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ORIGINAL ARTICLE **OPEN ACCESS**

Development and Validation of Uv-Spectrophotometric Method for the Estimation of Cetirizine Hydrochloride in Bulk and Pharmaceutical Dosage Form

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ABSTRACT
A simple and cost effective UV-Spectrophotometric method was developed for the estimation of Cetirizine Hydrochloride. It is a piperazine class of drug belonging to the category of antihistamine. A cost effective and simple method is developed using distilled water as a solvent, spectrum was produced and maximum absorbance was found at 230 nm, as per ICH guidelines. The method was validated for various parameters like linearity, recovery, accuracy, precision. The validation results showed, linearity in the range 4-32 µg/mL; correlation coefficient (R^2) was found to be 0.9995. By conducting accuracy the mean percentage recovery was found to be 99.5%; from precision and intermediate precision studies %RSD was found to be 0.29 & 0.33 respectively. LOD & LOQ were found to be 4.8 µg/mL and 14.5 µg/mL respectively. Assay was conducted by using marketed formulation of cetirizine & the percentage purity was found to be 99.3%, hence the validated data were within allowable limits and therefore, the proposed method is recommended for routine quality control analysis.
Keywords: *Cetirizine Hydrochloride, UV-Spectrophotometric method, Method development, Validation, Assay.*

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INTRODUCTION

Cetirizine Hydrochloride (CTZ), chemically [2-[4-[(4- chlorophenyl) phenyl methyl]-1-piperazinyl] ethoxy] acetic acid[1]. It is a member of the diphenylmethyl piperazine group of antihistamines and it is a non-sedating antihistamine with long acting activity for treatment of urticarial and rhinitis and also used as adjuvant in seasonal asthma. It acts as a selective antagonist of the histamine H_1 receptor[2]. Cetirizine is a fast-acting, highly selective antagonist of the histamine receptors and also an inhibitor of histamine-induced bronchospasm[3]. Cetirizine exert significant anti-inflammatory activity, reducing the infiltration of inflammatory cells in the setting of allergic rhinitis[4]. The dug absorbs rapidly in gastrointestinal tract and has the protein binding of 93%, undergoes oxidative O-dealkylation to a metabolite with antihistaminic activity. It is excreted through the kidneys[5]. The elimination half-life of cetirizine is 8.3hrs.The drug is sold under the brand name of zyrtec and available in the form of 5 and 10 mg tablets[6]. The chemical formula of cetirizine is $C_{21}H_{25}ClN_2O_3$[7].The structure of Cetirizine Hydrochloride is shown in fig. no-1.

Literature survey reveals that many spectrophotometric methods [8-12] are specified for the determination of cetirizine in combination with other drugs. Since no method is reported for single drug analysis, an attempt was made to develop a simple, precise, and sensitive and validated method for the estimation of the drug in pharmaceutical formulations.

MATERIAL AND METHODS

Instruments: For recording UV-spectra of the study Model:T60 UV-visible spectrophotometer and quartz cells of 10mm path length has been used.

Materials: Cetirizine pure drug was obtained from Almelo Private Limited., Hyderabad. Marketed drug was purchased from local pharmacy.

Solubility: The drug is soluble in water.

Preparation of standard stock solution: Standard stock solution was prepared by transfering accurately weighed 100 mg of cetirizine to 100 ml volumetric flask and 50 ml of distilled water was added to dissolve the drug, diluted up to the mark with distilled water to get 1000 µg/ml of cetirizine. Pipette

out 1 mL from the above solution and was further diluted to 10 mL to give 100 µg/ml. Then pipette out 1 mL from the 100 µg/ml and further diluted to 10 mL to give 10 µg/ml.

Determination of wavelength of maximum absorption: A stock solutionof10 µg/ml was taken from the above dilutions. An UV-Spectrum was obtained by scanning from 200 nm to 400 nm and absorption maximum was found to be 230 nm using solvent as blank. The absorption spectrum of cetirizine hydrochloride was shown in fig.no-2.

RESULTS AND METHODS

VALIDATION OF PROPOSED METHOD

The method was validated according to ICH guidelines to study linearity, accuracy, precision, robustness, stability, LOD & LOQ and assay of marketed formulation.

Linearity: To establish linearity the aliquots of working standard solution were diluted with water to obtain the solutions concentration range from 2 µg/ml to 32 µg/ml. a calibration curve for cetirizine was obtained by taking concentration on x-axis and absorbance on y-axis. The absorbance values of these solutions were measured at 230nm and the parameters like slope, intercept, coefficient of correlation, standard deviation were determined. The results of linearity was shown in table No-1 and the calibration curev of cetirizine hydrochloride was at 230nm was shown in fig.no-3.

Discussion: Calibration curve was plotted and correlation coefficient was found to be 0.999 so there is a good correlation between absorbance and concentration.

Precision: The reproducibility of proposed method was determined by analyzing the mid concentration i,e the standard solution (16µg/ml) at different time intervals on same day in six replicate absorbance measurements (Intraday assay precision) and on three different days (Interday assay precision). From the homogenous solution the % RSD was calculated and the results were expressed as %RSD of the measurement. The intraday and interday precision results were shown in table No.3.

Discussion: The %RSD for intraday and interday precision was found to be ≤ 2%. It indicates that the method was precise.

LOD and LOQ: The LOD & LOQ were calculated from the average slope and standard deviation from the calibration curve as per ICH guidelines. LOD value of cetirizine Hydrochloride was derived by calculating the signal to noise ratio, using the following equations designated by ICH guidelines. The results of LOD & LOQ was shown in table No.5.

$$LOD = 3.3 \times \sigma/S$$

$$LOQ = 10 \times \sigma/S$$

Where

σ = Standard deviation of y-intercept of calibration curve &

S = The mean slope of the calibration curve

Discussion: The LOD & LOQ values for Cetirizine Hydrochloride was found to be 4.8µg/ml & 14.5 µg/ml and it indicates the method was sensitive.

Robustness: The robustness of an analytical procedure is measure of it's capacity to remain unaffected by small but deliberate changes in the spectrophotometric conditions. The effects on the results were examined small variation in wavelength i,e -1 nm & +1 nm. The data was shown in table No.6.

Discussion: There was no much variation in the absorbance with change in wavelength.

Stability: The change in the absorbance initially was compared with 24 hour's time period. Standard solution of cetirizine containing 16 µg/ml was taken to test the solution stability. The data was given in the table No.7.

Discussion: It was observed that there is no much difference in the absorbance for standard solution indicating stability of Cetirizine Hydrochloride..

Accuracy: Accuracy of an a analytical method is the closeness of agreement between result obtained by the method to that of true value. The accuracy of the method was determined by calculating the recoveries of Cetirizine Hydrochloride standard solutions and working standard solutions. The method was demonstrated at three different concentration levels 80%, 100% and 120%. The accuracy was performed by spiking 1.6 ml of standard solution (40 µg/ml) with 0.8 ml, 1.6 ml, and 2.4 ml of working standard solution. They were made up to 10 ml with water & the samples were carried out in triplicates. The accuracy data was given in table No.8.

Discussion: The average % recovery of Cetirizine Hydrochloride was found to be within the limits i,e 98-102%.

Assay: Marketed formulation of cetirizine was purchased from Apollo pharmacy (Cetzine 10mg). From that 10 tablets were randomly selected & weighed and powdered using mortar and pestle. The quantity of powder which is equivalent to 10mg of Cetirizine Hydrochloride was transferred to 100ml volumetric flask and make up the volume to 100ml with water. The above solution was sonicated for 15min. Then the solution was filtered through the whatman filter paper to get clear solution. The aliquot portions of

the solution was further diluted to get 16 µg/ml & the absorbance was measured at 230nm. Assay data of Cetirizine Hydrochloride was shown in table No.9.

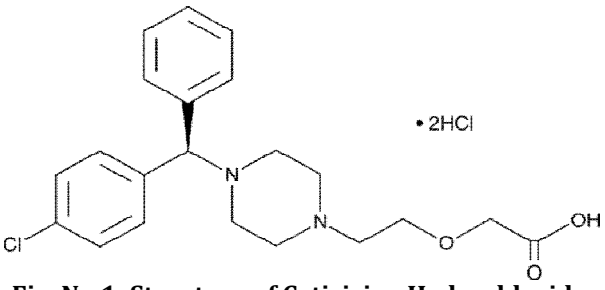

Fig. No.1: Structure of Cetirizine Hydrochloride

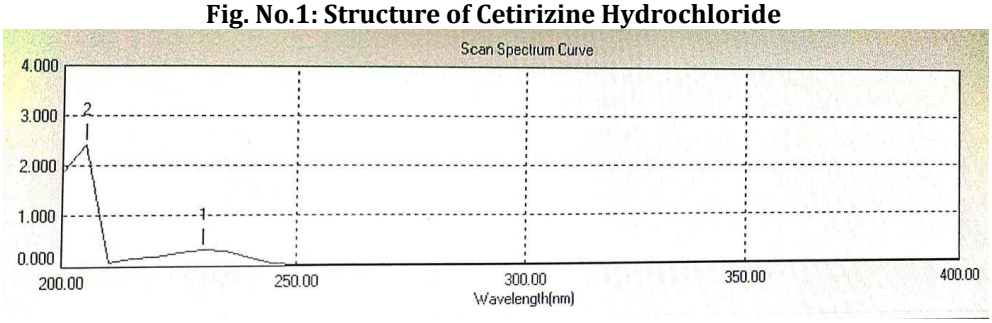

Fig. No.2: Absorption spectrum of Cetirizine Hydrochloride

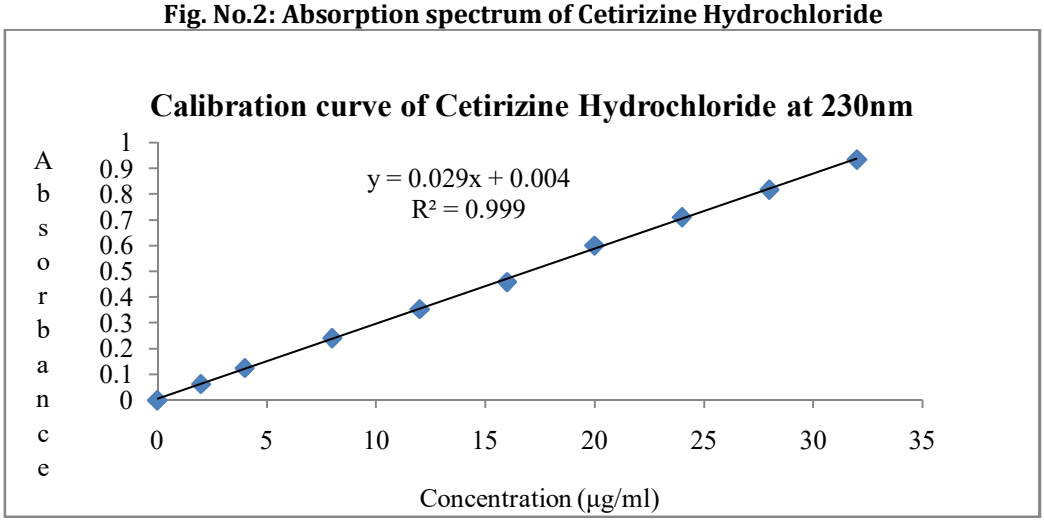

Fig. No.3: Calibration curve of Cetirizine Hydrochloride at 230nm

Table No.1: Linearity data of Cetirizine Hydrochloride

S.No	Concentration (µg/ml)	Absorbance
1	2	0.063
2	4	0.125
3	8	0.241
4	12	0.354
5	16	0.459
6	20	0.601
7	24	0.711
8	28	0.818
9	32	0.935

Table No.2: System suitability parameters of Cetirizine Hydrochloride

S.No	Optical characters	Results
1	λ max	230 nm
2	Beer's law limit(µg/ml)	2-32(µg/ml)
3	Regression equation (y*)	y=0.0292x + 0.0045
4	Slope	0.0292
5	Intercept	0.0045
6	Correlation coefficient	0.999

Table No.3: Intraday precision data of Cetirizine Hydrochloride

Concentration (µg/ml)	Absorbance
16	0.457
16	0.455
16	0.454
16	0.454
16	0.455
16	0.453
Mean	0.454
Standard deviation	0.00136
%RSD	0.29959

Table No.4: Interday precision data of Cetirizine Hydrochloride

Concentration (µg/ml)	Absorbance DAY-1	Absorbance DAY-2	Absorbance DAY-3
16	0.451	0.451	0.450
16	0.453	0.448	0.449
16	0.450	0.450	0.452
16	0.452	0.452	0.451
16	0.454	0.451	0.451
16	0.450	0.449	0.450
Mean	0.451	0.450	0.450
Standard deviation	0.00163	0.00187	0.00103
%RSD	0.3615	0.4152	0.2293

Table No.5: LOD & LOQ data of Cetirizine Hydrochloride

Parameters	Cetirizine (µg/ml)
LOD	4.8
LOQ	14.5

Table No.6: Robustness data of method

S.no	Wavelength	Absorbance
1	229	0.449
2	230	0.456
3	231	0.450

Table No.7: Stability data of Cetirizine Hydrochloride

Time	Concentration	Absorbance
Initial	16 µg/ml	0.453
24 hr's	16 µg/ml	0.448

Table No.8: Accuracy data of Cetirizine Hydrochloride

S.No	Spiked level (%)	Amount taken (µg/ml)	Amount added (µg/ml)	Amount recovered (µg/ml)	Mean of amount recovered	% Recovery
1	50	16	8	23.8	23.86	99.4
	50	16	8	24.0		
	50	16	8	23.8		
2	100	16	16	31.7	31.87	99.6
	100	16	16	32.0		
	100	16	16	31.8		
3	150	16	24	39.9	39.7	99.3
	150	16	24	39.7		
	150	16	24	39.6		

Table No.9: Assay data of Cetirizine Hydrochloride marketed formulation

Label claim	Amount found	Assay
Tablet Cetzine (10mg)	9.93mg	99.3%

CONCLUSION

The statistical analysis data of proposed method was simple, rapid, accurate, precise, sensitive and cost effective; therefore the proposed method can be easily adopted for the routine quality control analysis of marketed formulation of Cetirizine Hydrochloride.

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