NOTE

Spectrophotometric Determination of Desloratadine in Bulk and Tablet Forms

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A new simple and sensitive spectrophotometric method in UV has been developed for the quantitative estimation of desloratadine in bulk and dosage forms. Desloratadine shows maximum absorbance at 282.5 nm. Beers law was obeyed in concentration range of 16–24 mcg/mL. The developed method was validated statistically and by recovery studies. The recovery study was found to be between 97 to 101%.

Key Words: Spectrophotometric determination, Desloratadine.

Desloratadine (DES) is chemically 8-chloro-6,11-dihydro-11-(4-piperidinylidene)-5H-benzo-[5,6]-cycloheptal-[1,2-b]-pyridine decarboethoxyl oratadine having m.f. C₁₉H₁₉ClN₂.¹ It is non-sedating antihistaminic agent²; active metabolite of loratadine. A survey of literature reveals that DES is estimated by 96-well solid phase extraction liquid chromatography tandem mass spectrometry method³. The present work deals with a spectrophotometric estimation of the DES in its bulk form and in tablet form.

All the chemicals used were of analytical grade. Spectral and absorbance measurements were made on shimadzu-1601 UV/visible spectrophotometer with matched quartz cells.

Preparation of stock solution: A solution of DES of concentration 1000 mcg/mL was prepared by dissolving 50 mg of pure drug in 0.1 N HCl and volume was made to 50 mL with 0.1 N HCl.

Procedure: Standard stock solution was diluted to give working standards of range 16-24 mcg/mL. The absorbance was measured at 282.5 nm against reagent blank. The calibration curve was found to be linear in the range of 16-24 mcg/mL.

Determination from tablets

Twenty tablets of DES were weighed and powdered. The powder equivalent to 10 mg of DES was transferred into 100 mL volumetric flask containing 50–60 mL 0.1 N HCl, the solution was shaken at 190 rpm for 15 min, volume was made with 0.1 N HCl and filtered through a Whatman filter No. 1. Then 1 mL filtrate

was diluted to 50 mL and absorbance was measured at 282.5 nm. The results are shown in Table-1.

In order to study the accuracy and precision of the method recovery experiment was carried out using standard addition method. The recovery of the added standard were studied at three different levels, i.e., 50, 100 and 150% of labelled claim of the tablet.

Each set of addition was repeated six times and percentage recovery for added standard was calculated using the formula

% Recovery =
$$\frac{N(\Sigma xy) - (\Sigma y)(\Sigma x)}{N(\Sigma x^2) - (\Sigma x)} \times 100$$

where N = number of observations

x = amount of standard drug added per tablet

y = amount of standard drug found per tablet.

The optical characteristics such as absorption maxima, Beer's law limit, molar extinction coefficient, standard deviation were calculated and the results are summarized in Table-1.

TABLE-1 OPTICAL CHARACTERISTICS AND PRECISION DATA

Parameters	Value 282.5 nm	
Absorption maxima (nm)		
Beer's Law limit (mcg/mL)	16-24 mcg/mL	
Molar extinction coefficient (L mole ⁻¹ /cm ⁻¹)	9.69634×10^3	
Regression equation	Y = 0.0305X - 0.0226	
Slope	0.0305	
Intercept	-0.0226	
Standard deviation on slope	2.9200×10^{-4}	
Standard deviation on intercept	2.9826×10^{-2}	
Correlation coefficient	0.9991	

Interference studies revealed that the common excipients and other additives usually present in dosage form did not interfere in the proposed method. The method was applied for analysis of the drug in pharmaceutical formulation (tablet) and those results are presented in Table-2.

TABLE-2

Dosage form	Labeled amount(mg)	Estimated amount		Percentage
		mg	Percentage	recovery
Tablet	5	5.03	100.73	98.85

^{*}Each reading is average of six determinations

In conclusion the proposed spectrophotometric method for the estimation of DES is simple, sensitive, cheap and accurate and has its application in the routine quality control analysis and quantitative determination of DES from its bulk and pharmaceutical formulations.

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