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Original Article

UV spectrophotometric assay of Ceterizine formulations and their comparative study

Safila Naveed[1*], Fatima Qamar[1], Ghulam Sarwar[1], Khan Usmanghani[1,2] and Muhammad Tanweer Alam[1,3]

[1]Faculty of Pharmacy of Pharmacy, Jinnah University for Women, Karachi, Pakistan
[2]Herbion Pakistan (Pvt.) Ltd., Karachi, Pakistan
[3]Drug Regularity Authority of Pakistan, Government of Pakistan, Karachi
*Corresponding Author: Safila Naveed

Abstract

A rapid, simple, accurate, and economical least time consuming spectrophotometric method has been developed for the assay of ceterizine and then compare assay of brand available in Pakistan. The assay is based on the ultraviolet UV absorbance maxima at about 229 nm wavelength of ceterizine using methanol as solvent. A sample of drug was dissolved in methanol to produce a solution containing ceterizine. Similarly, a sample of ground tablets of different brand were extracted with methanol and diluted with the same methanol. The absorbance of sample preparation was measured at 229 nm against the solvent blank and the assay was determined by comparing with the absorbance of available brand. The method can be applied for the routine QC quantitation of ceterizine in tablet formulation and active.

Keywords— ceterizine, assay, UV pectrophotometry

Introduction:

Cetirizine is the fourth addition to a new generation of allergy medication called “non sedating” antihistamine. These new antihistamines are classified as non-sedating agents because they cause less sedation than their predecessors . Cetirizine displays a series of advantages over its predecessors as it is free of both sedative and cholinergic effects and has potent antiallergic activity. However, it is more sedating than the other non-sedating antihistamine. Cetirizine was among those drugs which were widely prescribed in Europe for allergy before it was introduced in America.

Cetirizine dihydrochloride (fig 1) (RS)-2-[2-[4-[(4-chlorophenyl)phenyl methyl)]piperazin-1-yl]ethoxy]acetic acid dihydrochloride, dried substance is primarily acid metabolite of hydroxyzine resulting from complete oxidation of primary alcohol moiety. It is available as a crystalline powder that is soluble in water and insoluble in acetone and in methylene chloride[1].

There are are different methods have been reported for determination of cetirizine in drug, blood and serum by using colorimeter and fluorimetric [2,3].Some UV methods also reported for determination of ceterizine these methods were based on chloroform complexed formation between cetirizine with bromocresol purple (BCP) or bromophenol blue (BPB). The system obeyed Beers Law for BCP & BPB [4-5] In another method roxatidine was employed as the internal standard for quantification of cetirizine and the internal standard (IS) [6].

But there is no simple method reported like this using single methanol.Our research group has done this type of assay for different drugs.[7-14]

EXPERIMENTAL

Ultra Violet visible 1601 Shimadzu double beam spectrophotometer was used for the analysis of spectra. The solvent used for the assay was simple analytical grade methanol.

Wavelength Selection

About 100 ppm of cetirizine solution was accurately prepared in methanol . This active standard solutions was scanned in the UV region 200-400 nm. The wavelength maxima (λmax) was observed at 229 nm and this wavelength was used for absorbance measurement.

Standard Stock solution

Accurately weighed 10 mg of cetirizine standard was transferred to a volumetric flask and add sufficient water to produce 100 ml this is 100 ppm in 100 ml.

Sample Preparation

The four different brands of ceterizine Zyrtec, zanlan , ronex and sedil belong to pharma AGP, Novartis,Hilton and Sami pharmaceuticals were purchased from different medical store of Karachi,Pakistan. Each brands of ceterizine tablets have same batch number and were labeled to conatin ceterizine 10mg per tablet. All the four brands have 5 year shelf life.

20 tablets of four different brands (Zyrtec, zanlan , ronex and sedil) from the marketed sample were weighed and crushed uniformly with the help of a mortar and pestle. By calculating the average weighed sample powder equivalent to 10 mg of ceterizine was transferred into a volumetric flask containing 10mL water. The solutions were sonicated for about 5 min and than make up volume upto 100 ml with water.

PROCEDURE

After preparation of standard and tablet solutions, strength of solution 100 ppm in 100 ml absorbance of the sample preparation and standard preparation in 1cm cell at the wavelength of maximum

absorbance at about 229nm, using a spectrophotometer, using the blank solution. Calculate the quantity in mg, of ceterizine per tablet.

RESULTS AND DISCUSSION:

Pharmaceutical assay of ceterizine was carried out by using UV spectrophotometer . Table-1 shows regression equations of different brands of ceterizine.Four different brands of ceterizine Zyrtec, zanlan , ronex and sedil is taken and their solutions of 100ppm, 50ppm, 25,12.5ppm and6.25 ppm prepared for linearity study. Their percent assay is calculated and regression equation is obtained to predict further availability of drug. For linearity study I have prepared solutions of 100ppm, 50ppm, 25,12.5ppm and6.25 ppm and three absorbances were taken. Figure 2 shows percent assay of different brands and figure 3-6 shows linearity of different brands at level 100ppm, 50ppm, 25,12.5ppm and 6.25 ppm. Correlation coefficient was found 1.00 for zyrtec and zanlan and 0.99 for ronex and sedil. According to guideline it should not be less than 0.99 and results of all brands squared correlation coefficient found within the limit.

CONCLUSION

Linear relationship was observed for different brands of ceterizine zyrtec, zanlan , ronex and sedil in the concentration ranges of 100, 50, 25,12.5 and 6.25 ppm with correlation co efficient < 2. The correlation coefficient 1.00 for zyrtec and zanlan and 0.99 for ronex and sedil was found.

Table 1:% Regression equations of different brands of ceterizine

Brand Name	**Regression equations**	R2
Zyrtec	y = 0.0261x - 0.005	1
Zanlan	y = 0.0261x - 0.005	1
Ronex	y = 0.0262x - 0.0125	0.99
Sedil	y = 0.0263x - 0.0154	0.99

Table 2:% assay of different brands of ceterizine brands

Brand Name	**Average wt of tablet mg**	**Wt for 100 ppm**	**Absorbance at 229 nm**	**% assay**
Zyrtec	11.5	11.5	2.62	100.383
Zanlan	18	18	2.62	100.383
Ronex	16.8	16.8	2.61	100
Sedil	10.1	10.1	2.61	100

Table 3:Descriptives of different brands

ASSAY

	N	Mean	Std. Deviation	Std. Error	95% Confidence Interval for Mean		Minimum	Maximum
					Lower Bound	Upper Bound		
Zyrtec	3	100.2967	.00577	.00333	100.2823	100.3110	100.29	100.30
Zanlan	3	100.2967	.00577	.00333	100.2823	100.3110	100.29	100.30
Ronex	3	99.9333	.05774	.03333	99.7899	100.0768	99.90	100.00
Sedil	3	99.9667	.05774	.03333	99.8232	100.1101	99.90	100.00
Total	12	100.1233	.18480	.05335	100.0059	100.2408	99.90	100.30

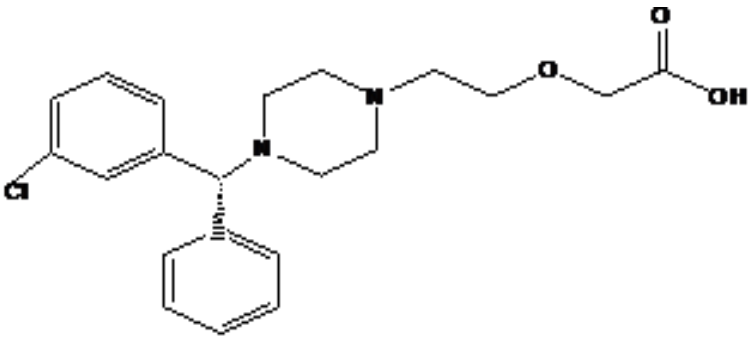

Figure 1:Structure of ceterizine

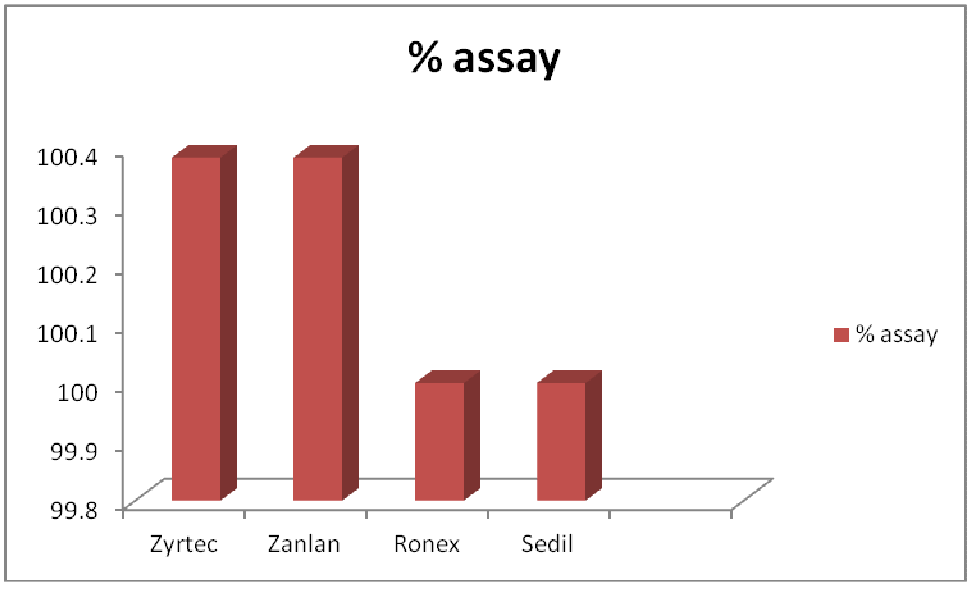

Figure 2:% assay of different brands

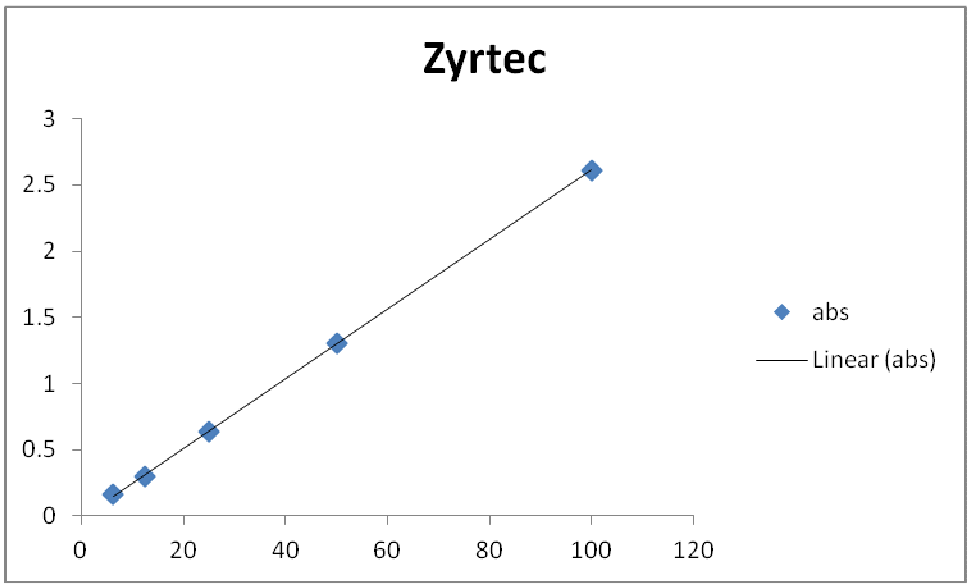

Figure 3:Linerity of Zyrtec

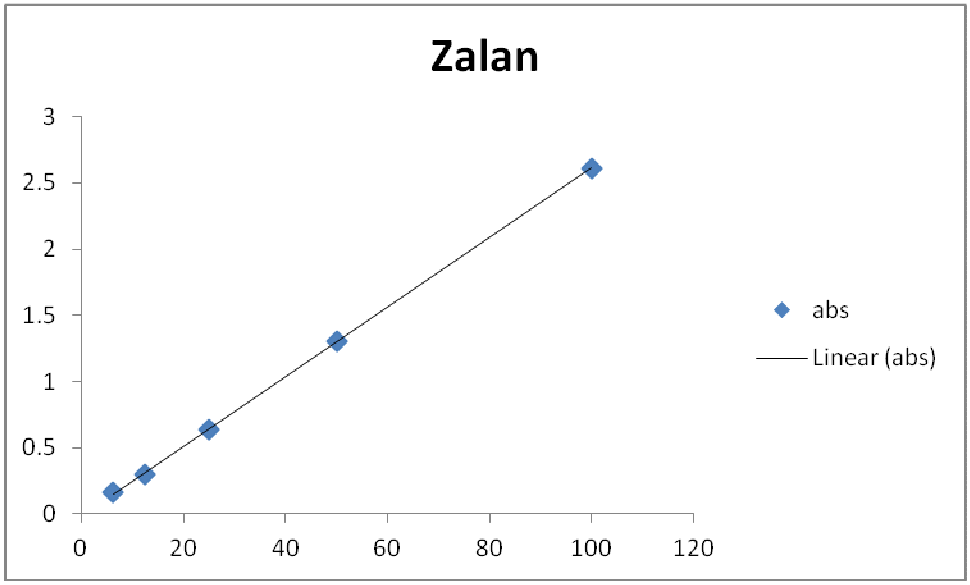

Figure 4:Linerity of Zalan

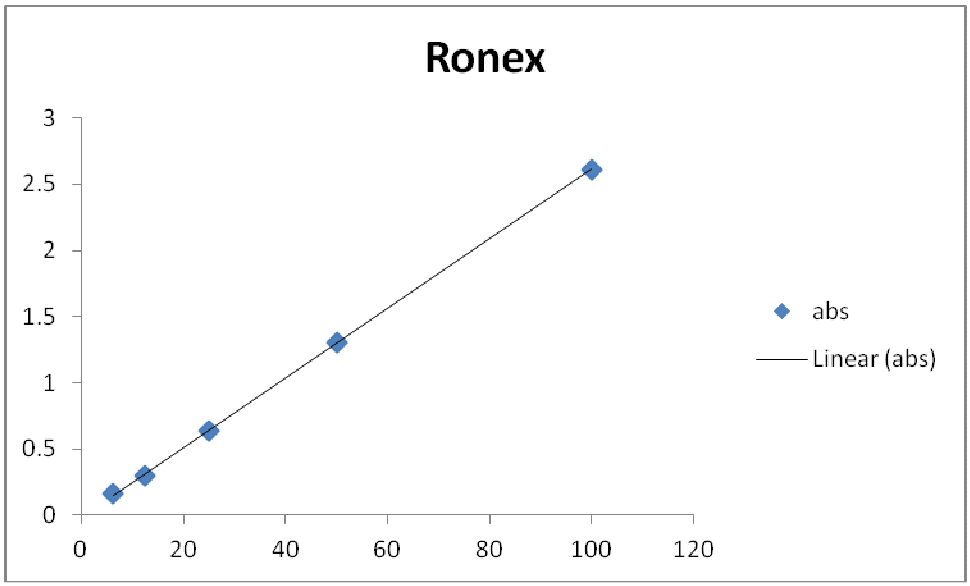

Figure 5:Linerity of Ronex

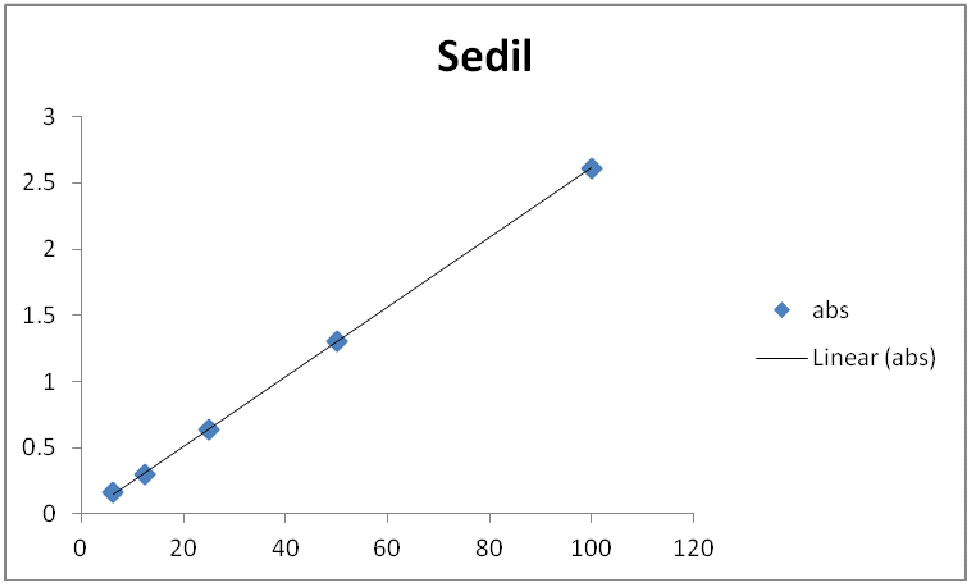

Figure 6:Linerity of Sedil

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