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NEW SPECTROPHOTOMETRIC METHOD FOR THE DETERMINATION OF DESLORATADINE IN PHARMACEUTICAL FORMULATIONS

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ABSTRACT

An Economic, precise, accurate, sensitive and simple spectrophotometric method developed for the quantitative estimation of desloratadine in pharmaceutical formulations. The method was based on the formation of ferric chloride and potassium ferricyanide, which forms a coloured chromgen exhibit the absorbance at λ_{max} 710 nm and obeyed Beer's law in the concentration ranges 1-5 µg/mL. Spectrophotometric parameters were established for standardization of the method including statistical analysis of data. The method has been successfully extended to the Pharmaceutical formulations

Key words: Spectrophotometry, Desloratadine, Ferric chloride, Potassium ferricyanide, Formulations.

INTRODUCTION

Desloratadine (DSE) [5H -benzo (5,6) cyclo helpta (1,2 -b) pyridine, 8-chloro-6, 11-dihydro-11-(4-piperidnylidene)] is the histamine[1] H1 -receptor and one of the most effective antihisminic[2] drug and is effective in smaller doses. It is used to treat the symptoms caused by the Histamine a chemical that is responsible for many of the signs and symptoms of allergic reactions. For example swelling of the nose, sneezing and itchy eyes. Histamine is released from storage cells (mast cells) and then attaches to other cells that have receptors for histamine. It is a member of small family of non-sedating antihitamines which includes loratadine[3], cetirizine[4], desloratadine[5] was approved by the FDA in December 2001 as anti histamine.

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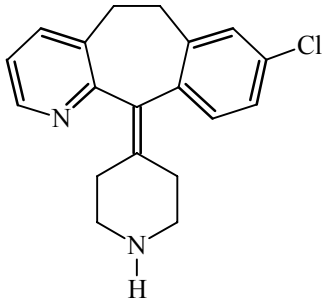
Some literature reported about the visible spectrophotometric methods for the quantification of DSE in pure drug and in pharmaceutical formulations such as HPLC[6], GC[7], LC[8], NMR[9] and simple spectrophotometry[10], conversing UV and visible methods has been reported for the estimation of DSE in pharmaceutical preparations.

The proposed method is based on the reaction of the drug with ferric chloride and potassium ferricyanide, which forms a coloured chromgen[11-12], which exhibits the absorption maximum at λ_{max} 710 nm and obeyed Beer's law in the concentration ranges 1-5 µg/mL. In the method, the drug reduces ferric chloride to ferrous form, which in turn forms complex with potassium ferricyanide to give a coloured potassium ferroferrous complex. Spectrophotometri parameters are established to standardization of the method including statistical analysis of data. This method has been successfully extended to the pharmaceutical preparation (tablets) containing DSE. The chemical structure of DSE is shown in Fig. 1.



Desloratadine

Fig. 1

EXPERIMENTAL

A Milton roy UV-Visible spectrophotometer Model-1201 with 1 cm matched quartz cells was used for all spectral measurements.

Chemicals and reagents

All the solutions were freshly prepared. All chemicals, solvents used through this study were of analytical grade. Diluted with double distilled water.

Preparation of standard stock solution

A standard stock solution containing 1 mg/mL was prepared by dissolving 100 mg Desloratadine of in 100 mL of double distilled ethanol. From this, a working standard

solution containing 100 µg/mL was prepared for the proposed method. $FeCl_3$ solution (Merck; 0.1% w/v) Prepared by dissolving 100 mg of $FeCl_3$ in 100 mL of double distilled water. $K_3[Fe(CN)_6]$ Solution (BDH; 0.1% w/v 3.04×10^{-3} M) Prepared by dissolving 100 mg of $K_3[Fe(CN)_6]$ in 100 mL of double distilled water.

Assay procedure

Solutions of DSE raising from (0.5 mL -2.5 mL) 2 µg/mL were transferred into a series of 20 mL volumetric Flask. To each flask 3.0 mL of ferric chloride reagent and 1.5 mL of potassium ferricyanide were added, after 10 minutes at room temperature. The solution was made up to 20 mL with double distilled waters. The absorbance of coloured complex formation was measured at 710 nm (Fig. 2) against a reagent blank. The amount of the drug present in the sample solution was composed from the calibration curve (Fig. 3).

Preparation of sample solution

Twenty tablets of Desloratadine were accurately weighed and powdered. Tablet powder equivalent to 100 mg of Desloratadine was dissolved in 50 mL of distilled water, sonicated for 15 min, filtered and washed with distilled water. The filtrate and washings were combined and the final volume was made to 100 mL with distilled water. The solution was suitably diluted and analyzed as given under the assay procedure for bulk samples. The results are represented in Table 1. None of the excipients usually employed in the formulation of tablets interfered in the analysis of Desloratadine, by the proposed methods.

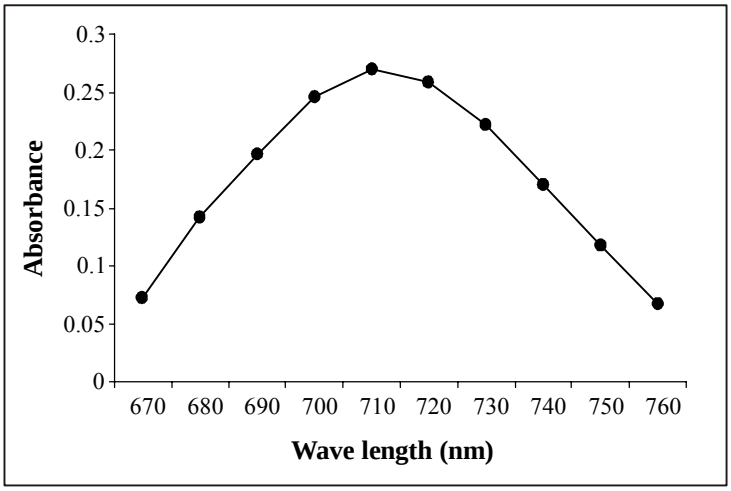


Fig. 2: Absorbance spectra of DSE-$FeCl_3$/$K_3[Fe(CN)_6]$

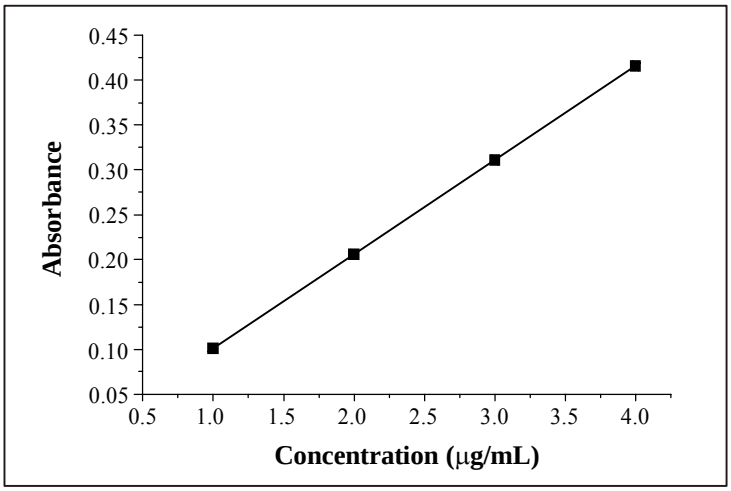


Fig. 3: Beer's Law plot of DSE- $FeCl_3/K_3$ $[Fe(CN)_6]$

RESULTS AND DISCUSSION

The optimum conditions were established by varying one parameter at a time and keeping the others fixed and observing the effect on absorbance of chromogen**.** In the present work, the method was developed for the estimation of Desloratadine from tablet formulation. Recovery studies were close to 100% that indicates the accuracy and precision of the proposed methods. The optical characteristics such as absorption maxima, Beer's law limits, molar absorptivity and Sandell's sensitivity are presented in Table 1. The regression analysis using the method of least squares was made for slope (b), intercept (a) and correlation obtained from different concentrations and the results are summarized in Table 1. The high molar absorptivities of the resulting colored complexes indicate the high sensitivity of the methods. The percent relative standard deviation, standard deviation and student's 't' test values calculated from the two measurements of Desloratadine are presented in Table 2. Relative standard deviation values and standard Statistical parameters Proposed method λ_{max} 710 nm. deviation were low that indicates the reproducibility of the proposed methods. In the student's 't' tests, no significant differences were found between the calculated and theoretical values of the proposed method at 95% confidence level. This indicated similar precision and accuracy in the analysis of Desloratadinein its tablets.

To ensure the accuracy and reproducibility of the results obtained, known amounts of pure drug was added to the previously analysed formulated samples and these samples were reanalyzed by the proposed method and also performed recovery experiments. The percentage recoveries thus obtained were given in Table 1.

Table 1: Optical characteristics of proposed method

Parameter	Method
λ_{max} (nm)	710
Beer's law limits (μg mL^{-1})	1-5
Detection limit (μg mL^{-1})	0.2173
Molar absorptivity (1 $mole^{-1}$ cm^{-1})	3.1392×10^{4}
Sandell's sensitivity	0.0099
(μg/cm^2/0.001 absorbance unit)	
Regression equation (Y^*= a + bC)	0.1025
Slope (b)	2.711×10^{-3}
Standard deviation on slope (S_b)	-0.001
Intercept (a)	7.4246×10^{-3}
Standard deviation on intercept (S_a)	6.0621×10^{-3}
Standard error of estimation (S_e)	0.9999
Correlation coefficient (r)	1.575
Relative standard deviation (%)	
% Range of error (Confidence limits)	
0.05 level	± 1.6526
0.01 level	± 2.5931

*Y = a+ bC, where Y is the absorbance and C concentration in μg/mL Recovery studies

Table 2: Assay and recovery of Desloratadine in tablet formulations

Tablets	Labeled amount (mg)	*Amount found, mg ± S.D*	% Recovery	% RSD*	*t value
Delorta	5	99.94 ± 0.35	100.2	1.575	0.3628
Delotid	5	100.12 ± 0.3	100.02	1.480	0.8758

*Average of five determinations based on label claim

CONCLUSION

The proposed methods are simple, sensitive, accurate and economical for the routine estimation of Desloratadine in bulk and in its tablet dosage form.

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REFERENCES

1. M. E. Wolf, Edt. Burger's Medicinal Chemistry, Part IV, 4th Edn., Wiley Interscience, New York (1981).
2. A. Korolkavar, Essentials of Medicinal Chemistry, 2nd Edn., Wiley Interscience, New York (1988).
3. CIMS, Ist Ed., At Medice (India) Private Limited, Bangalore (2006).
4. The Merck Index – An Encyclopedia of Chemicals, Drugs and Biological, Merck & Co., Ranway, USA, 1947 (1996)
5. T. Radhakrishna, J. Satyanaraya and A. Satyanarayan, Indian Drugs, **39(6)**, 13-15 (2002)**.**
6. Lihe Liu, Meiling Qi, Peng Wang and Haozhi Li., J. Pharmaceut. Biomed. Anal., **34(5**), 1013-1019 (2004).
7. Dina T. El-Sherbiry Nahed El. Enamy, Fathalla F. Belal and Steenh Hansen, J. Pharmaceut. Biomed. Anal., **43(4)**, 1236-1242 (2007).
8. Mei Ling Qi, Peng Wang and Yang Shu Geng, J. Pharmaceut. Biomed. Anal., **38(2)**, 355-359 (2005)
9. M. Gergov, J. N. Robson, E. Duchoslav and I. Ojanpere, J. Mass Spectrum, **35**, 912-916 (2000).
10. Ch. Chandra Sekhar and U. Viplava Prasad, J. Pharm. Res., **5(3)**, 1316-1317 (2012).
11. M. Sivanadh, V. Prasanthi and M. V. B. Rao, Int. J. Chem. Sci., **5(1)**, 380-384 (2007).
12. K. Ratna Kumari and G. Devala Rao, IJPRD, **2(1)**, 1-5 (2010).

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