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Short Communication

Spectrophotometric Determination of Cetirizine Dihydrochloride in Pure and Pharmaceutical Formulations

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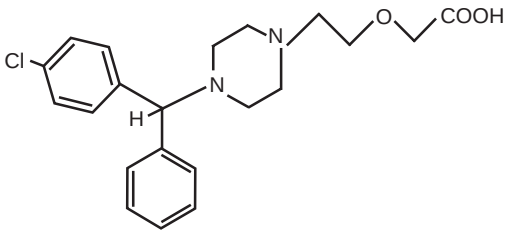
Abstract. A rapid, simple and sensitive spectrophotometric method has been developed for determination of antihistamine (cetirizine dihydrochloride) in pure and pharmaceutical formulations, based on the charge transfer complexation between cetirizine dihydrochloride as *n*-electron donor with dichloronitrobenzene as π-acceptor in basic medium. The resulting yellowish orange coloured complex had absorption maxima at 410 nm. Beer's law is obeyed in the concentration range I0 µg to 250 µg/mL. Molar absorptivity is 0.4805×10^4/mol/cm and relative standard deviation is 0.95%.

Keywords: cetirizine dihydrochloride, dichloronitrobenzene, spectrophotometry, pharmaceutical formulation

Cetirizine, a metabolite of hydroxyzine, is a long acting non-sedative antihistamine with some mast-cell stabilizing activity (Sweetman, 2007). Many analytical techniques involving HPLC and spectrometry have been employed for the determination of cetirizine dihydrochloride (Koichiro *et al*., 2006; Jaber *et al*., 2004; Paw *et al*., 2002; Drozd *et al*., 2002; Garg *et al*., 1995).



Structural formula of cetirizine dihydrochloride

Here, a new spectrophotometric method for the determination of cetirizine dihydrochloride (CD) in pure and dosage forms has been developed. The method is simple, accurate, precise and sensitive and not yet reported in the literature. It employed standard instruments, chemicals and solutions.

For studying the interferences, standard chemicals and instruments were used. To an aliquot of CD containing 10 µg to 250 µg/mL, 1 mL of 1N sodium hydroxide and 3.5 mL of 2% (w/v) dichloronitrobenzene were added and the contents were heated for 120 sec., in a water bath at 100 °C. After cooling the volume was made up to 10 mL with ethyl alcohol. The resulting absorbance of colour was measured at 410 nm, employing all reagents except CD, to be used as a blank. The experiment was repeated with different volumes of standard CD solution and a calibration curve was prepared.

In order to study the interferences standard instruments and chemicals were used. To an aliquot solution containing 1.0 mg/mL of CD, different amounts of various compounds (1 mg/mL) were added individually until the solution showed the same (±0.01) absorbance as that of pure CD solution without the addition of the organic compound. The value was calculated as the percentage of organic compound with respect to the amount of CD.

Tablets containing 10 mg and syrup cotaining 60 mg of CD were separately dissolved in distilled water and filtered to get 1 mg/mL solution of CD. The absorbance of aliquot containing 10 µg to 250 µg/mL was measured at 410 nm and the quantity of CD was calculated from the standard calibration curve.

CD reacted with dichloronitrobenzene at 100 °C in basic media to give yellowish orange complex; its absorption spectra under optimum conditions lies at 410 nm (Fig. 1). The reaction obeys Beer's law in the concentration range 10 µg to 250 µg/mL. Heating at 100 °C for 120 sec., gave the maximum colour. Above and below this time and temperature, the colour intensity decreased. The colour remained stable for more than 24 h.

Dichloronitrobenzene 20 mg/mL gave maximum absorbance at pH 11.5. This pH was maintained by addition of 1 mL of 1N sodium hydroxide. The probable mechanism of colour reaction is that on addition of sodium hydroxide, piperazine moiety is

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generated furnishing a pair of electrons for interaction with electron deficient dichloronitrobenzene. A charge transfer is formed having absorption maxima at 410 nm.

Different organic solvents e.g., as chloroform, *n*-hexane, xylene, acetone, benzene, dichloromethane (except ethyl alcohol) were tried for colour extraction and stability but none was effective. Ethyl alcohol was used for dilution purpose only.

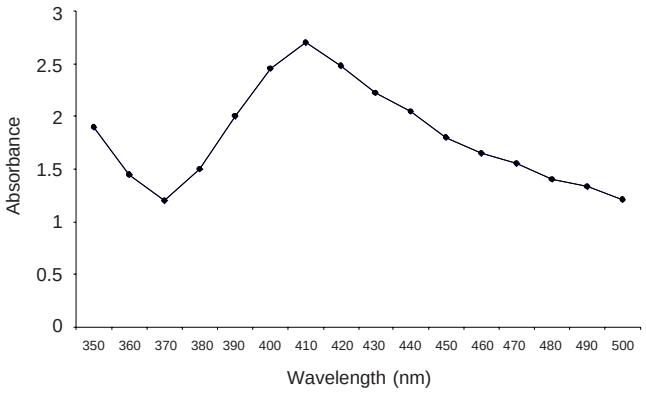

Fig. 1. Absorption spectra of cetirizine dihydrochloride.

The results (Table 1 and 2) show the sensitivity, validity and repeatability of the method. It is also reasonably precise and accurate, as the amount found in the identical known samples, does not exceed the relative standard deviation (RSD) 0.95% which is the replicate of five determinations.

The optimization was done at lower analyte concentration. The calibration graph is linear in the range 10 µg to 250 µg/mL. The apparent molar absorptivity calculated was 0.4805×10^4 and the regression was calculated by the method of least squares from ten points (Christian, 2004) each of which was the average of five determinations. The regression coefficient of determination (r^2) comes out to be 0.9938. The regression equation employed is Y=a+bc, where 'a' stands for intercept, 'b' for slope, c the concentration of analyte and Y is absorbance.

Table 1. Cetirizine dihydrochloride determined in pure solution

CD taken (µg/mL)	CD found (µg/mL)	RSD (%)
10	10.5	0.95
20	19.95	0.50
30	29.6	0.34
60	60.1	0.164
90	90.5	0.110
100	99.0	0.101
140	139.50	0.071
200	210.50	0.047
250	250	0.04

Table 2. Optical characteristics, precision and accuracy of the method

Parameters	Values
λ_{max} (nm)	410
Molar absorptivity (mol/cm)	0.4805×10^4
Regression equation:	
Slope (b)	0.99
Intercept (a)	0.0284
Regression coefficient of determination(r^2)	0.99
Relative standard deviation (RSD%)	0.95
Range of error (confidence limit) at 95% confidence level (%)	9.92 ± 0.0248

Studies were also conducted on tolerable amount of other drugs and diverse interfering compounds with CD. The proposed method was successfully applied for the quality control of pure CD and in the pharmaceutical dosage form as shown in Table 3. Application of spectrophotometry for the determination of individual compounds is of major interest in the analytical pharmacy, since it offers distinct possibility of quality control in the assay of pharmaceutical formulations.

Table 3. Determination of cetirizine dihydrochloride in pharmaceutical preparations

Drug	Trade name	Pharmaceutical preparation	Amount present (mg)	Amount found (mg)	Recovery (%)
Cetirizine dihydrochloride	Zyrtec	Tablet	10	9.99	99.5
	Zyrtec	Syrup	60	59.5	99

The developed method is simple, reliable and sensitive. Colour reaction does not require stringent conditions nor many reagents or solvents. It can be successfully applied for microdetermination of CD either in pure or pharmaceutical preparations.

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