NEW UV SPECTROPHOTOMETRIC METHOD FOR THE DETERMINATION OF DESLORATADINE IN BULK AND TABLET DOSAGE FORMS

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ABSTRACT

A simple, rapid, accurate, economical, sensitive and precise UV spectrophotometric method has been developed for the estimation of desloratadine in bulk and tablet dosage forms. Desloratadine exhibited maximum absorbance at 280 nm in 0.1 N HCL with molar absorptivity of 1.54×10^4. Beer's law was found to be obeyed in the concentration range of 5-30 ìg/mL.Correlation coefficient was found to be 0.9999. The developed method was validated respect to linearity, precision and accuracy. The proposed method is useful for the routine estimation of desloratadine in bulk and tablet dosage forms.

KEY WORDS: Spectrophotometry, Desloratadine, Beer's law, dosage form.

1.INTRODUCTION

Desloratadine (Fig.1), chemically it is 8-chloro-6, 11- dihydro-11-(4-piperdinylidene)-5*H*-benzo [5, 6] cyclohepta [1, 2-*b*] pyridine. It is a selective peripheral H_1 receptor antagonist (Graul,2000). It has an empirical formula of $C_{19}H_{19}ClN_2$ and a molecular weight of 310.8. It is a white to off-white powder and is slightly soluble in water, but very soluble in methanol, ethanol and propylene glycol. It is indicated for the relief of the nasal and non-nasal symptoms of seasonal allergic rhinitis and perennial allergic rhinitis and also symptomatic relief of pruritus. Literature survey reveals that few analytical methods have been reported so far for the

determination of desloratadine in pharmaceuticals and biological fluids. Desloratadine was determined in human plasma by LC-MS/MS (Liyu,2003; Hong and Xue,2007) ion pair HPLC (Jinjian and Abu,2010), RP-HPLC (Meiling,2005; Mahbubul,2006) and UPLC (Durga rao and Satyanarayana,2010), but no UV spectrophotometric method has been reported so far. The present study describes a simple, sensitive, accurate, precise and economical UV spectrophotometric method for the estimation of desloratadine in bulk and tablet dosage forms. UV analysis of desloratadine was performed in 0.1 N HCL. The spectrum was recorded from 200 nm to 380 nm. The quantitative analysis was carried out at 280 nm. The method was validated and applied for the determination of desloratadine in tablet dosage forms.

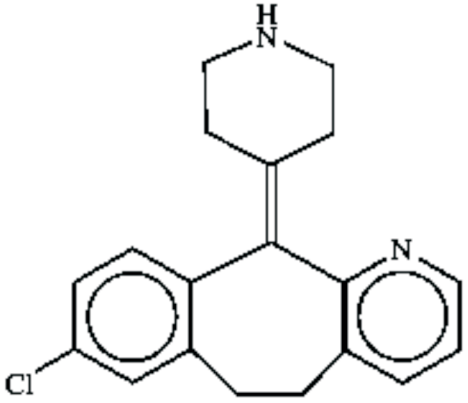

Figure 1. Chemical structure of desloratadine

2.MATERIALS AND METHODS

Apparatus

ELICO SL-164 UV-Visible double beam spectrophotometer equipped with 10 mm matched quartz cells. A sartorius analytical balance was used.

Chemicals

Pure Desloratadine obtained from Orchid chemicals and Pharmaceuticals Ltd., Chennai. Hydrochloric acid from Merck and double distilled water were used for preparation of solutions and different brands of tablets of desloratadine were supplied from local pharmacy.

Preparation of Standard solution and linearity solutions

Standard stock solution of desloratadine (1000 ìg/ml) was prepared by dissolving 100 mg of desloratadine in 100 ml of 0.1 N HCL. It was further diluted with 0.1 N HCL to obtain a working standard solution of 100 ìg/ml.A series of concentrations ranging from 5-30 ìg/ml was prepared after diluting 0.5 – 3.0 ml of working standard solution (100 ìg/ml) in 10 ml

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of 0.1 N HCL.The absorbance was measured at 280 nm against 0.1 N HCL as blank. The calibration curve was plotted in the concentration range of 5 to 30 ìg/ml.

Preparation of Sample solutions

Twenty tablets containing desloratadine were weighed accurately and powdered. The powder equivalent to 50 mg of desloratadine was taken into a 50 ml volumetric flask, dissolved in 30 ml of 0.1 N HCL, sonicated for 10 minutes and then made upto the volume with 0.1 N HCL and filtered through Whatman filter paper No.1.Transferred10 ml of the filtrate into a 100 ml volumetric flask and diluted to 100 ml with 0.1 N HCL to get a concentration of 100 ìg/ml. Suitable volume of this solution was taken in 10 mL volumetric flask and volume was made up with 0.1 N HCL and the absorbance of the above solution was measured at 280 nm against 0.1 N HCL as a blank.

3.RESULTS AND DISCUSSION

The UV spectrum of standard solution of desloratadine (10 ìg/ml) in 0.1 N HCL was illustrated in Fig.2. The linearity plot between absorbance and concentration of desloratadine showed that the system obeys Beer's Law limit (Fig. 3).

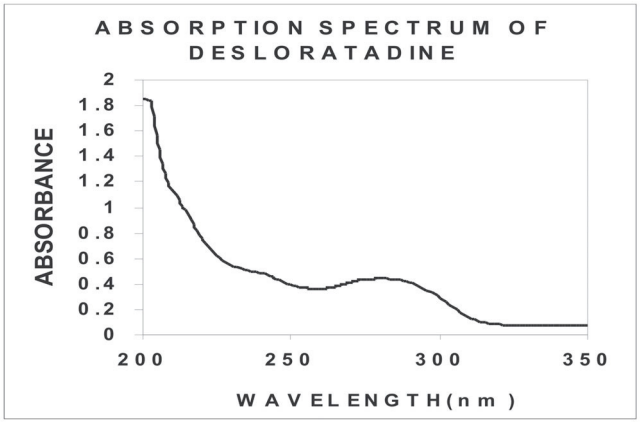

Figure 2. UV spectrum of desloratadine in 0.1 N HCL (10 ìg/ml).

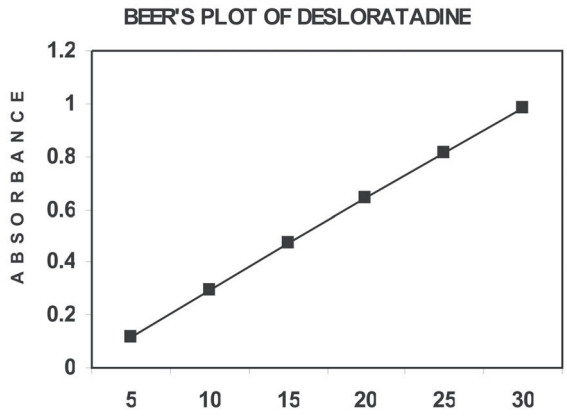

Figure 3. Standard graph of desloratadine.

The optical characteristics such as Beer's law limit, molar absorptivity, Sandell's sensitivity, Correlation coefficient, slope and intercept, % Relative Standard Deviation, % Range of error (0.05 and 0.01 confidence limits) were calculated and are summarized in Table1.

Table-1. Optical characteristics and Precision of the proposed method

S.NO.	PARAMETER	RESULTS
1	λ max	280
2	Beer's law limit (µg/mL) and Range	5-30
3	Molar absorptivity (L $mole^{-1}$ cm^{-1})	1.54×10^4
4	Correlation coefficient (r)	0.9999
5	Regression equation (Y = a + bC) ** Slope (b) Intercept (a)	 0.0345 -0.0527
6	Relative standard deviation (%)*	0.42
7	Sandell's sensitivity (µg cm^{-2} / 0.001 Abs unit)	0.018
8	%Range of error (Confidence limits)* 0.05 level 0.01 level	 0.5187 0.7245

* Average of eight determinations

**Y = b + ac, where 'c' is the concentration in µg/mL and Y is the absorbance unit.

S.NO.	BRAND	LABEL CLAIM		AMOUNT FOUND (mg)	%ASSAY
1	DELORTA	5 mg		5.01	100.2
2	DEXLY	5 mg		4.98	99.6
STATISTICAL ANALYSIS				Mean	99.9
				%RSD	0.42

To ensure the reproducibility and accuracy of the method, recovery studies were carried out by adding a known quantity of pure drug to the preanalyzed sample and contents were reanalyzed by the proposed method. From the amount of drug found, percentage recovery was calculated. The results of assay and recovery studies are presented in table 2 and table 3.

Table 2. Results of Assay in marketed formulation

Table 3. Results of accuracy/recovery studies in marketed formulation

S.NO.	TEST CONC.	AMOUNT ADDED (mg)	AMOUNT RECOVERED (mg)	% RECOVERY	% SD*
1	50%	5	5.012	100.24	0.36
2	75%	10	9.975	99.75	0.52
3	100%	15	14.989	99.92	0.49

* Average of three determinations

4.CONCLUSION

In this study a simple, rapid, sensitive, accurate, precise and economical UV Spectrophotometric method for the determination of desloratadine in bulk and tablet dosage forms has been developed and validated. It was found that the common excipients present in the formulation did not interfere with the proposed method and can be used for the routine quality control analysis of desloratadine in bulk as well as in Pharmaceutical dosage forms.

5.ACKNOWLEDGEMENT

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