ejpmr, 2021,8(7), 280-289

SJIF Impact Factor 6.222

EUROPEAN JOURNAL OF PHARMACEUTICAL AND MEDICAL RESEARCH

www.ejpmr.com

Review Article

ISSN 2394-3211

EJPMR

A REVIEW ON: ANALYTICAL METHOD DEVELOPMENT AND VALIDATION OF CETIRIZINE AS AN ANTIHISTAMINIC DRUG

Pritam S. Jain and *Shubham Chandrashekhar Patil

R. C. Patel Institute of Pharmaceutical Education and Research. Shirpur.

***Corresponding Author: Shubham Chandrashekhar Patil**

R. C. Patel Institute of Pharmaceutical Education and Research. Shirpur.

Article Received on 10/05/2021 **Article Revised on 31/05/2021** **Article Accepted on 21/06/2021**

ABSTRACTS

In this article, we describe the methodology for the development and validation of cetirizine which is an antihistaminic drug, and a description of the structure, Biochemistry, and pharmacology, the layout, the rate of its absorption, distribution, and identification of the antihistaminic drug. Cetirizine is also a member of the class of piperazines, that is, piperazine, in which the hydrogen attached to the nitrogen is replaced by a (4-chlorophenyl) (phenyl)methyl 2-(carboxymethoxy)ethyl group, respectively. It has an significant role as an anti-allergic agent, an H1-receptor antagonist, environmental degradation, and a xenobiotic. It is a monocarboxylic acid, a member of the piperazines, as well as a member of the monochlorobenzenes, and in the air. Cetirizine Hydrochloride is a synthetic (man-phenylmethyl-piperazinyl derivatives, antihistaminic Cetirizine, a metabolite of hydroxyzine, more explicit for fringe histamine H1-receptor antagonist. It is used to treat the symptoms of seasonal and perennial allergic rhinitis and chronic urticaria (hives).

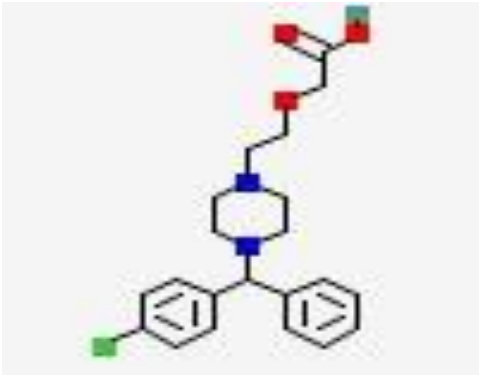
KYEWORDS: Antihistaminic drugs, validation, absorption, distribution, piperazine, cetirizine Hydrochloride.

INTRODUCTION

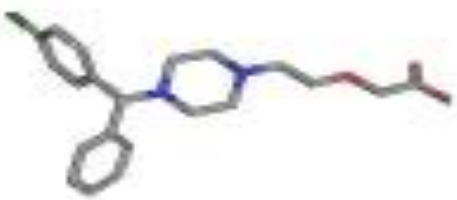
Cetirizine dihydrochloride (CTZ), a piperazine derivative and metabolite of hydroxyzine. It has been described as a long-acting, non-sedating antihistamine used for the relief of symptoms of allergic conditions such as rhinitis and chronic urticaria (hives). CTZ provides a fast-to-the-runny nose, itching of the nose or throat, and, as a result of respiratory allergy, urticaria (hives). In certain allergic conditions, it is important to co-prescribe a, CTZ, and with paracetamol (PCM), and in diseases such as allergic rhinitis, which antihistamines are the primary drugs should be used. (PCM), a para-aminophenol derivative, which has an analgesic, antipyretic and weak anti-inflammatory activity. The PCM is of the combination or co-administration of CTZ) is widely used as an anti-allergic and fever and for treating severe allergies, and the common cold . The vast majority of the post-cold medication containing the active ingredients, which has antipyretic, analgesic, antitussive agents, mucolytic agents, and anti-histamines, etc, etc., A new analytical issues raised by the development of a new drug, a form of classical surfactants.[1]

The literature survey reveals few analytical methods reported for the simultaneous determination of cetirizine HCl and a high-performance liquid chromatography (HPLC) with isocratic elution , with the passage of a high-performance, HIGH-performance liquid chromatography and capillary zone electrophoresis, HIGH-performance liquid chromatography , however, our detailed study shows that, up to now, no stability-indicating the isocratic high-performance liquid CHROMATOGRAPHIC method to determine which of the four ingredients together and are, therefore, an attempt was made to develop a simple, sensitive and validated, stability-indicating RP-HPLC method with UV detection to determine the CTZ in addition to its significant anti-microbial preservative in the dispensing of liquid forms and bodily fluids. This work describes the method development, method validation, forced degradation study of the ingredients. The application of the method has been validated for the assay of the drug in the body fluids of their studies. The results of the analysis have been validated according to International Conference on harmonisation (ICH), and the Association of Official Analytical Chemists (AOAC guidelines.[2]

STRUCTUR O CETIRIZINE



2D Structure



3D Structure

Drug profile

Molecular Formula	**C21H25ClN2O3**
Synonyms	Cetirizine, Cetirizin ,Cetirizina, Virlix
Molecular Weight	388.9

Biochemistry and Pharmacology

effects of respiratory effects, Cetirizine, the principal metabolite of the piperazine H1-receptor antagonist hydroxyzine, which will reduce or eliminate the symptoms of chronic idiopathic urticaria, perennial allergic rhinitis, seasonal allergic rhinitis, allergic asthma, physical urticaria, and atopic dermatitis. The clinical efficacy of cetirizine for allergic diseases in the respiratory tract have been observed in several studies [FDA label].The effects of the cups/anti-inflammatory effects and anti-inflammatory properties, which may play a role in asthma management . There is also evidence that cetirizine improves the symptoms of urticaria. Selected clinical inhibition of the wheal and flare reaction that occurs in infants, children, and adults alike, are all within a 20-minute oral dose and continues for 24 hours The concurrent use of cetirizine reduces the duration and the dose of the anti-inflammatory formulas that you can use for the treatment of atopic dermatitis.[3]

Pharmacological Classification

Histamine H1 Antagonists, Non-Sedating

For a class of non-sedating drugs that tight spot to yet don't activate the receptors of histamine (DRUG INVERSE AGONISM), thereby blocking the actions of histamine or histamine agonists. These antihistamines represent a heterogenous group of compounds with varying chemical structures, adverse effects, distribution and metabolism. In comparison with the beginning of the first-generation antihistamines, non-sedating antihistamines have greater receptor specificity, lower penetration of BLOOD-brain barrier (bbb), and are less likely to cause drowsiness or psychomotor impairment.[4]

The Anti-Allergic Agents

The funds are used for the treatment of allergic reactions. However, a large portion drugs act by preventing the release of inflammatory mediators or inhibiting actions of released mediators on their target cells.

The Absorption, Distribution, Metabolism, and Cetirizine

Absorption

Cetirizine was quickly absorbed with a time to maximum concentration (Tmax) of around 1 hour following oral administration of tablets or syrup formulation in adult volunteers . The bioavailability was found to be similar between the tablet and syrup dosage forms. Healthy study volunteers were given various doses of cetirizine (10 mg tablets once daily for 10 days), a mean peak plasma concentration (Cmax) of 311 ng/mL was measured . The effects of food on rate of absorption by Food, and there was no effect of cetirizine exposure (AUC) but Tmax was delayed by 1.7 hours and Cmax decreased by 23% in the fed state.[5]

Route of Elimination

At the primarily eliminated in the urine. Between 70% and 85% of an orally administered dose is found in the urine and 10 to 13% in the feces.

The volume of Distribution

The apparent volume of distribution: 0.44 +/- 0.19 (L/kg).

Approval

The obvious total body clearance is approximately 53 mL/min . Cetirizine is mainly eliminated by the kidneys. No dosage adjustment is necessary in patients with moderate-to-severe renal insufficiency and in patients who have the disease who are treated with dialysis.

Metabolism

A mass-balance approach in a clinical trial, and is made up of 6 healthy male study volunteers and found that 70% of the administered radioactivity was measured in the urine and 10% in the feces after cetirizine administration. For more than 50% of the radioactivity was measured in the urine as unchanged cetirizine. Most of the rapid increase in peak plasma radioactivity was associated with parent drug, which is one of the first-pass metabolism. This is in order to avoid potential drug-drug

interactions of cetirizine drug-drug interactions with hepatic cytochrome enzymes .Cetirizine is partly metabolized by oxidation, O-dealkylation to a metabolite with negligible antihistaminic activity. The enzyme or enzymes responsible for this step in the cetirizine and metabolism have not been identified.[6]

Pharmacokinetic parameters of hydroxyzine, and its dynamic metabolite, cetirizine, were dictated after oral and intravenous administration of 2 mg kg -1) of hydroxyzine, is a six healthy dogs. Plasma drug levels was determined by high-pressure liquid chromatography. Pharmacodynamic studies have evaluated the inhibitory effect of histamine and anticanine IgE-mediated cutaneous wheal formation. Pharmacokinetic and pharmacodynamic correlations were calculated using a computer model. The mean systemic availability of the oral hydroxyzine was 72%. Hydroxyzine, and was soon converted to cetirizine, regardless of the route of administration. The mean area under the curve was eight- and ten-fold higher for cetirizine than that of hydroxyzine, after intravenous and oral administration, respectively. After oral administration of hydroxyzine, and to ensure that the highest concentration of cetirizine was approximately 2.2 microg mL(-1), and hydroxyzine, 0.16 µg mL(-1). The Terminal half-life of cetirizine, 10 to 11 hr after intravenous and oral administration of hydroxyzine. A sigmoidal relationship of fit to the data, and comparing cetirizine plasma concentration of the wheal suppression.[7] The maximum inhibition (82% and 69% for histamine and anticanine IgE-mediated skin reactions, respectively, have been observed during the first 8 h, which was correlated with the plasma concentration of cetirizine, is a larger-than-1.5 µg mL(-1). Quantitative modeling suggests that the increase or hydroxyzine dosage or frequency of administration should not have the effect of histamine levels is better than that obtained by using a two-times-a-day, hydroxyzine 2 mg / kg. kg(-1). In conclusion, there was a rapid conversion of hydroxyzine, is that of cetirizine. The reduction in the wheal formation was almost entirely due to cetirizine. Pharmacodynamic modeling predicted that the maximum amount of antihistamine effect, this would be the perform of twice-daily oral administration of hydroxyzine 2 mg / kg. kg(-1).[8]

Formulation and Presentation of Cetirizine

Table: Cetirizine Hydrochloride Preparations.

Route	Dosages Form	Strength	Brand Name or Generic Name (Manufacturer)
Oral	Solution	5 mg/5 mL	Children's Zyrtec Hives Relief Syrup (McNeil); Children's Zyrtec Syrup (McNeil)
Oral	Tablets, chewable	5 mg	Children's Zyrtec Chewables (McNeil)
Oral	Tablets, chewable	10 mg	Children's Zyrtec Chewables (McNeil)
Oral	Tablets, film-coated	10 mg	Zyrtec (McNeil)

Identification

Analyte: ceterizine; lattice: blood (plasma), tissue (brain); procedure: high performance liquid chromatography with ultraviolet detection at 230 nm; limits of detection: 10 mg/mL (plasma), 15 ng/mL.

Analyte: ceterizine; matrix: urine; procedure: high performance liquid chromatography with ultraviolet recognition at 230 nm; limit of detection: 20 ng/mL.[9]

SPECTROPHOTOMETRIC METHOD

MATERIALS AND METHODS

A double beam UV- Visible spectrophotometer was used. Absorption spectra of both test and standard solutions were recorded over the frequency range of 200-400nm utilizing 1cm quartz cell. Cetirizine hydrochloride was supplied as gift sample, all other chemicals and reagents utilized were of analytical grade.[10]

Preparation of standard stock solution

Method 1.

Cetirizine hydrochloride, a stock solution was prepared by dissolving 40 mg of drug in 100 ml of methanol, and further dilution has been carried out in methanol in order to obtain the desired concentration.

Method 2.

Accurately weigh 50 mg of Cetirizine hydrochloride was transferred into a 100 ml volumetric flask and made up to 50 ml of distilled water was added to dissolve the drug and make up to the mark with distilled water in order to 500µg/ml for Cetirizine hydrochloride.

Method 3.

Accurately weigh 50 mg of Cetirizine hydrochloride was transferred into a 100 ml volumetric flask and made up, and the drug was dissolved in methanol(10 ml) and diluted to the mark with 0.1 N NaOH, in order to 500µg/ml for Cetirizine hydrochloride.

The detection of the Absorption Maxima

For the selection of analytical wavelength, the standard stock solution of Cetirizine hydrochloride is ready to be scanned in the range of from 200 to 400 nm in a 1 cm cell in a suitable solvent, of which a piece of land. The UV spectrum is obtained, which exhibits absorption maxima (λ max) at 238nm (method 1) and 230nm (method 2) & (3).

Preparation of sample solution

Method 1.

Cetirizine hydrochloride, the sample solution was prepared by dissolving the tablet is equivalent to 40 mg of each drug in 100 ml of methanol, and further dilution

has been carried out in order to achieve the desired concentration. Different dilutions of the stock standard solution was prepared to give a concentration of 80-90µg/ml. The amount of Cetirizine has been established on the basis of the calibration curve.[11]

Method 2.
A number of tablet powder equivalent to about 10 mg of Cetirizine hydrochloride was transferred into a 100 ml volumetric flask and made up to 60 ml of distilled water was added to dissolve the drug and the volume was made sufficient with distilled water. The solution was a mixed and filtered through whatmann filter paper No. 42. Of the sample, 5 ml of the solution was diluted to 25 ml with distilled water to obtain a final concentration of about 20µg/ml).

Method 3.
The tablets were weighed and ground into a fine powder, and the average weight was determined. An accurately weighed quantity of tablet powder equivalent to 25 mg of Cetirizine hydrochloride was dissolved in 25 ml of methanol with stirring, filtered, and diluted to 100 ml in a volumetric flask and made up with 0.1 N NaOH. Further dilution was carried out to obtain the desired concentration.

Absorption spectra of Cetirizine
Method 1
The calibration plot of Cetirizine HCl on the rate of absorption maximas, and the linearity was observed in concentration range of 2-20µg/ml for Cetirizine HCl. The co-efficient of correlation (R) was 0.999 for Cetirizine HCl is found in the optical properties. The high value of the correlation coefficient (R) shows a good linearity of the calibration curve of the drug.

According to the ICH guidelines, the method validation parameters studied at 238nm (Method 1), linearity, accuracy, precision, and assay of the drug. The Precision of the studies have been carried out in order to study during the day and interday variations of it in the comments. The instrumental precision of a study of the repeatability of the study. The low RSD values, as well as the LOD and LOQ values indicate that the method is precise and sensitive.[13] The optical properties of the data are given in table 1.

Method 2.
The method is discussed, and it provides you with a convenient and reliable tool for the quantitative determination of Cetirizine in a dose of the tablet formulation. The wavelength of maximum absorption of Cetirizine and 230nm were selected for quantitative analysis. According to the ICH guidelines, the method validation parameters checked were linearity, accuracy, precision, LOD, and LOQ.

The linearity of Cetirizine was observed in the concentration range of 12-60µg/ml and the correlation coefficient is always larger than that of 0.9988 to take the drug. A percentage of the label of Cetirizine hydrochloride tablet for analysis, it was found to be in the range of 98.99% -100.94%. The percent recovery of Cetirizine hydrochloride was found to be in the range of 99.38% by 100.64% with a standard deviation of indication of the accuracy of the date-and interday precision studies were carried out by means of analysis of tablet formulation. The percent RSD for the day and interday precision studies, the drug was well within the acceptable range (< 2%), LOD, and LOQ was found to be 2.95 µg/ml), and 8.94 g/ml for Cetirizine, respectively.[14] The optical properties of the data are shown in table 1.

Method 3.
The absorption maximum of 230(λmax) were selected for analysis on the ground in a 0.1 N NaOH. The linearity was observed in the range of 5-30µg/ml(r2=0.9988), and the amount of the drug was estimated by the proposed method agree well with the label claim. The proposed method has been validated. The precision and accuracy of the method was assessed by recovery studies carried out on 3 different levels. Recovery experiments indicated the absence of interference from, along with the additives. This method has been proven to be more accurate, as indicated by the repeatability, interday, intraday analysis, % RTSD is less than 2. The results showed no statistically significant difference between the operators, some of which suggest that the method developed, it was fine. The results of accuracy and precision to be displayed. All of the statistical data, it appears that the validity of the method, and it can also be used for the routine analysis of pharmaceutical formulation containing a single drug. The optical properties of the data are given in the table below.1.

Table 1.

Optical characteristics	Method 1	Method 2	Method 3
λmax(nm)	238	230	230
Beer- Lamberts law limit(µg/ml)	2-20	12-60	5-30
Regression equation(y=mx+c)	Y=0.032x+0.011		
Slope (m)	0.032	0.007	0.010
Intercept(c)	0.011	0.001	0.030
Correlation coefficient(R)	0.999	0.998	0.996
LOD(µg/ml)	0.457	2.95	2.86
LOQ(µg/ml)	1.386	8.94	8.92
Precision(/RSD)			
Repeatability	0.381	0.252,0.250	
Intraday	0.461	0.235,0.234	101.92
Interday	0.863	0.610,0.610	100.69

The aftereffects of SD and RSD and the recovery studies for Cetirizine HCl following method1, 2 and 3 are given in table 2 and 3 respectively.

Table 2.

Methods	Drug	Amt. of drug estimated (mg/tablet)	% label claim	SD	RSD
Method 1	CTZ	9.89	98.99	0.377	0.380
Method 2	CTZ	9.97	99.79	1.427	1.427
Method 3	CTZ	9.98	99.00	1.427	1.427

Table 3.

		Method 1		Method 2		Method 3	
Level of recovery	Amount of pure added(mg)CTZ	Amount of drug recovered CTZ	% Recovery	Amt.of drug recovered CTZ	% Recovery	Amt.of drug recoverd CTZ	% Recovery
80%	8.1	8.13	100.4	8.09	99.87	8.07	99.72
	8.1	8.13	100.4	8.09	99.87	8.08	99.54
	8.0	8.10	101.3	7.85	98.12	7.92	97.99
100%	10.1	10.17	100.7	10.09	99.90	10.00	99.89
	10.2	10.15	99.54	10.21	100.0	10.00	99.89
	10.0	10.13	101.3	10.02	100.2	10.02	100.2
120%	12.1	12.09	99.92	12.08	99.83	11.99	98.89
	12.1	12.11	100.1	11.93	98.59	11.08	98.50
	12.0	12.10	100.8	11.82	98.50	12.00	99.58
Mean % recovery			100.5		99.38		99.54
SD			0.615		0.781		0.754
RSD			0.615		0.781		0.754

High Performance Liquid Chromatography Method

A new, simple and rapid high-performance liquid chromatography (HPLC) method has been developed for the determination of cetirizine hydrochloride (CTZ) of the tablet in a CLC-ODS reversed-phase column (4.6 mm ×250 mm, 5 µm). Salicylic acid was used as an internal standard. A mixture of methanol and water (70:30with the pH 4 (adjusted with o-phosphoric acid) was used as the mobile phase. The eluents were detected at 231 nm. The coefficient of determination of the calibration curve of the CTZ and the salicylic acid in the cell-phasewere 0.9898 and 0.9925, respectively. The limit of detection of the CTZ was 4 µg ml-1. The proposed methodwas successfully applied for the stability of the CTZ. The CTZ was found to be stable, faster, status, temperature, and relative humidity for an additional six months of the year. This method can be applied for routine quality control and dosage form assay of the CTZ in the pharmaceutical preparations.[15]

A number of authors have reported the CTZ methods for detection in biological fluids and pharmaceutical formulations (Arayne et al., 2005; Si et al. In 2007, Kuchekar et al., In 2003, Azhagvuela, and Sekar, 2007; Maith99.38, 2010). Arayne et al. (2005) have developed a sensitive and rapid high-performance liquid

CHROMATOGRAPHIC method for the analysis of the CTZ, the use of hyoscine butyl bromide as an internal standard. Beer's law obeyed in the concentration range of 5 to 30 nm.ml-1. T, et al. (2007) have developed a simple, selective and sensitive high performance liquid chromatography with tandem mass spectrometry method for the determination of the plasma concentrations of pseudoephedrine and cetirizine in human beings. Kuchekar et al. (2003) found, in a high-performance liquid CHROMATOGRAPHIC method for the determination of the double-a mixture of pseudoephedrine hydrochloride of the CTZ. The chromatographic separation of the TABLE, FEX, and pacific time) were obtained on a Zorbax column (C8), with UV detection at 218 and 222 nm. The mobile phase consisted of a triethanolamine solution (0.5%, pH 4.5%), and methanol-acetonitrile (50:20:30 pm) and Sekar, et al. (2007) have developed a capillary zone electrophoresis method for the detachment and determination of cetirizine dihydrochloride, phenylpropanolamine hydrochloride and paracetamol in tablets. The LOQ of cetirizine, paracetamol and phenylpropanolamine hydrochloride was found to be 2.0, 2.0, and 4.0 g ml−1, respectively. Maithani et al. (2010) reported a highly selective method for the simultaneous determination of hydroxyzine and cetirizine in human serum. Haloperidol was used as an internal standard [16]. The linearity in the range of 0.025 to 2.00 mg ml -1 of hydroxyzine and cetirizine. However, some of these methods are simple and fast, as these methods is expensive and time-consuming procedures, such as the use of solid-phase extraction, using a mobile phase containing buffer, etc, etc. In this presentation, we report a simple, rapid assay with sufficient sensitivity for the quantification of the CTZ in the form of a brief period of time, and the use of a liquid-phase extraction, as well as the mobile phase, which does not have a buffer at all. The aim of the current study was to develop, optimize and validate a simple.[18]

Calibration of HPLC system

HIGH-performance liquid chromatography analysis was carried out with the help of the system, from a G1311A quaternary pump, a G1315B DAD detector, auto sampler Agilent Technologies 1200 series). A quaternary pump G 1311A) of Agilent Technologies, 1200 series, it was used for. The flow rate of the quaternary pump is switched on and by the time the water from the filtered and distilled water, at a temperature of 25 ± 2°C), at a flow rate of 1 ml min and the effluent was collected in a pre-calibrated in a 50-ml volumetric flask and made up. The amount of time needed to collect 50 ml of water was recorded with the help of a pre-set stop looking at. The accuracy of the flow; it is up to ±0.3%.The accuracy of the diode-array detector, and the detector was switched off from the rest of your gear, and a spectral scan of the holmium-per-chlorate solution is in a stopped-flow mode, has been achieved. 4% (m/v) solution of holmium oxide in a 1.4-M perchloric acid was used for this purpose. First, the flow cell with water, and it is the starting point has been adjusted to zero, between 200 nm and 400 nm, while in the case of a solution of holmium perchlorate was circulated through the system. Do a manual scan of the array, subject to the maximum of the absorption 241.0, 361.4, and the 536.0 nm) of torque. These values have been used for the allowed tolerance range. The tolerance is within 3 nm of the 240.1, 361.4, and the 536.0 nm) of torque. The length of the reproducibility of the results was within ± 0.1 nm.[19]

Method development

Standard

Standards of different concentrations of CTZ (to powder) were prepared in the mobile phase, consisting of methanol-water 70:30 ratio. 100 mg is the standard of CTZ was dissolved in 100 ml of mobile phase-prepare a 1 mg ml-1solution. This solution is further diluted to prepare solutions of different concentrations. The prepared standard solutions are to be scanned with the use of a UV/vis range (200-800 nm) of torque. The maximum withdrawal amount is set at 231 nm. The Standard solutions of concentrations ranging from 10 to 200 µg ml-1 were prepared. The absorbance of these solutions was measured, and a graph of concentration versus absorbance was plotted. BeersLambert the Law was regulated in accordance with this part.

Examples of the solution

An example of the solution of CTZ (tablets) have been prepared by the grinding of the 20 tablets with a smooth mortar. Then, with a certain amount of pills, powders, weighed in order to prepare a 1 mg ml-1 solution. Since then, the absorbance of the samples was observed by UV/Visible.[20]

Thin Layer Chromatography- Densitometrt Method

Materials and reagents

Cetirizine Dihydrochloride is working with the standard of Glochem Industries Ltd., In india, ethanol, methanol, chloroform, and ethyl acetate (Merck, Germany). The commercial tablets containing Cetirizine Dihydrochloride was obtained from a local pharmacy.

The preparation and processing of the drug tests, the Standard solution is to always be freshly prepared by dissolving 50 mg of the CTZ in 70% ethanol ad 25 ml). The Standard solution of the CTZ (2000 ppm) of each of the diluted solutions can be in the range of 200 to 800 ppm). For the preparation of the sample, out of a total of 20 tablets, which includes the CTZ, which are the active ingredients were weighed and finely powdered. A portion of the powder equivalent to 5 mg of CTZ was weighed accurately and transferred into a 10 ml volumetric flask and suspended in 5 ml of 70% ethanol. The flask was placed in an ultrasonic bath prior to the completion of a volume with the same solvent.[21]

Chromatographic condition

Planar chromatography was carried out through the detection of the sample's on precoated TLC silica gel GF

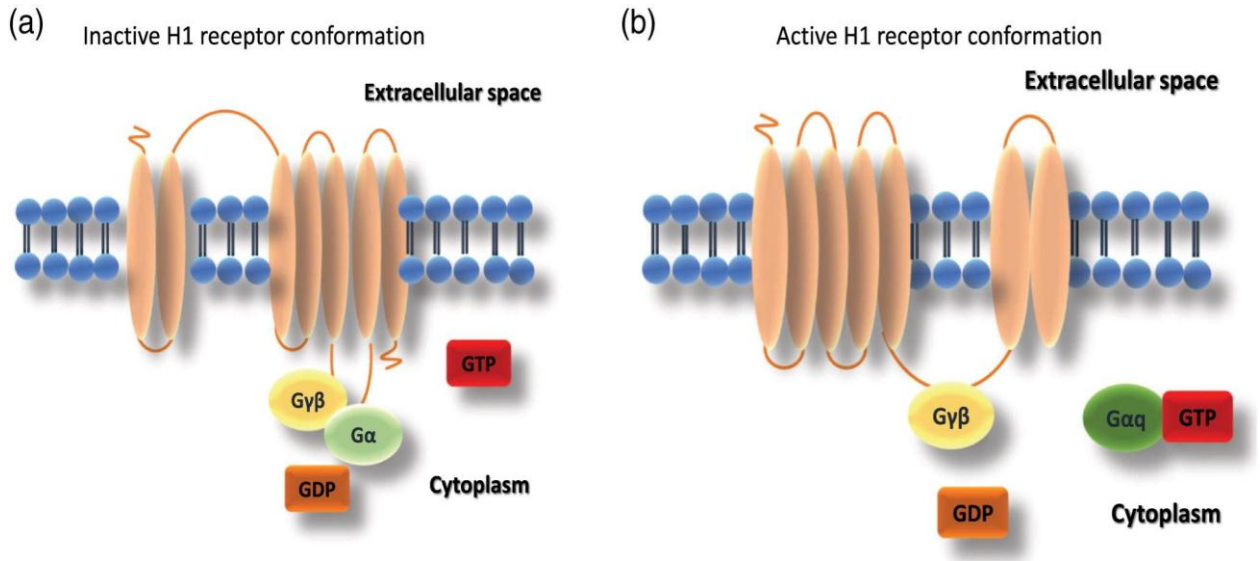
254 (20 x 10 cm), and 2.0 µl glass capillaries. In a Camag Twin Through Chamber with a mixture of chloroform: methanol : ethyl acetate (2 : 7 : 3) (v/v), and it was filled to capacity. The move, up to a distance of 9 cm. Densitometric scanning was performed on Camag TLC Scanner 3 in the absorbance mode at 234 nm for all measurements. The slit dimension was 6.00 mm x 0.30 mm), and a scanning speed of 20 mm/s was employed. Cetirizine Dihydrochloride was established by the Rf 0.49. A quantitative analysis was carried out using the peak areas of the WinCats softwarere.[22]

Analytical method validation

- Accuracy
- Precision
- Linearity
- Range
- Limit of Quantitation
- Limit of Detection
- Ruggedness
- Robostnes
- Specificity

Pharmacological blockade of histamine function via antihistamine

Antihistamines have been formed as a block of links at the action of histamine, which is to stabilize the inactive conformation of the heptahelical H1-receptors and cross-link. As a result of the differences in the chemical structure of the website, such as antihistamines, are subject to the H1 receptor is different to that of histamine-binding site and, therefore, antihistamines are classified as inverse agonists rather than the competitive antagonists, (. Both histamine and antihistamines act by a combination of stabilization, either in the active or non-active state, a change in the natural balance of the antihistamines.[25]



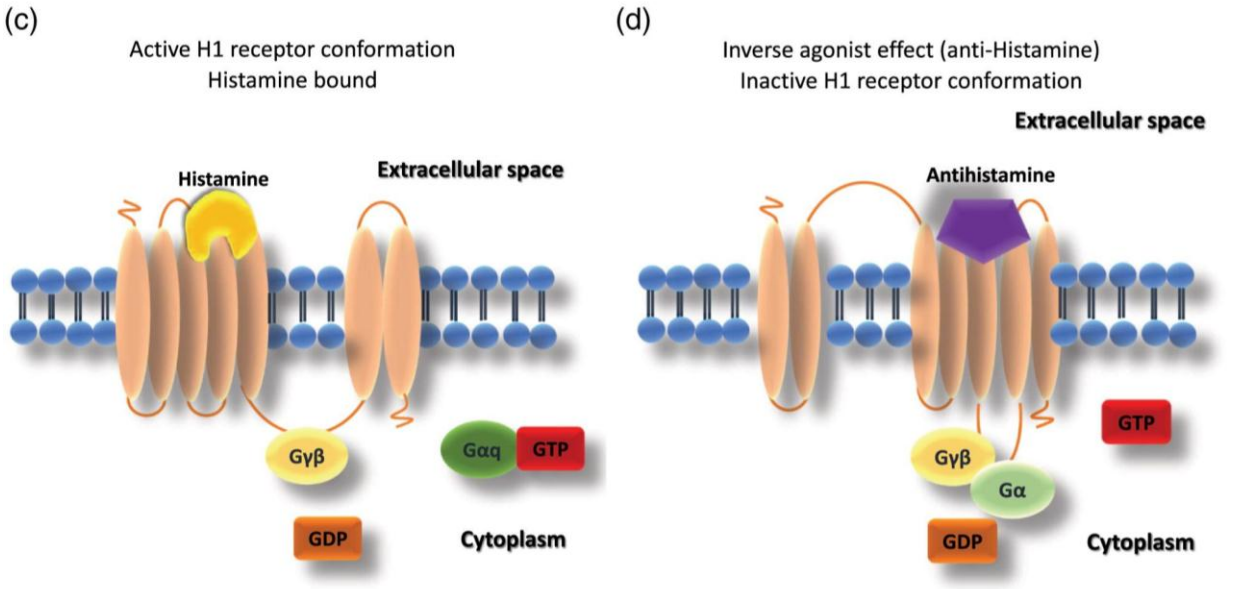


Fig: Structure and function of Receptors.

Method Validation

The method validation was carried out by following ICH and AOAC guidelines, according to the report, the verification process is carried out with the use of a variety of methods, such as the specificity, linearity, range, accuracy, intra-day and inter-day precision and system suitability, etc, etc., the Study of the linearity of the solutions were prepared from the stock solution and the B and B-to-the-view-of-the-box solutions in the range of from about 10% to 200%, or even more of the features of the content, and the products on the market. The Standard calibration curve was generated with the help of regression analysis. The specificity of the response in the form of a syrup, and the preparation was spiked into a pre-weighed amount of a drug, and the peak areas are measured and calculated in order to determine the amount of the drug, which has been re-established. The accuracy was carried out by means of the analysis of the corresponding standards, as well as the day-to-day basis, for a period of three consecutive days (Inter-day precision, or repeatability), and the three-times-a-day, with a time of 08 pm (Intra-day precision, or repeatability) of the freshly prepared standard solutions. In order to determine the accuracy of any of the reference standards were accurately weighed and added to the previously analyzed in a syrup of three different concentrations, i.e. 110%, 120%, 130% of the APIS. At each step, the samples were prepared in triplicate, and the recovery rate has been set.[27]

Limit of detection (LOD) and limit of quantification (LOQ) of the method is determined by the progressive dilution of the standard solutions and the reduction of its concentration in the range of 100 ng mL-1 and from 0.01 ng mL-1) was injected into the hplc system. The limit of detection (lod, defined as the concentration at which the signal-to-noise ratio of 3:1 was obtained for the assessment of the threshold, and the signal-to-noise ratio of 10:1 will be charged for it. The robustness was tested by the analysis of the same samples of the drink, as it's the result of deliberate variations in the method parameters, such as high-performance liquid chromatographic conditions such as mobile phase pH, flow rate, temperature, etc.). The system suitability of the method is evaluated by analyzing the symmetries of the standard peaks, screen resolution and theoretical plates of the column.[28]

CONCLUSION

The analysis shows that the method is a method that can be used for the purpose of study, cetirizine .There is a wide range of studies, including HIGH-performance liquid chromatography-UV/Vis-spectroscopy, and TLC-densitometry method, etc). The method has been developed for the identification and quantification of Cetirizine. The method was found to be simple, rapid, specific, sensitive, precise and accurate for the estimation, which can be easily used for routine quality control analysis of Cetirizine tablets.

ABBREVIATIONS

AOAC = Association of officials Analytical chemists
CTZ = Cetirizine
HPLC = High performance liquid chromatography
LOQ = limit of quantification
LOD = limit of detection
TLC = Thin layer chromatography

REFERENCES

1. Portnoy JM, Dinakar C: Review of cetirizine hydrochloride for the treatment of allergic disorders. Expert Opin Pharmacother, 2004 Jan; 5(1): 125-35. doi:10.1517/14656566.5.1.125. [PMID: 14680442].
2. Zhang L, Cheng L, Hong J: The clinical use of cetirizine in the treatment of allergic rhinitis. Pharmacology, 2013; 92(1-2): 14-25.

doi:10.1159/000351843. Epub 2013 Jul 18. [PMID: 23867423].
3. Wheatley LM, Togias A: Clinical practice. Allergic rhinitis. N Engl J Med, 2015 Jan 29; 372(5): 456-63. doi:10.1056/NEJMcp1412282. [PMID: 25629743].
4. Church MK, Church DS: Pharmacology of antihistamines. Indian J Dermatol, 2013 May; 58(3): 219-24. doi:10.4103/0019-5154.110832. [PMID: 23723474].
5. Spicak V, Dab I, Hulhoven R, Desager JP, Klanova M, de Longueville M, Harvengt C: Pharmacokinetics and pharmacodynamics of cetirizine in infants and toddlers. Clin Pharmacol Ther, 1997 Mar; 61(3): 325-30. doi:10.1016/S0009-9236(97)90165-X. [PMID: 9084458].
6. Sweetman SC (ed) (2011) Martindale, the complete drug reference, 37th edition. The Pharmaceutical Press, London.
7. British Pharmacopoeia (2013) vol II, The stationary office, electronic version, London, 305, 1227, 1099. Karakus S, Kucukguzel I, Kucukguzel SG (2008) Development and validation of rapid RP-HPLC method for the determination of Cetirizine or ferofenadine with psedoephedrine in binary pharmaceutical dosage form, J Pharm Biomed Anal 46.
8. Moncrieff J (1992) determination of Cetirizine in serum using reversed phase high performance liquid chromatography with ultraviolet spectrophotometric detection. J Chromatogr B, 583: 128-130.
9. Sunil K, Yogesh K, Abhizith K (2013) Simultaneous estimation of Cetirizine hydrochloride, Phenylpropanolamine hydrochloride and paracetimol by PR-HPLC method. Int.J Pharm life Sci (IJPLS), 4: 3122-3132.
10. Suryan AL, Bhusari VK, Rasal KS, Dhaneshwar SR (2011) Simultaneous determination quantitation and validation of paracetamol, phenylproponalamine hydrochloride and Cetirizine hydrochloride by RP-HPLC in bulk drug and formulation. Int. J Pharm Sci Drud Res, 3: 303-308.
11. Makhija SN and Vavia PR (2001) Stability indicating HPTLC method for the simultaneous determination of Pseudoephedrine and Cetirizine in pharmaceutical formulations. J Pharm Biomed Anal, 25: 663-667.
12. Azhagvuel S, and Sekar R (2007) method development and validation for the Simultaneous determination of cetirizine in pharamaceutical formulations. J Pharm Biomed Anal, 25: 663-667.
13. Wankhede S.B, Lad K.A and Chitlange S.S (2012) Development and validation for the simultaneous determination of cetirizine dihydrochloride, paracetamol, and phenylpropanolamine hydrochloride in tablets. Int J Pharm Sci Drug Res, 4: 222-226.
14. S. Gopalkrishan, T. A. Chithra, A. Aruna, and A. Chenthilnathan, "Development of RP-HPLC method for the simultaneous estimation of ambroxyl hydrochloride, Cetirizine hydrochloride and anti microbial presentation in combined dosage form. Der Pharma Chemical, 2012; 4(3): 1003-1015.
15. M. Maithani, R. Raturi, V. Gautham, D. Kumar, A. Garurav, and R. Singh, "Simultaneous estimation of ambroxyl hydrochloride and Cetirizine hydrochloride in tablet dosage form by Rp-HPLC method; International Journal of Comprehensive Pharmacy, 2010; 2(3): 1-3.
16. T.P. kumar, M.A. Haque, K.P, Kumar, G. Nevedita, and V.P. Dewan, "Simultaneous determination of cetirizine dosage form by using RP-HPLC method, American Journal of Pharm Tech Research, 2012; 2(6): 716-723.
17. M.G. Raja, G. Geetha, A. Sankaranarayan, K.M.G. raju, and P.S, Kumar, "Simultaneous and stability indicating method for determination of Cetirizine hydrochloride and ambroxyl hydrochloride in syrup. International Journal of Pharmaceutical Sciences and Research, 2012; 3(8): 2658-2668.
18. N.M. Bhatia, S.K. Ganbavale, M.S. Bhtia, H.N. More, and S.V. Kokil, "RP-HPLC and spectroscopic estimation of ambroxyl hydrochloride and cetirizine hydrochloride in combined dosage form, Indian Journal of Pharmaceutical Sciences, 2008; 70(5): 603-608.
19. B.A. Patel, S.G. Patel, D.P. Patel, and M.M. Patel, "stability indicating HPTLC method development and validation for estimation of ambroxyl hydrochloride and cetirizine hydrochloride in combine tablet dosage form, International Research Journal of Pharmacy, 2011; 2(3): 95-99.
20. P. Arora, V. Arora, and S. Jain, "Simulataneous estimation of cetirizine dihydrochloride formulation by a novel HPLC method, International Journal of Pharmaceutical Sciences and Research, 2012; 2(12): 3149-3151.
21. P. Venkateshwari, G.V.S., Kumar, S.B. Puranic et al.," Development of stability. Indicating RP-HPLC method for simultaneous estimation of ambroxyl hydrochloride and cetirizine hydrochloride". International Journal of Advances in Pharmaceutical Analysis, 2012; 2(2): 34-40.
22. Berajdar AS, Meyyanathan RB, Kreshanaveni N. Simultaneous estimation of ambroxyl hydrochloride and cetirizine hydrochloride in combine dosage form. Indian Journal of Pharmari, 2008; 4: 411-421.
23. Laxshman P.S, Shirwainkar AA. Shirwaikar A.K., Simultaneous UV Spectrophotometric determination of ambroxyl hydrochloride and Levocetirizine di hydrochloride. Indian Journal of Pharmari, 2008; 70(2): 236-238.
24. Tejaswini tonde et, al., Simultaneous estimation of Cetirizine hydrochloride and phenylephrine hydrochloride in tablet dosage form by RP-HPLC. International Journal of Biomedical and Advance Research, 2017; 8(12): 465-472.
25. Bhatia NG, More H.S. Spectrophotometric estimation of Ambroxol and Cetirizine hydrochloride in tablets. Asian Journal of Pharmaceuticals, 2008; 76(3): 45-47.

26. Drozd. J, Hopkala H, Mesztal G, Paw. B. Applications of derivative UV-spectrophotometry for the determination of cetirizine dihydrochloride in preparations, Acta poloniac Pharmaceutical Drug research, 2002.
27. Anonymous. Three new non-sedative antihistamines; worth keeping an eye open for. Drug Ther Bull, 1990; 28: 38-40.
28. Spencer CM, Faulds D and Peters DH. Cetirizine: a reappraisal of its pharmacological properties and therapeutic use in selected allergic disorders. Drugs, 1993; 46: 1055-80.
29. Barnes CL, Mckenzie CA, Webster KD and Poinsett- Holmes K. Cetirizine: a new, nonsedating antihistamine. Ann. Pharmacother, 1993; 27: 464-70.