

Comparative Analysis of Four Brands of Levocetirizine Tablets Available in Karachi, Pakistan

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ABSTRACT

The basic purpose to prepare any drug is to increase quality of life; therefore, different quality control tests have been performed to achieve the desired outcome. One of the most frequently used dosage form is tablet which requires different techniques to prepare his study is aimed to examine the comparison in formulation of oral dosage form of Levocetirizine tablets available in the local pharmaceutical market of Karachi, Pakistan. It is a selective H₁ antagonist used as anti-allergy and it is available in many brands in retail pharmacies of Karachi. The sample tablets of four different brands of Levocetirizine were analyzed. The analysis includes weight variation, hardness test, friability test, disintegration and dissolution tests as well as U.V. absorbance is also checked. All the four brands of the tablets are successfully analyzed in BP/USP standards for average variation in weight, hardness, disintegration, friability and dissolution tests.

The study reveals that all four brands of Levocetirizine HCL marketed in Karachi meet BP/USP requirements for the quality specification.

Keywords: Levocetirizine, Comparison, Analysis.

INTRODUCTION

Levocetirizine is an active enantiomer of Cetirizine, a second generation H₁ receptor antagonist. It is used in treatment of different allergies, pruritus, rhinitis, nasal congestion and asthma^{1,2}. It has low chance of CNS toxicity because of inability to pass over the blood brain barrier and has non-sedating effect. It is pharmacodynamically and pharmacokinetically more effective than Cetirizine because of rapid absorption, limited distribution and high first pass metabolism. Its clinical trials also indicates that it is also helpful in treating chronic urticaria. Levocetirizine do not block the histamine released from the mast cells, but blocks its attaching to its receptor's sites. As a result, allergy producing chemicals and higher supply of blood in the specific part of the body is stopped, it also provides relieve in hay fever³.

According to USP, Levocetirizine Hydrochloride is available in powder form. It is white or nearest to white in color and highly soluble in water⁴. The aim of this study is to analyze the uniform quality of different Levocetirizine HCL tablet brands available in Karachi. Evaluation of characteristics of these drugs in term of their quality will provide an ease in selection of better brand of particular

medicine. Different tests are performed in order to optimize their therapeutic effect. These techniques are written in literature to progress in formulations of tablet^{3,5}.

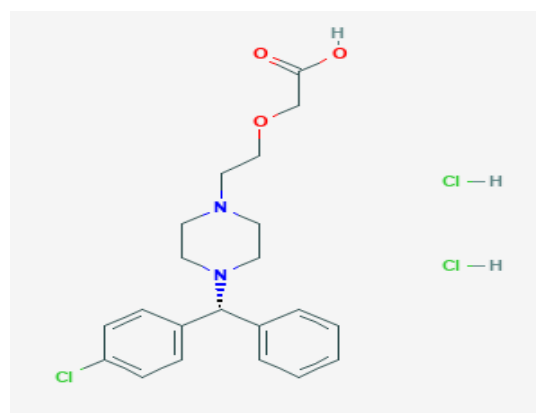


Figure 1. Structure of Levocetirizine.

METHODOLOGY

A comparative study of physicochemical properties is conducted in Faculty of Pharmacy, Jinnah University for Women (JUW), Karachi. From local market, four different tablet brands of Levocetirizine HCL are obtained and tests are performed to analyze average weight hardness, friability, disintegration test dissolution test^{3,6}. The brands are T-DAY, Lixer, Belair and Leozin.

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Table 1. List of brand names and their code.

Brand Name	Marketed by	Code No.	Batch No.	Retail Price/10 Tablets (Rs.)
T-DAY	GlaxoSmithKline OTC PVT.LTD	LCTZ1	JKWJ	172.00
Lixer	Hilton Pharma (PVT) Limited	LCTZ2	B9341	68.99
Belair	Bayer Health Care	LCTZ3	KH05903	60.00
Leozin	Barrett Hodgson Pakistan (PVT) LTD	LCTZ4	125381	63.25

Weight variation and average weight

Table 2. Average weight of tablet allowed.

Average weight of tablet (mg)	% Difference allowed
130 or less than	± 10
130-324	± 7.5
More than 324	± 5

This test explains that each tablet of all the batches have same weight within deviation written in USP/BP. All tablets in the batch should be uniform in weight. To perform the test for average weight ten individual tablets selected and each tablet was weighed by using Electronic Balance FX-400. Weight of each tablet is noted on sheet and average weight is calculated. Weight variation was calculated by comparing each individual tablet weight with average weight in order to verify their weight is within the reported values.

Hardness Test

It is the strength require for a tablet to withstand the breakage during the manufacturing or packaging of any tablet. According to USP/BP required hardness of tablet should not be less than 4kg. A tablet must have sufficient hardness to tolerate pressure.

10 tablets of each brand selected is place one by one to check hardness using manual hardness tester. Average hardness evaluated and then compared with other brands.

Thickness Test

Thickness of 10 tablets of each selected brand of Levocetirizine is determined by using Vernier calipers. Each tablet is placed one by one between the jaws of vernier calipers. Readings are noted in mm.

Friability Test

This test is performed to analyze the tendency of a tablet from effects of physical factors. Weight of ten tablets per brand is taken and then loaded in friabilator which revolves at 25 revolutions per minute. The tablets were rotated for 4 minutes. Tablets were removed from friabilator and again weighed. The loss in weight specifies the friability of the tablet. USP/BP limit is not more than 1%.

Disintegration Test

Purpose of this test is to verify disintegration time of the tablets or capsules within the standard time when placed in a liquid medium. Disintegration Tester was Curro DS-0702.

From each brand, six tablets taken and placed in the basket rack assembly of six tubes hanging in 900 ml beaker at 37°C and a small disc is placed on each tablet. Disintegration time is noted when no particle if found in mesh and then compared with other brands.

Dissolution Test

It is a standard method to calculate the extent and rate of formation of a solution of drug constituent from a dosage form in specified condition. It determines the physiological availability of drug. Dissolution test was carried out on GDT-7L of Galvano Scientific apparatus to carried out the test we take four beakers each containing 900 ml water which is used as medium_at 37°C at 100 rpm for 60 minutes. One tablet of each brand is placed in individual beaker and tested on the apparatus.

The sample was manually drawn from each beaker carrying the formulation and filtered with a time period of 15 min i.e., 15, 30, 45, 60, 75, 90, 105 minutes. Absorbance of each sample was measured at 231nm by UV spectrophotometer and the amount of Levocetirizine is calculated in the sample.

Price Variation Study

Retail Price of each tablet is noted and compared with other marketed tablets. Price of LCTZ1 is more as compared to other three brands. While other three brands price are approximately same.

RESULTS AND DISCUSSION

In this study we evaluate physicochemical property of four brands of third generation H1 receptor antagonist marketed in Karachi. As allergic conditions such as rhinitis, urticaria are much common in the city due to pollution and change in climatic condition, as a result people need an effective H1 antagonist⁷. Levocetirizine which is a third generation H1 antagonist is an isomer of Cetirizine and more frequently prescribed in allergy due to its less sedative action on brain. Four brands of Levocetirizine HCL are purchased from a local pharmacy of Karachi. Physicochemical analysis of Levocetirizine hcl of 5mg in tablet dosage form of four different brands are as follows.

In BP/USP official limits for weight variation of each tablet should be $\pm 7.5\%$ (w/w) Table 3.1 shows that weight variation of all brands is within accepted limits.

Hardness of 10 tablets from the four different levocetirizine brands is given in table 3.1 with acceptable upper and lower limits. According to USP/BP hardness of a tablet should be between 4 to 7kg. The calculations for hardness of four different brands of Levocetirizine Hcl tablets are within the official range. Mean, Standard deviation, upper & lower control limits of thickness for the tablets of different brands are in table. Range of deviation in thickness is within $\pm 7.5\%$ which is acceptable in tablet manufacturing shown in table 3.1. Friability of Levocetirizine tablets was less than 1%. According to the BP/USP it is in the permissible range given in Table 3.2 All four brands compete the limit i.e. each of the four tablets disintegrate in less than 15 min 7.4 to 9.1 min, therefore all four brands disintegrate at official limit shown in Table 3.2 Dissolution test is very important in order to evaluate the drug bioavailability. All four brands dissolve within an hour and absorbance is 0.564 to 0.529 in Table 3.3.

Table 3.1. Weight variation, hardness and thickness.

Code no	Weight variation gm Mean ($\pm$ SD)	Hardness kg Mean ($\pm$ SD)	thickness mm Mean ($\pm$ SD)	Deviation from BP/USP
LCTZ01	0.1263(0.00073)	4.065(0.3334)	3.2611(0.05159)	All passed
LCTZ02	0.1304(0.00052)	4.119(0.3099)	3.071(.04408)	All passed
LCTZ03	0.1012(0.00070)	4.057(0.26077)	3.248(0.16356)	All passed
LCTZ04	0.1171(0.00093)	4.108 (0.1712)	3.433(0.13977)	All passed

Table 3.2. Disintegration and friability test.

Serial number	Code Number	Disintegration Time(min)	Friability (%)	Remarks
1	LCTZ 01	7.4	0.15	Pass
2	LCTZ02	8.11	0.12	Pass
3	LCTZ 03	9.1	0.7	Pass
4	LCTZ 04	8.9	0.31	Pass
Official Limit		NMT 15min	Not more than 1%	

Table 3.3. Dissolution test.

Brand Name	Absorbance (λ)							
	0 min	15 min	30 min	45 min	60 min	75 min	90min	105min
LCTZ01	0.00	0.561	0.589	0.578	0.593	0.555	0.568	0.571
LCTZ02	0.00	0.594	0.612	0.58	0.588	0.552	0.565	0.55
LCTZ03	0.00	0.584	0.555	0.546	0.548	0.556	0.557	0.534
LCTZ04	0.00	0.568	0.541	0.54	0.578	0.605	0.552	0.529

CONCLUSION

The outcome of the study is that all four brands of Levocetirizine HCL fulfilling the official quality control requirements of a tablet which are tested for weight, hardness, thickness, disintegration and dissolution. Therefore, the tablets can be exchanged regardless of price.

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