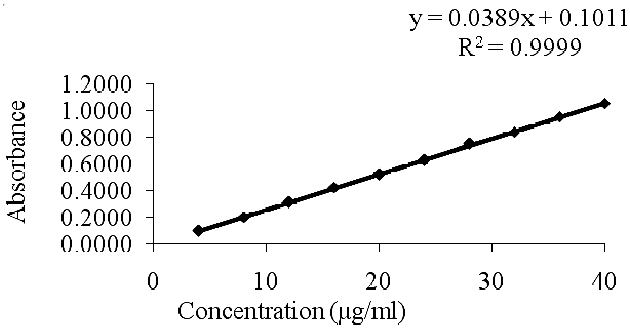

Fig. 3. Calibration curve of loratadine

TABLE-2
OPTICAL CHARACTERISTICS AND CALIBRATION CURVE PARAMETERS

S. No.	Concentration of solution (µg/mL)	Mean absorbance value*	± RSD
1	4	0.1012 ± 0.016	16.0100
2	8	0.2050 ± 0.013	6.5583
3	12	0.3153 ± 0.014	4.4019
4	16	0.4250 ± 0.013	3.0285
5	20	0.5242 ± 0.015	2.9031
6	24	0.6314 ± 0.019	2.9504
7	28	0.7525 ± 0.019	2.5331
8	32	0.8396 ± 0.022	2.6671
9	36	0.9560 ± 0.039	4.0613
10	40	1.0574 ± 0.027	2.5803

*Values are mean of ten determinations.

RESULTS AND DISCUSSION

Precision: Assay of method precision (intra-day precision) was evaluated by carrying out four independent assays of test samples of loratadine. The intermediate precision (inter-day precision) of the method was also evaluated using two different analysts, systems and different days in the same laboratory. The per cent relative standard deviation (% RSD) and assay values obtained by two analysts were 1.670, 100.484 and 1.482, 99.556 respectively (Table-3).

TABLE-3
DETERMINATION OF PRECISION

Sample No.	Assay of loratadine as per cent of labeled amount	
	Analyst-I (Intra-day precision)	Analyst-II (Inter-day precision)
1	101.328	100.948
2	99.215	99.200
3	99.373	99.250
4	103.271	101.652
5	100.853	98.545
6	98.866	97.738
Mean	100.484	99.556
% RSD	1.670	1.482

Accuracy (recovery test): Accuracy of the method was studied by recovery studies. The recovery studies were performed by adding known amounts to tablet. The recovery was performed at three levels, 80, 100 and 120 % of loratadine standard concentration. The recovery samples were prepared as mentioned above. Three samples were prepared for each recovery level. The solutions were then analyzed and the percentage recoveries were calculated from the calibration curve. The recovery values for loratadine ranged from 99.982 to 101.4908 % (Table-1).

Linearity: The linearity response of the drug was verified at 0 to 50 µg/mL concentrations, but linearity was found in between 4-40 µg/mL concentration range. The calibration curve was obtained by plotting the absorbance *versus* concentration data and was treated by linear regression analysis (Table-2). The equation of the calibration curve for loratadine was obtained as y = 0.0389x + 0.1011 and the calibration curve was found to be linear. The correlation coefficient (r^2) for determination was 0.9999 (Fig. 3).

Limit of detection (LOD) and limit of quantification (LOQ): The LOD and LOQ of loratadine were determined by using standard deviation of the response and slope approach as defined in International Conference on Harmonization (ICH) guidelines (ICH Harmonized tripartite guidelines 1996). The LOD and LOQ is shown in Table-4.

TABLE-4
VALIDATION PARAMETERS

S. No.	Parameter	Result
1	Absorption maxima (nm) (λ_{max})	275
2	Standard regression equation	y = 0.0389x + 0.1011
3	Regression coefficient (r^2)	0.9999
4	Accuracy (% recovery ± SD)	100.93 ± 0.824
5	Precision	100.484 and 99.556 %
6	Range (µg/mL)	0 to 50
7	Linearity (µg/mL)	4 to 40
8	LOD (µg/mL)	1.678001
9	LOQ (µg/mL)	5.084851
10	Molar absorbtivity ($LMol^{-1}cm^{-1}$)	99572
11	A (1 %, 1 cm)	262.3756
12	Sandell's sensitivity ($\mu g/cm^2$/0.001 absorbance units)	0.038124

Determination of active ingredients in tablets: The validated method was applied for the determination of loratadine in tablets. Six tablets were assayed and the results are shown in Table-2, indicating that the amount of drug in tablet samples were within required range (97.738 and 103.271 % of the label claim).

Conclusion

The developed method was found to be simple, economical, sensitive, accurate, precise, reproducible and can be used for routine quality control analysis of loratadine in bulk and pharmaceutical formulations. As the solvent is 0.1 N HCl the method has genuine advantage to use for the evaluation of floating and sustained drug delivery systems of loratadine effectively.

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