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Development and Application of Validated Spectrophotometric Method for Estimation of Cetirizine Di-Hydrochloride (CD)in Bulk Drug and Tablet Dosage Form

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Abstract: In the present research work development and validation of a simple, sensitive, rapid, accurate, precise and economical UV Spectrophotometric method for the estimation of cetirizine di-hydrochloride in bulk and pharmaceutical dosage form was donebased on the measurement of absorption maxima at 231.40 nm.In this method the simple uv spectrum of cetirizine di-hydrochloride in 0.1 N NaOH was obtained which exhibits absorption maxima (λmax) at 231.40 nm and linearity range was found to be 5-30 ug/ml (r^2< 1). The proposed method was validated for its accuracy, precision, specificity, ruggedness and robustness. No interference was found from tablet excipients at the selected wavelength and assay conditions.
Keywords: Cetirizine Di-hydrochloride,methanol,0.1N NaOH, UV-spectrophotometry.

INTRODUCTION

Cetirizine Di-hydrochlride (CD)chemically is (±)-[2-[4-[(4-chlorophenyl) phenyl methyl]-1-piperazinyl] ethoxy] acetic acid[1,2,3,4]. It is a second generation H_1 receptor antagonists used in the symptomatic treatment of various immediate hypersensitivity reactions and allergic diseases. CD competitively inhibits the action of histamine on tissue containing H_1- receptors and most useful in acute types of allergy and symptoms of seasonal rhinitis and conjunctivitis.CD is rapidly absorbed after oral administration and undergoes metabolism in the liver. The metabolite produced has negligible antihistaminic activity[5,6,7].Literature review reveals number of analytical methods for quantitative determination of CD alone or in combination with other drugs. Some of these methods include spectrophotometry [8,9] , RP-HPLC [10] and TLC [11] .The aim of the present work to develop simple, precise, selective and economical instrumental spectrophotometric method for estimation of CD.

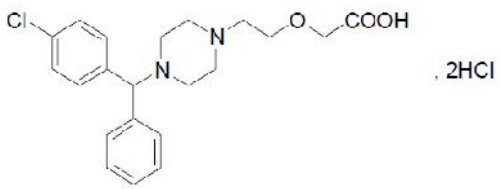

Fig.1: Structure of Cetirizine di-hydrochloride

EXPERIMENTAL

Materials and Methods

The spectrophotometric measurements were carried out by using a Shimadzu UV/Vis spectrophotometer 1800 double beam with a fixed slit width (2 mm) and 1cm matched quartz cell.

Reagents

Cetirizine di- hydrochloride was obtained as a gift sample from SunPharmaPvt. Ltd., Vadodara, Gujarat. The solution of 0.1 N NaOH was prepared in double distilled water as per IP 1996 procedure (1mg/ml).

Stndard solutions

Standard stock solution of CD was prepared in methanol. Suitable aliquot of standard stock solution was diluted with 0.1N NaOH to obtain solution of 10 ug/ml. This solution was scanned in the range of 200-400 nm in 1 cm cell against 0.1 N NaOH as blank. The uv spectrum obtained exhibits absorption maxima (λmax) at 231.40 nm. Suitable aliquots of standard stock solution of CD were diluted with 0.1 N NaOH to obtain concentration range of 5-30µg/ml, the absorbance of each of the solutions were measured against solvent blank at 231.40 nm. A calibration curve was constractedby plotting drug concentration versusabsorbance. The calibration curve was found to be linear in the concentration range of 5-30ug/ml. Statistical data for calibration curve is depicted in Table 1.

Table 1: Statistical Data Of Calibration Curve

Parameters	Values
Wavelength (nm)	231.40 nm
Beer's law limit	5-30 µg/mL
A (1%,1cm)	300.7766
Regression equation	Y=0.028x + 0.0186
Correlation coefficient	0.9988
LOD	0.12143
LOQ	0.36786

Y=mx+c; where x is the concentration of drug in ug/ml, y is the amplitude at specified wavelength, m is the slope and c is the intercept.

Analysis of tablet formulation

Twenty tablets were weighed and crushed to fine powder, average weight was determined. An accurately weighed quantity of tablet powder equivalent to 10 mg of CD was transferred to 10 ml volumetric flask and dissolved by sonication with sufficient quantity of methanol, volume was made upto mark with methanol. The solution was then filtered through Whatmann filter paper No.1. A 2.5 mlportion of the filtrate was further diluted with methanol in a 25 ml volumetric flask.From this solution apropriate dilutions were made with 0.1 N NaOH to obtained the concentration of 10ug/ml and amount of CD was determined from the calibration curve.Five replicate estimations were done in similar way.

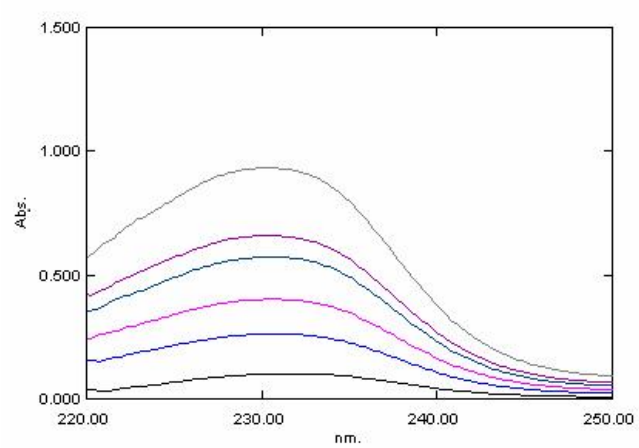

Fig.1 Spectra of Cetirizine di-hydrochloride in 0.1 N NaOH of concentration 5-30ug/ml

Validation

Developed method was validated statistically in terms of linearity, precision, accuracy, LOD and LOQ.

Linearity

The Linearity of the method was established by measurement of varing concentration versus absorbance. CD was found to be linear in the range of 5-30 ug/ml.(r^2=0.9988). Regression line showed excellent linearity relationship between absorbance and concentration of CD. Result of linearity studies are shown in Table 3.

Precision

Precision was studied by analyzing five replicates of sample solutions and concentrations were calculated results are shown in Table 3.

Accuracy

Accuracy of the method was ascertained on the basis of recovery studies, carried out by standard addition method in which pre- analyzed samples were taken and standard drug was added at three different levels.(80%, 100% and 120% of the test concentration).the % recovery ±SD lies in the range of 100.81±0.444.Results are depicted in Table 2.

Table 2 Recovery Study Data

Level of standard addition(%)	% Recovery* ±SD
80	99.625±0.254
100	102.0±0.327
120	100.83±0.753

*Results are mean of three determinations,SD is standard deviation

Table 3. Results Of Validation Studies Of Proposed Method

Validation parameters	Results
Linearity	R^2 = 0.9988
Precision (% Label claim ± SD,n=5)	99.68±0.143
Ruggedness(%Label claim,n=3)	
Intraday	101.92
Interday	100.69
Different analyst	99.15
Specificity	specific

n is number of determinations,SD is standard deviation

Ruggedness

Ruggedness was established by carrying out experiment at different conditions like intra-day,inter-day and by different analyst.

Limit of Detection and Quantitation

The LOD and LOQ of Cetirizine di-hydrochloride were estimated from the standard deviation of the response and the slope of the calibration curve by using following formula.

LOD =3.3 x σ/ S
LOQ = 10 x σ/S
Where σ = the standard deviation of the response
S = the slope of the calibration curve

LOD and LOQ were found to be 0.00012143µg / ml[0.12143 mg/ml] and 0.00036786 µg / mL [0.36786 mg/mL]respectively. And results are indicated in Table 1.

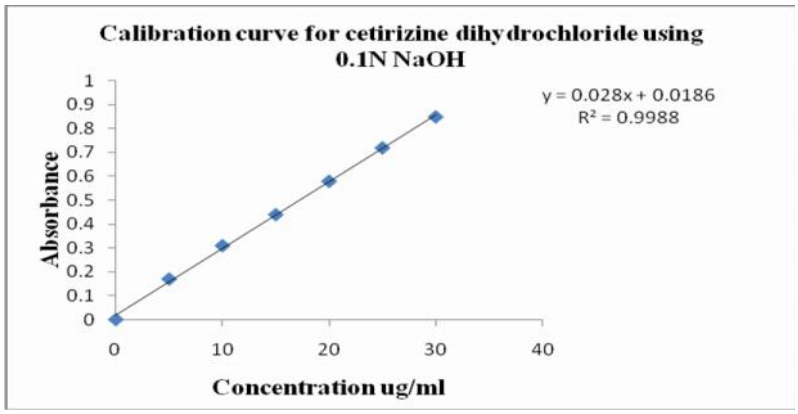

Fig.2 Calibration curve for Cetirizine dihydrochloride using 0.1N NaOH

Table 4. Result Of Analysis Of Commercial Formulation

Drug	% Label claim* (mg)	±SD*
Cetirizine dihydrochloride	100.12	0.5613

*Mean of three determination.*SD is standard deviation

Results And Discussion

The absorption maxima at 231.40 (λmax) was selected for analysis of drug in 0.1N NaOH. Linearity was observed in the range 5-30ug/mL (r^2=0.9988) the amount of drug estimated by the proposed method was in good agreement with the label claim. The proposed method was validated. The accuracy of the method was assessed by recovery studies atthree different levels. Recovery experiments indicated the absence of interference from commonly encountered additives. The method was found to be precise as indicated by the repeatability,inter-day,intra-day analysis, showing %RSD less than 2. The results did not show any statistical difference between operators suggesting that method developed was rugged. The results of accuracy and precision are shown inTable 2 and Table 3. All statistical dada proves validity of the method and can be used for routine analysisof pharmaceutical formulation containing single drug.

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