WORLD JOURNAL OF PHARMACEUTICAL RESEARCH
SJIF Impact Factor 8.453
Volume 13, Issue 24, 1009-1022. Research Article ISSN 2277–7105

EVALUATION AND DRUG STABILITY STUDIES SOME LEVOCETIRIZINE TABLETS BRANDS AVAILABLE IN SANA'A MARKET YEMEN

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Article Received on
05 November 2024,

Revised on 26 Nov. 2024,
Accepted on 15 Dec. 2024

DOI: 10.20959/wjpr202424-35045

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ABSTRACT

Levocetirizine hydrochloride (LCZ) is an orally administered drug used as anti-histaminic with almost no sedation. The analysis done can conveniently give a general survey of different brands of levocetirizine hydrochloride tablets where the difference in parameters tested can relate to difference in the bioavailability of drugs. Quality of tablets should fulfill certain specifications. The aim, to analysis and evaluate various pharmaceutical parameter, such as thickness, diameter, hardness, weight variation, disintegration, and dissolution, of different brands of Levocetirizine hydrochloride tablets available in the local market. According to the BP the result show that all brand pass weight variation. In diameter test all brand tablets were pass except Lazine. Thickness of all brand tablets were pass except Levar, Scohist, Levozin and Vapi mast. Hardness of all brand tablets were pass except Lazine, Scohist, Cetrizal and Vapi mast. Friability of all brand uncoated tablets were pass. Disintegration of all brand tablets were pass according to the BP. It was concluded that there are all brands tablets it evaluated according to (USP) and (BP) specifications by use different parameters mainly in dissolution test Scohist has the best result followed by Levozin > L-cetgen > Lecet > Xyex > Lazine > Vapi mast > Xaltec >

Cetrizal > Utilev > Levar. Assay test results for all the brands doses not reached satisfactory limit expect, Lazine, Scohist and Xyex brands., which reached more than 90% of the drug.

KEYWORDS: Levocetirizine hydrochloride, Tablets, Anti-histaminic, Quality control**.**

INTRODUCTION

Levocetirizine is a non-sedative third-generation antihistamine indicated for the relief of symptoms affiliated with seasonal and perennial allergic rhinitis along with uncomplicated chronic idiopathic urticarial skin manifestations. It was approved Food and Drug Administration on May 25, 2007, and marketed by Sanofi-Aventis.[1]

The common side effects of LCZ include sleepiness, dry mouth, cough, vomiting, and diarrhea.[2] In pregnancy appears safe and when breastfeeding is of unclear safety.[3] Levocetirizine is used for allergic rhinitis.[4]

Cardiac safety with repolarization may be better than some other antihistamines, as levocetirizine does not significantly prolong the QT interval in healthy individuals.[5,6]

Many tests are frequently applied to tablet dosage forms to render their optimum therapeutic effects. The technique of optimization is well reported in the literature for the development of tablet formulations.[7,8]

This experiment was performed to evaluate and compare the dissolution pattern of commercially available different local brands of levocetirizine 2HCL tablets available in Sana'a.

The purpose of our experiments was to carry out the best possible formulation from a pharmaceutical as well as consumer point of view, include (weight uniformity and content uniformity test), (dissolution test), (hardness and friability test), (visual observation, weight variation, thickness and diameter of the tablet) The formulation of a tablet is thus designed so that the final tablet has all these essential properties as well as being stable.[9]

An important variable in any tablet system is the rate at which the drug substance dissolves; for many solid dosage forms, disintegration precedes drug dissolution. Hence, the proper choice of disintegrants and their consistency of performance are of critical importance to the formulation development of such tablets.[10]

The drug stability studies are important in all stages of pharmaceutical manufacturing, marketing, or post-marketing follow up because the drug stability is the basis for the effectiveness and safety of drug and to ensure that its bioavailability reach the site of action. Studying the factors that affect the validity of drug stability is part of the drug development stage and pharmaceutical innovations in manufacturing. Good medicine and advanced drug delivery systems. Drug stability is required preformulation, formulation, evaluation studies, in the marketing and clinical use stage. Formulation scientist from his experience and knowledge have to significantly in the stability study stage and is an important factor in the ADDS (Advanced Drug Delivery Systems) product development process and bioavailability.[11-50]

OBJECTIVES

The objective of the present study was to evaluate the different brands of Levocetirizine tablets available in Sana'a, Yemen market.

MATERIALS AND METHODS

Materials

Different brands of levocetirizine hydrochloride were used in the study and were purchased from the local market. The brands analyzed include, Utilev (Swiss Garnier, India), Lazine (Hetero healthcare, India), Levar (Al Taqaddom, Jordan), Scohist (Scot Edil, India), Levozin (Modern pharma, Yemen), Cetrizal (Y.E. Pharma, Yemen), Xaltec (Borg, Egypt), L-Cetgen (Genom Biotech, India), Xyex (Shiba Pharma, Yemen), Lecet (Ambix Healthcare, India), Vapi Mast (Vapi care Pharma, India), as shown in Table 1.

Various pharmaceutical parameters were employed as in USP 31 (2008), i.e., thickness, hardness, weight variation, friability, disintegration, and dissolution, to test the different brands of levocetirizine hydrochloride tablets available.

Table 1: General Table of Different Brands of Levocetirizine Collected from Sana'a Market Yemen.

Trade Name	Batch No	Company	Country	MFD Date	EXP Date
Utilev	11TUV002	Swiss Garnier	India	12/2019	1/2022
Lazine	E190899I	Hetero healthcare	India	…….	03/2022
Levar	19201	Al Taqaddom	Jordan	11/2019	11/2023
Scohist	XT9C030	Scott Edil	India	03/2019	03/2022
Levozin	191320	Modern Pharma	Yemen	11/2019	11/2022

Cetrizal	19089	Y.E. Pharma	Yemen	02/2019	02/2022
Xaltec	045044	Borg	Egypt	03/2020	03/2024
L-Cetgen	8M010	Genom Biotech	India	12/2018	11/2021
Xyex	19257	Shiba Pharma	Yemen	03/2019	03/2022
Lecet	AT-18164	Ambix Healthcare	India	01/2019	12/2021
Vapi Mast	YM80801	Vapi Care Pharma	India	08/2018	07/2021

Equipment

Analytical balance (Electronic balance type BL-220H, Shimadzu corporation Japan), thickness & diameter tester G.T. Tools micrometer Japan., hardness tester Ptb111e (Erweka GmbH, Germany), disintegration test apparatus (Digital tablet disintegration test apparatus), friability tester (Veego, India), dissolution Spectrophotometer tester (Veego, India).

METHODOLOGY

Organoleptic Properties

Appearance of different brands of Levocetirizine collected from Sana'a market Yemen, were shown in Table 2.[2]

Weight Variation Test[51]

The weight of tablets is routinely evaluated to ensure the proper amount of the drug in the tablet. An analytical balance (Electronic Balance type BL-220H, Shimadzu Corporation Japan) was used for proper weighing of individual tablets mean ± S.D. of each brand of Levocetirizine hydrochloride was calculated.

Thickness Test[51]

(G.T. Tools Micrometer Japan) were used to determine the thickness of 20 tablets. Table 3, shows mean ± S.D. of each brand tested.

Diameter Test[51]

(G.T. Tools micrometer Japan) were used to determine the diameter of 20 tablets. Table 3, show the mean ± S.D. of each brand tested.

Hardness Test[51]

Hardness of the tablet is affected by the degree of the pressure applied during the compression stage. It is an important criterion since it can affect disintegration and dissolution. A hardness tester (YPJ-200A Manual hardness tester. Minhua pharmaceutical

machinery Co., Limited, China) in which 20 tablets were measured randomly. Table 3, show the mean ± S.D. of each brand calculated.

Friability Test[51]

As shown in Table 3, 20 tablets were taken randomly and placed on a sieve. Loose dust was removed with the aid of a soft brush. Tablet samples were weighed accurately and placed in the friabilator (VEEGO, INDIA). After 100 rotations/4 min., loose dust was removed from the tablets and finally, the tablets were reweighed. The loss in weight indicates the ability of the tablets to withstand this type of wear. Mean ± SD were calculated.

Disintegration Test[51]

Disintegration time was observed for 10 tablets using a disintegration apparatus (Digital tablet disintegration test apparatus) Mean ± SD were calculated, as in Table 3.

Dissolution Test[52-54]

Dissolution studies were conducted using a USP apparatus II, paddle type with 50 rpm at 37°±1C. For standard preparation, about 10 mg of Levocetirizine hydrochloride was placed in a 100 ml volumetric flask and dissolved with 0.1 M hydrochloric acid and then the volume was made up to 100 ml with 0.1 M hydrochloric acid. 2 ml of this solution was transferred to another 100 ml volumetric flask and diluted to 100 ml with the same solvent. For the sample, about 900 ml of 0.1 ml HCl was placed in the dissolution bowl with one tablet and the apparatus was started. The sample was drawn at time intervals of 10, 15 and 30 minutes for each formulation. Absorbance of the sample preparation and that of standard were taken at 220 nm using a 0.1 M hydrochloric acid solution as a blank. Drug concentrations were measured spectrophotometrically. (VEEGO, INDIA) was used. The result was shown in Table 3, and mean ± SD were calculated.

Assay Test[55]

Twenty tablets were weighed and pulverized. The amount of tablet powder equivalent to 35.7 mg of LCZ was transferred into a 100 mL volumetric flask. The content was shaken well with about 50 mL of water for 20 min and diluted to the mark with water. It was filtered using Whitman No. 42 filter paper. First 10 mL portion of the filtrate was discarded. Twenty milliliters of the tablet extract (lg ml^{-1}) were diluted to 300ml quantitatively transferred to a separating funnel, pH was raised by adding 5.0 mL of 1.0 M NaOH and the content was mixed well. The Levocetirizine base was extracted with three 20 ml portions of

dichloromethane, the extract was passed over anhydrous sodium sulphate and collected in 100 ml volumetric flask, the volume was made up to mark with dichloromethane and the resulting solution (lg ml^{-1} LCZ) was used in method C and diluted to 30 and 40ml (lg ml^{-1} LCZ) for method A, method B, respectively, and used for the assay. The result was shown in Table 3, and mean ± SD were calculated.

RESULTS AND DISCUSSION

Results

As shown in Table 3. Weight variation of LCZ of all brand tablets was pass according to the BP., thickness of LCZ of all brand tablets were pass except Levar, Scohist, Levozin and Vapi brands mast according to the BP., diameter of LCZ of all brand tablets were pass except Lazine according to the BP., hardness of LCZ of all brand tablets were pass except Lazine, Scohist, Cetrizal and Vapi mast according to the BP., friability of LCZ of all brand uncoated tablets were pass according to the BP., disintegration of LCZ of all brand tablets were pass according to the BP., dissolution of LCZ of all brand tablets were pass Lazine(80.30%), Scohist (100%), Levozin (94.79%), L-cetgen (86.28%), Xyex (83.27%), Lecet (85.87%) except Utilev (66.54%), Levar(60.22%), Cetrizal (67.29%), Xaltec (75.46%) and Vapi mast (77.70)% according to the BP.

The assay of LCZ of all brand tablets were not pass Utilev (80.42%), Levar (79.82%), Levozin (89.32%), Xaltec (88.72%), L-cetgen (84.56%), Lecet (81.60%), Vapi mast (75.37%) except Lazine (92.88%), Scohist (100%) and Xyex (94.88%) according to the BP., while Cetrizal brands show higher concentration (124.33%).

The results of the assessment of various pharmaceutical parameters of Levocetirizine hydrochloride brands are shown in Tables 3. The data provides the view that these formulations, though having Levocetirizine hydrochloride as their active ingredient, show different behavior within specification limits after their analyses. Among the brands tested, Scohist showed best results while the other tablets had nearly marginal differences between them.

DISCUSSION

In this study, eleven different brands of Levocetirizine hydrochloride, i.e. Utilev, Lazine, Levar, Scohist, Levozin, Cetrizal, Xaltec, L-cetgen, Xyex, Lecet and Vapi mast were analyzed. The results of the Levocetirizine hydrochloride brands show that differences are

present during the manufacture of these products, i.e., excipients, speed of machine, etc. The variation of the weight of individual tablets is a valid indication of the corresponding variation in the drug content.[56]

The results have shown that weight variation of the tablets is within specified limits. The prepared tablets had satisfactory hardness, diameter & thickness for Utilev, Levar, Levozin, Xaltec, L-cetgen, Xyex and Lecet. However, Scohist, Cetrizal and Vapi mast had not reached satisfactory result.

Moreover, Lazine have no satisfactory hardness, diameter & thickness. Friability is another mechanical property of a tablet with a compendial specification not more than 1%.

The tablets showed satisfactory friability test results. The rate of disintegration is directly proportional to the rate of dissolution. Disintegration is evaluated to ensure that the drug substance is fully available for dissolution and absorption from the gastrointestinal tract.[57] All tablets disintegrated rapidly (less than 8 minutes) except Lazine and Levar which show 11.59 and 11.43 min. as in USP disintegration test.[58]

Out of the 11 brands studied, L-cetgen tablets disintegrated much more rapidly than the other brands in 0.29 min and this could be attributed to the relatively lower hardness of the tablets.

Dissolution test results revealed that Schist showed the highest dissolution rate, whereas Levar gave the lowest. Nearly all the brands had a little satisfactory dissolution rate. It can be concluded that, on the basis of the results shown, Scohist would be considered to be the product having the best priorities.

Results of the dissolution profile showed that, tested brands, Lazine, Levozin, L-cetgen, Xyex and Lecet, release more than 80% of the drug within 45 min. Assay test results for all the brands doses not reached satisfactory limit expect, Lazine, Scohist and Xyex brands., which release more than 90% of the drug. The results revealed that Scohist showed the highest dissolution rate whereas Vapi mast gave the lowest. Nearly all the brands had a little satisfactory drug content rate. It can be concluded that, on the basis of the results shown, Scohist would be considered to be the product having the best priorities. Calculations were done using Scohist as the reference brand since it complies to Pharmacopeia specifications, while the other brands comply to local specifications.

Table 2: Organoleptic Appearance of Different Brands of Levocetirizine Dihydrochloride Collected from Sana'a Market Yemen.

Tarde Name	Type of Tablet	Color	Shape	Odor
Utilev	Film-coated Tablet	Approved Colors	Circular	Odorless
Lazine	Film-coated Tablet	White	Circular	Odorless
Levar	Film-coated Tablet	White	Circular	Odorless
Scohist	Film-coated Tablet	Approved Colors	Circular	Odorless
Levozin	Film-coated Tablet	White	Circular	Odorless
Cetrizal	Film-coated Tablet	White	Oval	Odorless
Xaltec	Uncoated Tablet	White	Circular	Odorless
L-cetgen	Film-coated Tablet	Titanium Dioxide	Circular	Odorless
Xyex	Uncoated Tablet	White	Oval	Odorless
Lecet	Uncoated Tablet	White	Circular	Odorless
Vapi mast	Film-coated Tablet	Titanium Dioxide	Circular	Odorless

Table 3: Assessment of Physical Parameters of Various Formulations of Levocetirizine Hydrochloride Tablets.

Formulation	Average Weight mg (±SD)	Hardness (N) mean± (S.D.)	Thickness (mm) mean± (S.D.)	Diameter (mm) mean± (S.D.)	Friability Test %	Disintegration Test min	Dissolution Test %	Assay Test %
Utilev	168 ±7.45	98.75 ±8.56	3.43 ±0.07	8.12 ±0.02	0.75	5.10	66.54	80.42
Lazine	104 ±1.27	115.25 ± 11.52	3.44 ±0.02	6.34 ±0.34	0.72	11.59	80.30	92.88
Levar	105 ±1.63	103.5 ±17.32	3.38 ±0.29	6.57 ±0.13	0.64	11.43	60.22	79.82
Scohist	193 ±2.90	139.5 ±13.17	3.21 ±0.04	8.33 ±0.02	0.41	3.44	100	100
Levozin	160± 2.88	76.25± 12.34	3.34± 0.26	7.38± 0.08	0.11	3.21	94.79	89.32
Cetrizal	113± 2.43	98.5± 11.48	3.23± 0.02	5.64± 0.23	0.56	7.15	67.29	124.33
Xaltec	179± 3.07	100.25± 10.57	4.18± 0.01	7.64± 0.07	0.28	3.26	75.46	88.72
L-cetgen	187± 4.54	65 ± 8.73	3.37± 0.10	8.26± 0.21	0.71	0.29	86.25	84.56
Xyex	127± 4.70	98.5± 8.29	3.27± 0.04	5.18± 0.01	0.79	6.22	83.27	94.65

Lecet	294± 6.80	62± 7.32	4.37± 0.05	9.44± 0.12	0.17	1.03	85.87	81.60
Vapi mast	112± 2.04	113.75± 9.98	3.57± 0.22	6.44± 0.01	0.24	3.48	77.70	75.37

CONCLUSION

Quality control of Levocetirizine tablets is essential to determine the quality of brands. The drugs have been arranged according to the USP and BP quality control from the best to the lowest, as the following: Scohist > Levozin > L-cetgen > Lecet > Xyex > Lazine > Vapi mast > Xaltec > Cetrizal > Utilev > Levar. It was concluded that there are some brands tablets does not comply to (USP) and (BP) specifications in evaluation parameters. While assay test results for all the brands doses not reached satisfactory limit expect, Lazine, Scohist and Xyex brands., which reached more than 90% of the drug.

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