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**RESEARCH ARTICLE**

# COMPARATIVE *IN-VITRO* EVALUATION OF DIFFERENT MARKETED FORMULATIONS OF CETIRIZINE HCL TABLETS (10MG) AVAILABLE IN LOCAL MARKET

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**ABSTRACT**

Five Indian brands (coded as A, B, C, D, E) of 10 mg cetirizine hydrochloride (CTZ) tablets were evaluated for various *in-vitro* parameters, i.e. size and shape, uniformity of weight, hardness, friability, disintegration time and dissolution profile. The hardness of all the brands was found to be in the range of 4.2-4.4 kg, while friability was less than 1 %. The disintegration time of all brands were found to be in the range of 52 sec to 9 min 21 sec. All brands comply with the I.P weight variation tests while brands A, B, C, D and E comply with the I.P dissolution test. Formulation additives in the tablet, physical form of the drug used in the tablet and manufacturing process vary from manufacturer to manufacturer, responsible for the variation in the observed dissolution profiles. The main purpose of the study was to minimize health risk factors while maximizing the safety of the people of Lucknow to maintain and improve their health. The study is concerned to investigate and compare the physicochemical equivalence and efficacy of different brands of tablets containing Cetirizine prepared by various pharmaceutical industries under different trade names.



## INTRODUCTION

Cetirizine hydrochloride (CTZ), chemically [2-[4-[(4-chlorophenyl) phenyl methyl] -1-piperazinyl] ethoxy] acetic acid (Fig. 1), belongs to the group of second generations antagonists of H1-receptors, inhibits the allergic reaction mediated by histamine. It is a non-sedative antihistamine, used in the treatment of seasonal rhinitis, hay fever, running nose, control sneezing of allergic origin. The tablet is defined as a compressed solid dosage form containing medicaments with or without occupants. According to the Indian Pharmacopoeia pharmaceutical tablets are solid, flat or biconvex dishes, unit dosage form, prepared by compressing a drug or a mixture of drugs, with or without diluents. They vary in shape and differ greatly in size and weight, depending on amount of medicinal substances and the intended mode of administration. It is the most popular dosage form and 70% of the total medicines are dispensed in the form of tablet. All medicaments are available in the tablet form, except where it is difficult to formulate or administer (The Indian Pharmacopoeia, Government of India, Ministry of health and family welfare, Controller of publication, 2007).

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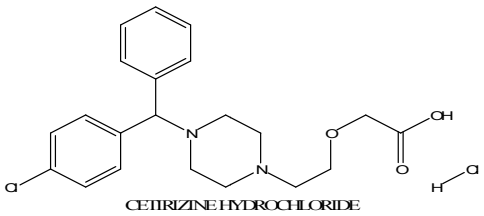


**Fig. 1. Chemical structure of cetirizine HCL**

## MATERIALS AND METHODS

### Instrumentation

For the analysis of cetirizine hydrochloride (CTZ), content in their dosage form a Lab India UV-3200 double beam spectrophotometer is utilized. Spectrophotometer system was integrated via Labindia model to PIII computer loaded with UV-Vis analyst software for data acquisition and mathematical calculations. Analytical balance, dissolution test apparatus, disintegration test apparatus, sonicator, pH meter and micropipette.

### Materials and reagents

Reference cetirizine hydrochloride (CTZ) was a kind gift sample from pharmaceutical industry. Five different brands of

cetirizine HCl were obtained from different retail pharmacies of Lucknow (India) market. Distilled water was prepared freshly to prepare different dilution.

**Spectrophotometric condition**

Baseline was adjusted to zero by using blank solvent (buffer solution). Standard and test sample was analyzed (the result is based on three average readings).

**Physiochemical parameters**

**Uniformity of thickness**

Thickness of tablet can vary without any change in its weight because of differences in the density of the granulation and the pressure applied to the tablets as well as speed of tablet compression. The thickness variation limits allowed were ± 5% of the size of the (Table 1) (Remington: The science and practice of pharmacy. Mack publishing company, 2005)

**Length and diameter**

Introduced a standard for tablet diameter to reduce patient confusion over generic equipment's. The stated diameter can deviate by + 5% up to 12.5 mm and by + 3% above 15mm (British Pharmacopoeia, licensing division HMSO, London stationary office, 2010)

**Hardness**

Hardness of cetirizine HCl tablets was determined by using a Pfizer hardness tester. This tester operates on the same principle as that of a pair of pliers. The force required to break the tablet was measured in kilograms and oral tablets normally have a hardness of 4 to 10kg/cm$^2$. The average hardness of tablets was calculated and reported (Table 1) (Aulton, 2007)

**Friability test**

Friability of cetirizine HCl tablets was determined by using Roche Friability tester (Veego, VFT-2D), Number of tablets to the combined effects of abrasions and shock by utilizing a plastic chamber that revolves at 25 rpm, for 10 revolutions and the percent friability of each brand of tablets is calculated and reported (Table 1).

**Uniformity of weight**

20 units selected at random were weighed individually in electronic balance (Essae, DS-852G), the average weight and maximum percentage deviation was calculated (Table 1) (Aulton, 2007)

**Disintegration**

Disintegration is required to break up tablets, capsules and granules into primary powder particles in order to increase the surface area of the drugs exposed to gastrointestinal fluids. The disintegration test was carried out by using Electro lab (ED2SAPO) disintegrator. A 1000 ml beaker was filled with buffer solution (approx. 900ml), equilibrated to 37±0.5ºC temparature. Six tablets from each brand were subjected to the test. The time required for the last tablet to disintegrate was recorded (Ansel *et al.,* 2009).

**Drug content**

Drug content was calculated as per the procedure described in I.P. The solution was filtered through a 0.45µm nylon disc filter and was analyzed for drug content by measuring UV absorbance at 230 nm on UV-visible spectrophotometer (Lab India UV-3200). Every unit of tablet should contain the amount of drug substance equivalent to its label amount. For the evaluation of content, assay should be performed. The results of the assay of the chemical content of cetirizine HCl tablets (Table 1) showed that the active content of all the brands was between 90% and 110% of the labeled amount specified for cetirizine HCl.

**Table 1. *in vitro* parameters of various brands of cetirizine HCl tablets**

| Parameters (Unit) | Acceptable limits (I.P) | Brand Name (Manufacturer) | | | | |
|---|---|---|---|---|---|---|
| | | Cetcip (A) (Cipla) | Cetri-10 (B) (Ikon) | CTZ (C) (Syncom) | Cetzine(D) (GSK) | CETZ(E) (Synthiko) |
| Size (Diameter, mm) | _ _ _ _ | 10.17±0.014 | 10.326±0.015 | 10.72±0.022 | 10.164±0.017 | 10.316±0.005 |
| Size (Thickness, mm) | _ _ _ _ | 2.656±0.069 | 2.646±0.021 | 3.214±0.005 | 2.850±0.010 | 2.938±0.008 |
| Uniformity of weight (mg, n=20) | 1% | 0.122±2.78 | 0.120±2.34 | 0.157±2.09 | 0.115±0.970 | 0.147±1.710 |
| Friability (% of core tablet) | Not more than 1% | 0.418±0.004 | 0.421±0.003 | 0.31±0.002 | 0.424±0.002 | 0.685±0.003 |
| Hardness (Kg/cm$^2$, n=10) | _ _ _ _ | 3.50±0.35 | 4.20±0.27 | 3.70±0.27 | 3.662±0.141 | 3.383±0.095 |
| Disintegration Time (min) | Less than 15 min | 4.95±0.40 | 9.21±1.03 | 0.52±0.015 | 4.405±0.280 | 2.268±0.487 |
| Dissolution test | N.L.T 75% ( 30 min) | 100.5±2.160 | 82.45±3.201 | 78.58±2.848 | 100.58±1.894 | 87.89±1.976 |
| Assay | N.L.T 95.0% - N.M.T100.5% | 99.83±0.43 | 97.24±2.10 | 95.30±1.26 | 98.88±0.81 | 96.88±2.78 |

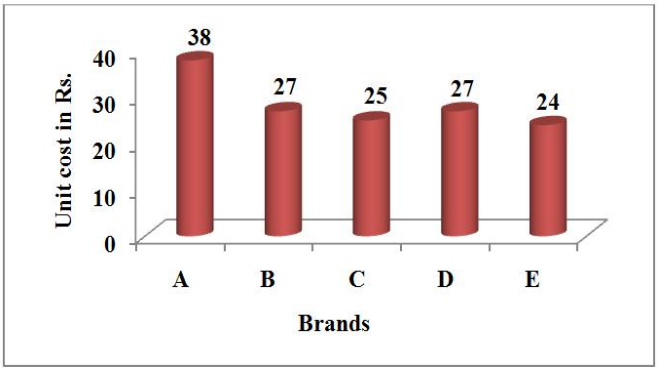


**Fig. 2. Price fluctuation among different brands of cetirizine HCl tablets**

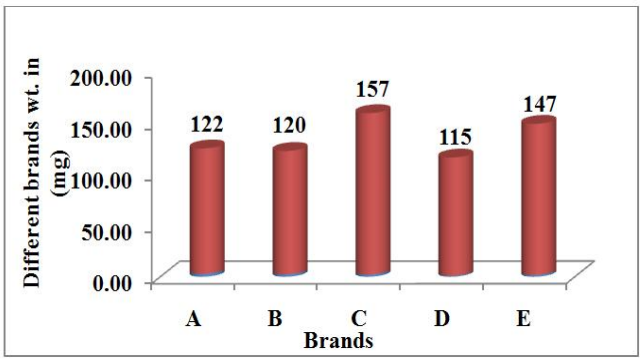


**Fig. 3. Weight difference in different brands of cetirizine HCl tablets**

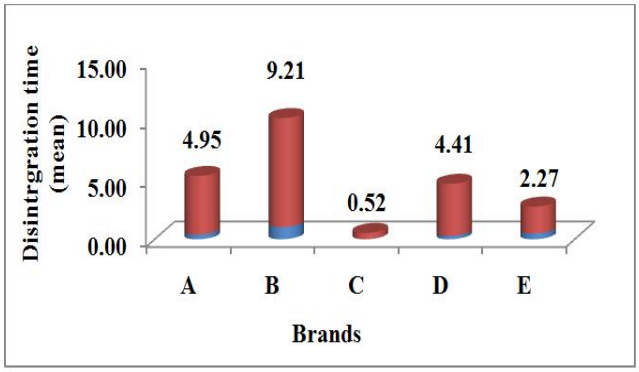


**Fig. 4. Mean disintegration time for different brands of Cetirizine HCl tablets**

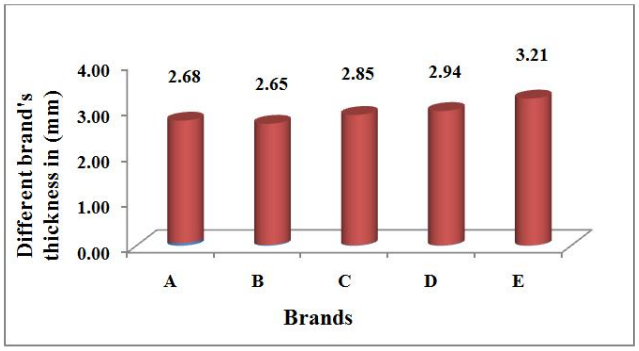


**Fig. 5. Mean thickness for different brands of Cetirizine HCl tablets**

**Table 2. Optical characteristics of cetirizine HCl**

| Optical Characteristics | Cetirizine hydrochloride |
|---|---|
| Wavelength (nm) | 230 |
| Beer Lambert's law limit (µg/ml) | 2-20 |
| Regression equation (y=mx+c) | y = 0.032x + 0.006 |
| Slop (m) | 0.032 |
| Intercept (c) | 0.006 |
| Correlation coefficient ($R^2$) | $R^2$ = 0.999 |

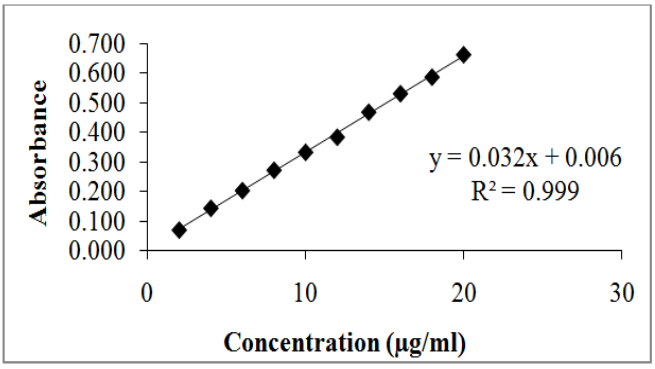


**Fig. 6. Standard calibration curve of cetirizine HCl at 238 nm in 0.1 N HCl solutions**

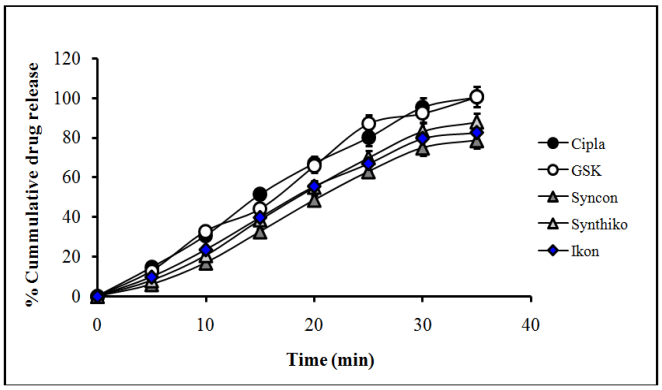


**Fig. 7. Percent drug release of different brands of cetirizine HCl tablets in 0.1 N HCl solution**

The results indicated that although different manufacturer formulates the different brands by different methods of formulation but all are under the I.P specification (The Indian Pharmacopoeia, Government of India, Ministry of health and family welfare, Controller of publication, 2007).

## Dissolution

*In vitro* dissolution studies of tablet formulations were performed in 900 ml of dissolution medium, 0.1 M hydrochloric acid using an Apparatus No. 1 (I.P), dissolution rate test apparatus (Electro lab, TDT 08L) at a speed of 100 rpm for 45 minutes with the temperature of 37±1°C are used in each test. A 5ml aliquot was withdrawn at different time intervals and filtered using a 0.45µm nylon disc filter; each sample was replaced with 5 ml of fresh dissolution medium. The filtered samples were suitably diluted, if necessary, and assayed by measuring the absorbance at 230 nm for cetirizine HCl. UV detection at 230 nm based on the peak

height ratios, Beer's law was obeyed in a concentration range of 2-20 µg/ml and the regression line equation was derived with a correlation coefficient of 0.999 (Table 1, Fig. 6). Drug not less than 75 per cent of the stated amount of $C_{21}H2_5C_lN_2O_3.2HCl$ (The Indian Pharmacopoeia, Government of India, Ministry of health and family welfare, Controller of publication, 2007; United States Pharmacopeia, United States Pharmacopeia / National Formulary (USP25/NF20, 2002).

## RESULTS

The assessment included the evaluation of physical parameters i.e. weight variation, thickness, hardness, friability, disintegration time, as well as dissolution test. All brands showed the general appearance as white color. All brands had capsule shape. All the brands exhibited good hardness strength, required for safe handling and transportation. The hardness was found to be in the range of 3.4-4.2 kg (Table 1). All brands had friability of less than 1%, brand A, B, C, D, and E had friability respectively 0.41%, 0.42%, 0.31%, 0.42, and 0.68. All brands had acceptable limits of friability and hardness, showing good mechanical strengths (Table 1). The content of cetirizine in each tablet brands complies as described in I.P.

## DISCUSSION

All the brands of tablet passed the weight variation test as prescribed by I.P. All brands of tablets passed the I.P disintegration time indicating that they would rapidly disintegrate in gastrointestinal tract fluid on oral administration. However, there was large variation in disintegration time from brand to brand. Formulation C showed a minimum disintegration time of only 52 Sec while formulation B showed maximum disintegration time of 9 min and 21 Sec (Table 1). Brands A, B, C, D and E fulfill the I.P dissolution test (Table 1).

**Conclusion**

Pharmaceutical quality control and quality assurance depend on monitoring the composition and uniformity of the drug substance during processing and in the final product. Compendia tests have traditionally been used to determine identity, strength, quality, and purity. Implementation of these approaches can reduce the time and cost required for manufacturing, while improving quality control.

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