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RESEARCH ARTICLE

THE EVALUATION OF SOME BRANDS OF LEVOCETIRIZINE DIHYDROCHLORIDE FILM-COATED TABLETS FOR QUALITY AND EQUIVALENCE SOLD IN ADEN, YEMEN

Sana Saleh Al-Kubati[1,*], Olfat Saleh Ahmed[1], Randa Mohammed Saif[1]

[1] *Dept. of Pharmaceutics, Faculty of Pharmacy, Aden University, Aden, Yemen*

***Corresponding author: Sana Saleh Al-Kubati; E-mail: ss.alkubati@pharm.adenuniv.com**

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Abstract

Generic drugs are less expensive than innovator drugs, and their proliferation has become a problem in low-income countries. They need to be therapeutically and pharmaceutically equivalent to the innovator. Levocetirizine dihydrochloride is an effective drug for relieving the signs of chronic urticaria, perennial allergic rhinitis, and seasonal allergic rhinitis. Our investigation into this drug in private pharmacies in Aden, Yemen, revealed that it is sold under the names of 28 brands from different countries of origin. Because of this, it is difficult for medical professionals and patients who use this medication without a prescription to select a suitable, safe, and cost-effective drug product. We assessed the quality and equivalency of six different brands of levocetirizine dihydrochloride film-coated tablets and assigned codes A, B, C, D, E, and F, with Brand A serving as the reference. The UV analytical method was evaluated for quantifying the drug from the tablets. The results indicated that it was accurate and precise. The tablets were evaluated for weight variation, thickness, hardness, friability, drug content, disintegration time, and dissolution. In order to compare the drug's dissolving profiles, the difference factor (f_1) and similarity factor (f_2) were used. For all six brands, the physicochemical parameter results met the acceptable limits. All six brands showed evidence of dissolving within 15 minutes, with values ranging from 80.05 ±0.81 to 103.83 ±0.90 which were within the recommended value of 80% within 30 minutes for oral solid dosage forms intended for immediate release. According to the f_1 and f_2 results, only brands B, D, and E were comparable to brand A and could be used interchangeably. In conclusion, four of the six brands are interchangeable. For high-quality public health, a thorough analysis and ongoing monitoring are needed to ascertain the quality and equivalency of the medications marketed under various brands.

Keywords: Levocetirizine dihydrochloride, Quality, Equivalence, Differential factor, Similarity factor.

1. Introduction

High-quality medicines are essential for the efficient management of illnesses, and substandard or counterfeit pharmaceutical products can have undesirable side effects, resulting in treatment failure and being risky to one's health. It is well recognized that, the spread of generic drug products has become an issue in low-income countries, which calls for more monitoring by pharmaceutical regulatory bodies [1]. The use of the generic product is acceptable if its therapeutic effectiveness is comparable to that of the reference innovator product. It is referred to as pharmaceutically equivalent to the reference product when it has the same active ingredient(s) in their amount, dosage form, and route of administration as the reference drug product at a lower price. It essentially aims to determine how closely generic products match those of the reference product by evaluating and comparing drug dissolution profiles. Patients in undeveloped countries received generic drug products without consideration for their efficacy [2, 3].

The Biopharmaceutic Classification System (BCS) grants a drug substance a classification based on its intestinal permeability and water solubility. How quickly and how much oral drug absorption occurs from immediate-release solid oral dose forms depends on these factors, together with the dissolution rate. The BCS

drug classes are therefore classified as follows: class 1: high solubility and high permeability; class 2: low solubility and high permeability; class 3: high solubility and low permeability; and class 4: low solubility and low permeability. [4]. In order to determine if the drug products are bioequivalent or not, dissolution tests can be performed instead of in vivo bioavailability and bioequivalence studies, saving time and resources. For immediate release, solid oral dosage forms with fast in-vitro dissolution are acceptable surrogates for determining the bioequivalence of generics with innovator drugs. The bioequivalence of class I and some class III drugs, such as levocetirizine dihydrochloride, can be determined only by the in-vitro dissolution test [5, 6]. The dissolution test is a tool for distinguishing acceptable from unacceptable products. Furthermore, it is used to evaluate the consistency of a pharmaceutical product's quality from lot to lot and can guide the development of new formulations [7].

Levocetrizine dihydrochloride has the physicochemical properties of a white to off-white crystalline powder. It is highly soluble in water and soluble in methanol, and it is classified as BCS-III under the biopharmaceutical classification system, a highly soluble and poorly permeable drug [8]. Chemically, it is [2-[4-[(r)-(4-chlorophenyl) phenylmethyl] 1-piperazinyl] ethoxy] acetic acid with a molecular weight of 461.82 (Figure 1) [9]. It is the active R-enantiomer of cetirizine, which is used to relieve the symptoms associated with seasonal allergic rhinitis, perennial allergic rhinitis, and chronic urticarial with no sedation. Since the effects last for 24 hours, just one dose of 5 mg film-coated tablets or oral solution (0.5 mg/mL) is indicated every day [10, 11].

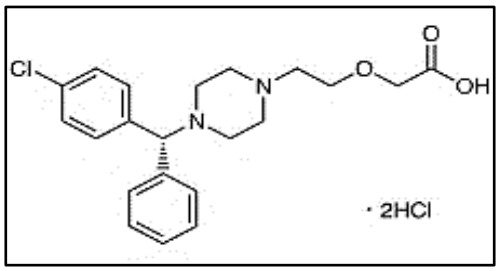

Fig. 1: The chemical structure of Levocetrizine dihydrochloride.

It was found during our investigation of this medication at Aden's private pharmacies that it is marketed by various different pharmaceutical brands and companies. Also absent is the innovative product. As a result, the healthcare system and patients are challenged by the availability of a large number of generic medications, uncertainty around the selection of an appropriate drug product, and the possibility of alternative uses. Typically, patients were administered LCD over-the-counter to treat their allergy symptoms. They are worried about their quality, safety, and treatment effectiveness.

Therefore, the study's objective was to evaluate the quality and equivalence of six brands of levocetirizine dihydrochloride, 5 mg film-coated tablets, marketed in private pharmacies in Aden, Yemen. Assessing their quality by measuring the control parameters, including weight variation, size and thickness, hardness, friability, and disintegration time, In-vitro dissolution studies were also conducted for the six brands, and the similarity was determined using the difference factor (f_1) and similarity factor (f_2).

2. Materials and Methods

2.1 Materials

Pure levocetirizine dihydrochloride (LCD) was obtained as a gift sample from Modern Pharmaceutical Company, Sana'a, Yemen. Six brands from six country of origin of levocetirizine dihdrochlorid (5 mg) film-coated tablets were purchased from the private pharmacies in Aden, Yemen. The brand (A) was chosen as a reference product and (B, C, D, E and F) were the tested products.

2.2 Methods

2.2.1 Survey on the drug products

In the private pharmacies of Aden, a survey was conducted on the levocetirizine dihydrochloride drug brands. The survey involves a search of the names of the brands, the country of origin, the status of registration, the dates of manufacture and expiration, the storage conditions, the coated and uncoated products, and whether or not information about these pharmaceutical items is available on Google.

2.2.2 Determination of the wavelength of maximum absorption

Ten mg of pure LCD were accurately weighed and diluted with distilled water up to 100 ml to get a stock solution of 100 µg/ml. From this stock solution, 10 ml were transferred into a volumetric flask and diluted with 100 ml of distilled water to get a working solution of 10 µg/ml. This solution was scanned using a UV spectrophotometer (Lasany UV-VIS, India) within the range of 200–400 nm to determine the wavelength of maximum absorbance using distilled water as a blank.

2.2.3 Validation of the UV spectrophotometer analytical method

The UV method for the quantitative determination of LCD in tablets was validated according to ICH Guidelines for validation of analytical procedures by using the following parameters [12]:

2.2.3.1 Linearity

For the standard calibration curve, five concentrations of 2, 4, 6, 8, and 10 µg/ml of LCD were prepared from the working solution. The absorbance was then measured

with a UV spectrophotometer set to its maximum, 232 nm. The linearity of the UV method was tested by analyzing LCD standard solutions at the concentration range of 2 to10 µg/ml. The linear calibration equation and correlation coefficients (R^2) were calculated using regression analysis on the five concentrations.

2.2.3.2 Limit of detection and quantification

The limit of detection (LOD) of a compound is defined as the lowest concentration of analytes that can be detected. The limit of quantitation (LOQ) is the lowest concentration of a compound that can be quantified with acceptable precision and accuracy. They were calculated from the linearity data using the standard deviation of the response and the slope of the calibration curve, as illustrated by equations 1 and 2.:

$$\text{LOD} = \frac{3.3\,\sigma}{S} \quad (1)$$

$$\text{LOQ} = \frac{10\,\sigma}{S} \quad (2)$$

where S is the slope of the calibration curve and σ is the standard deviation of the response.

2.2.3.3 Accuracy and Precision

A recovery study at three different concentration levels (80–120%) of the target concentration (6 µg/ml) was performed by spiking a known quantity of standard into a previously analyzed sample (6 µg/ml). The recovery percentages were calculated using Equation 3:

$$\%\,\text{Recovery} = \frac{\text{Amount Found}}{\text{Amount Added}} \times 100\% \quad (3)$$

The precision of the method was verified by repeatability studies. The repeatability (intra-day) precision was determined by performing six replicated samples using solutions of the LCD standard at 6 µg/mL over one day under the same conditions. Results were expressed by the relative standard deviation (% RSD).

2.2.4 Physicochemical Evaluation

2.2.4.1 Weight variation and Thickness

Ten tablets of each of the six brands were taken for weight variation, and their weight was taken individually and collectively on a digital weighing balance (AND, Japan). The thickness of 10 tablets of each brand was measured by using a micrometer screw gauge [13].

2.2.4.2 Hardness and friability Test

The tablet hardness of each brand was determined by a Monsanto hardness tester to measure the force required to break the tablet. Tablet friability was performed using the friability tester (Thermonik, India). Twenty coated tablets from each brand were weighed, and the weight was recorded. The tablets were placed inside the friability tester at a speed of 25 rpm for 4 minutes (100 rounds). After the designated testing time, the tablets were cleaned of any dust, weighed, and the percentage of weight loss was calculated [13].

2.2.4.3 Drug Content

One randomly selected tablet from each brand was dissolved in 100 ml of distilled water as well as 5 mg of pure standard LCD. Transfer 8 ml of the resulting solution into a 50 ml volumetric flask and complete the volume with distilled water to make a concentration of 8 µg/ml. A UV spectrophotometer set to a maximum of 232 nm was used to measure absorbance. The concentrations of LCD were calculated by using the linear equation of the calibration curve and then the percentages of LCD in each tablet of the six brands were calculated in comparison to that of the standard LCD. [14]. The experiments were carried out in triplicate.

2.2.4.4 Disintegration time

The test was carried out on six tablets of each brand using the disintegration apparatus (Erweka ZT41, Germny). One tablet was placed in each tube, and the basket rack was placed in one litter of distilled water at 37±2˚C. The time taken for complete disintegration of the tablet with no palpable mass remaining in the apparatus was measured in minutes [14].

2.2.5 Dissolution Studies

The dissolution studies were performed by using the USP dissolution apparatus type II, the paddle method (Erweka, Germany, DT126), to determine the amount of LCD that dissolves from the six selected brands of LCD film-coated tablets. The dissolution medium was 900 ml of distilled water, the temperature was set to 37 ±0.5 °C, and the paddle speed was set to 50 rpm [14]. After each time interval, samples of 5 ml of the solution were withdrawn at 5, 10, 15, 20, 25 and 30 and were replaced with equal volumes of fresh dissolution medium at the same temperature. The samples were filtered and assayed by a spectrophotometer at a wavelength of 232 nm. The experiments were carried out in triplicate, and the concentrations were calculated using the calibration curve equation. The dissolution curves were constructed by plotting the mean percentages of LCD released against time.

2.2.6 Statistical analysis

The results of the above evaluations of LCD were express as mean values and standard deviation (±SD). The dissolution profiles of the six drug products were statistically compared by using two independent- model parameters, the difference factor f_1 and similarity factor f_2. These factors were calculated from the obtained data from the drug dissolution studies of the six drug products using equations 4 and 5, respectively [15]. The difference factor, f_1, is the average difference between all the points of sampling between two brands: the reference brand and

one of the five test brands. The equation (4) of f_1 is given below:

$$f1 = \frac{\sum_{t=1}^{n} Rt - Tt}{\sum_{t=1}^{n} Rt} \times 100 \quad (4)$$

The similarity factor is calculated to determine the significant similarity between two brands. The equation (5) of f_2 is given below:

$$f2 = 50\log\left[\sqrt{\left\{1 + \frac{1}{n}\sum_{t=1}^{n}(Rt - Tt)^2\right\}} \times 100\right] \quad (5)$$

Where (n) is the number of withdrawal points, (R_t) is the percentage of drug release from the reference drug product and (T_t) is the percentage of drug release from the test drug product at time (t). The acceptable range of f_1 is between 0-15 and f_2 is between 50 and 100 which means an average difference $\leq$ 10% at each withdrawal time.

3. Results and discussion

3.1 Survey on the drug products

The results of the survey are presented in Table 1. The survey revealed that about 28 drug products of LCD from nine of country of origin, including local manufacturer were marketed in Aden, Yemen. The most common source of it was from one country of origin denoted by LCD1 (39.29%). The majority of them were 5 mg of LCD film-coated tablets, 24 (85.71%), and four (14.29%) drug products were uncoated tablets. Only 23 (82.14%) were registered and 5 (17.86%) unregistered (Figure 2). All the drug products packages contained the leaflet. To ensure the availability of information about these brands on Google, the results showed that 85.71 % of the brands given information about the drug product, while 14.29% did not. These numerous multisource products of LCD unpredictable, making it difficult for health care provider and consumer to choose safe and effective brands, besides the offered price. In addition, the innovator product is not present in the pharmaceutical market in Aden. Only the data on the six chosen brands of LCD 5-mg film-coated tablets from six countries of origin are shown in Table 2 with regard to the dates of manufacture, expiration, and storage conditions. The brands are also evaluated for quality and equivalent by selecting brand A as the reference brand and the other five brands as the tested brands.

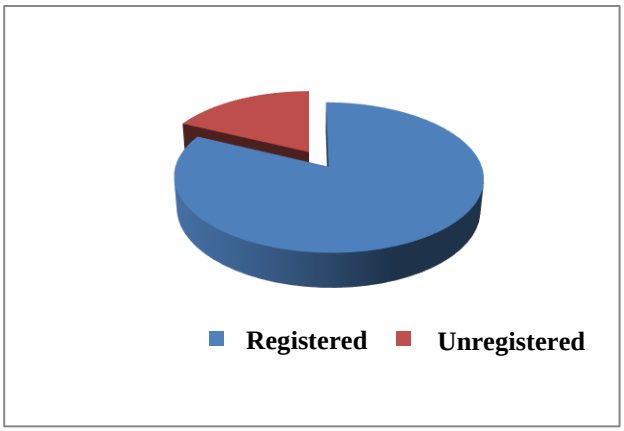

Fig. 2: The registered and unregistered products of levocetirizine dihydrochloride sold in private pharmacies in Aden, Yemen.

Table 1: The information on the brands of levocetirizine dihydrochloride tablets (5mg) sold in the private pharmacies in Aden, Yemen.

Country of origin	Frequency	%
LCD1	11	39.29
LCD2	6	21.43
LCD3	5	17.86
LCD4	1	3.57
LCD5	1	3.57
LCD6	1	3.57
LCD7	1	3.57
LCD8	1	3.57
LCD9	1	3.57
Type of tablet		
Film-coated	24	85.71
Uncoated	4	14.29
Information on Google		
Yes	24	85.71
No	4	14.29

Table 2: The information on the selected six brands of levocetirizine dihydrochloride (5mg) film-coated tablets sold in private pharmacies, Aden, Yemen.

Brand code	Mfg. date /batch No.	Exp. date	Storage condition	Information on Google
A*	8/2020 /BA02443	7/2023	Not exceeding 30°C	Present
B	11/2020 /J1952010	11/23	25°C	Present
C	2/2019 /192165	2/2023	Not exceeding 30°C	Present
D	11/2018 /18008	10/2023	Not exceeding 30°C	Present
E	9/2021 /520921	9/2024	Below 30°C	Present
F	6/2021 /21337	6/2024	Below 30°C	Present

*: reference brand

3.2 Determination of the wavelength of maximum absorption

Spectrophotometric scanning was done to determine the maximum wave length (λ_{max}) of LCD in distilled water. As shown in Figure 3, there is a well-defined maximum absorbance at 232 nm.

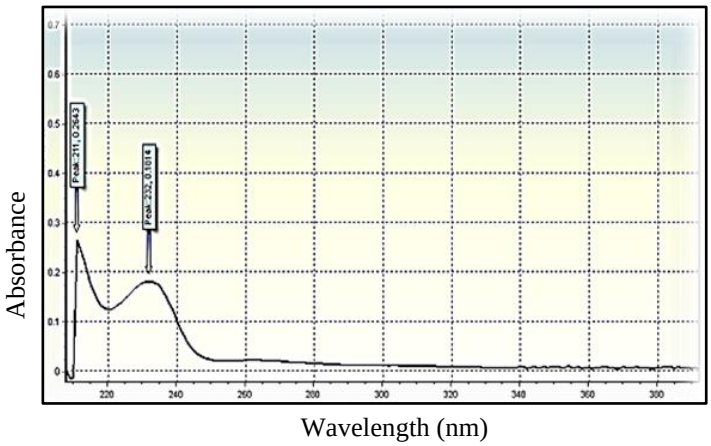

Fig. 3: UV spectrum of levocetirizine dihydrochloride in in distilled water.

3.3 Validation of the UV spectrophotometer method

3.3.1 Linearity

The standard calibration curve of the LCD was constructed by plotting the drug absorbance against the drug concentration (Figure 4). The calibration curve was linear over the concentration range of 2 to 10 µg/ml with the correlation coefficient $R^2 = 0.9996$.

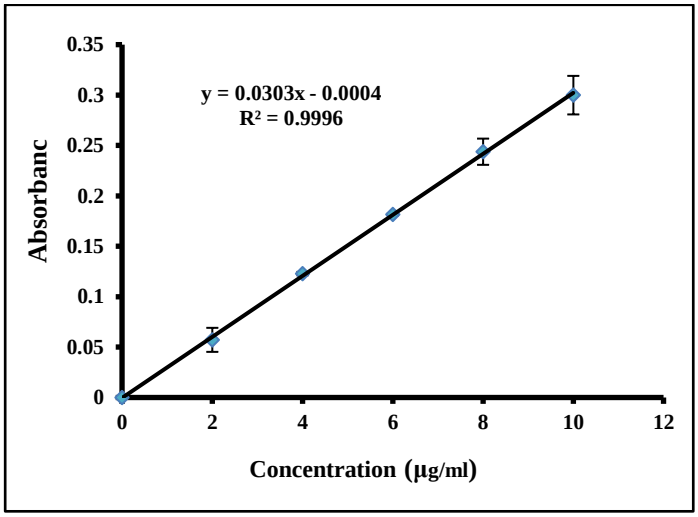

Fig. 4: Calibration curve of levocetirizine dihydrochloride in distilled water.

3.3.2 Limit of detection (LOD) and Limit of quantization (LOQ)

The limits of detection and quantitation were calculated from the linearity data using the relative standard deviation of the response and the slope of the calibration curve. LOD and LOQ values of LDC were found to be 0.2657 µg/ml and 0.8053 µg/ml respectively. Low LOD and LOQ indicate good sensitivity for the proposed method (Table 3).

3.3.3 Accuracy and Precision

The results of accuracy and precision are depicted in Table 3. The recovery study revealed that the method was accurate for the vitro release kinetics of LCD, as LCD was recovered in the range of 99.95 to 100.79 % for various concentrations that were within the acceptance range (100 ±2%). The precision of the method was verified by repeatability (intra-day precision). The results were evaluated by a common statistical approach, including the calculation of SD and %RSD, which indicated that the method was precise as the value of % RSD was less than 2 [16].

Table 3: The validation parameters of UV spectrophotometer analytical method of levocetirizine dihydrochloride in distilled water.

Validation parameter		Results
Linearity	Equation	Y = 0.0303X - 0.0004
	Slope	0.0303
	Intercept	0.0004
	Correlation coefficient (R^2 ±SD)	0.9996 ±0.00244
Limit of detection (LOD)	Concentration µg / ml	0.2657
Limit of quantification (LOQ)	Concentration µg/ml	0.8053
Accuracy	Concentration µg/ml (% Recovery)	4.8 (99.95%)
		6 (100.79%)
		7.2 (100.03%)
Precision	Mean (±SD)	101.465±0.106
	%RSD	0.104

SD: standard deviation, RSD: relative standard deviation

3.4 Physicochemical Evaluation

The results of physicochemical evaluation of the six brands of LCD are depicted in Table 4.

3.4.1 Weight variation and thickness

The weight variation test is used to ensure that the manufactured tablets have a uniform weight and that it is a reliable means of determining drug content uniformity. The mean weight of the film-coated tablets varied between the six brands, (0.097 ±0.01 to 0.153 ± 0.02 gm) as shown in Table 4. However, each brand had uniform weights that were within the permitted range as defined by USP requirements, with no tablets deviating from 7.5 [17]. Furthermore, the average thickness of these manufacturers' tablets ranged from 2.74 ±0.02 to 3.77 ±0.16 mm.

3.4.2 Hardness and friability

The results of the hardness tests of all brands were approximately 5 kg/cm^2, with the exception of brand C, which had a tablet hardness of 3.30 ±0.41 kg/cm^2. The friability test ranged from 0.24% to 0.01%. A friability test of less than 1% indicated good mechanical resistance of the tablets to abrasion or breakage. Although brand C had a low hardness value, it passed the friability test by less than 1% (0.051%). If the friability meets the criteria, a tablet with a hardness of less than 4 kg/cm^2 can be accepted [18].

3.4.3 Drug content

All tested brands' drug content was found to be consistent and uniform in the range of 98.8–102.2%, as the limit specified in the USP is 95 to 105% [14].

3.4.4 Disintegration time

The disintegration times for the six tested brands varied, with brand D having the shortest disintegration time at 2.5 ±0.84 minutes. The longest disintegration time, 9.67 ±1.63minutes, was displayed by brand F. The USP has set a 30 minute time limit for film-coated tablet disintegration tests [18]. This variation in the disintegration time between the six brands may be reflected in the difference in their dissolution.

3.5 Dissolution Studies

The generic brands of a drug can show the same therapeutic efficacy and safety if their bioequivalence is comparable with the innovator product. If the innovator products are not available, especially in developing countries, the World Health Organization (WHO) has proposed that a well-established drug product may be used as the comparator pharmaceutical product [19]. Accordingly, in this research, six brands of LCD from different sources were chosen for the evaluation of their equivalence, in which brand A was taken as the reference brand and brands B, C, D, E, and F were the tested brands.

The results of the dissolution studies are depicted in Table 5 as the cumulative amount dissolved of the drug (%) against time (minutes), and the dissolution profiles are shown in Figure 5. It was found that brands A, B, and F exhibited a cumulative amount dissolved of LCD of about 90.35 ±1.41%, 99.38 ±0.28%, and 103.83 ±0.90%, respectively, within 15 minutes, while brands C, D, and E achieved a cumulative amount dissolved of LCD of 91.43 ±1.25%, 99 ±4.52%, and 87.05 ±0.63% within 20 minutes. The results indicated that all six brands of LCD performed well in terms of dissolution rate, as the drug has a high water solubility. According to the Food and Drug Administration (FDA), the acceptance criteria for immediate release of solid oral drug products containing a highly solubilized drug substance is a dissolution criterion of 80% within 30 minutes [20].

Table 4: The physicochemical parameters of t3he six brands of levocetirizine dihydrochloride film-coated tablets

Physicochemical parameter		Brand code					
		A	B	C	D	E	F
Shape and color		Round & white	Oval & white	Round & white	Round& Pink	Oval & white	Round, & white
Weight variation	mean (gm ±SD)	0.104 ±0.01	0.100 ±0.0l1	0.097 ±0.01	0.136 ±0.01	0.115 ±0.01	0.153 ±0.01
	Upper limit (gm)	0.112	0.108	0.105	0.146	0.124	0.165
	Lower limit (gm)	0.096	0.093	0.090	0.125	0.106	0.142
Thickness (mm ±SD)		3.17 ±0.02	3.03 ±0.02	3.45 ±0.02	2.74 ±0.02	2.76 ±0.02	3.77 ±0.16
Hardness (kg/cm^2 ±SD)		5.60 ±0.56	5.73 ±0.90	3.30 ±0.41	4.54 ±0.21	4.02 ±0.44	5.57 ±1.46
Friability (%)		0.24	0.15	0.051	0.02	0.10	0.01
Drug content (% ±SD)		101.80 ±0.96	101.27 ±2.88	103.0 ±1.78	102.94 ±0.26	105.71 ±0.31	102.53 ±65
Disintegration time (minutes) ±SD		3.5 ±0.55	3.83 ±0.75	4.4 ±1.52	2.5 ±0.84	3.67 ±0.52	9.67 ±1.63

SD: standard deviation

A comparison of the dissolution of LCD of the six brands and their dissolution profiles over the course of 30 minutes revealed no similarity. The possible effect of excipients on the dissolution of LCD was not evaluated because only the brands B and E products listed the excipients on its packages. Drug dissolution profiles may be distinct due to differences in formulations and manufacturing processes, but the differences must not compromise product bioequivalence. In addition, the immediate-release tablet film coating does not significantly alter the drug release kinetics of its dosage form. The coating components provide protection to the coated material and facilitate swallowing or masking unpleasant tastes (21).

Dissolution profile analysis is an important tool for establishing the similarity between generic brands and their reference products. In addition, dissolution is important for monitoring approved and post-marketing drug products to assess their quality, therapeutic effectiveness, and safety for the public. The dissolution profiles of the six brands were subjected to comparison using the difference factor (f_1) and similarity factor (f_2) (Table 5). The results of f_1 and f_2 are completely different, and only brands B, D, and E are similar to brand A because the obtained values of f_1 are less than 15 and f_2 are greater than 50. Brands C and F, on the other hand, despite having f_1 values less than 15, had f_2 values less than 50. The use of f_1 and f_2 is simple and gives reliable results, as well as being commonly used and the most recommended method by the FDA. However, the similarity factor (f_2) is the most appropriate method to compare release profiles [6, 21]. It evaluates the degree of similarity between the two profiles and is sensitive to significant variations at any time point [5]. According to the obtained results, only brands B, D and E can be used as generic substitutes for brand A, and brands C and F showed dissimilarity with brand A.

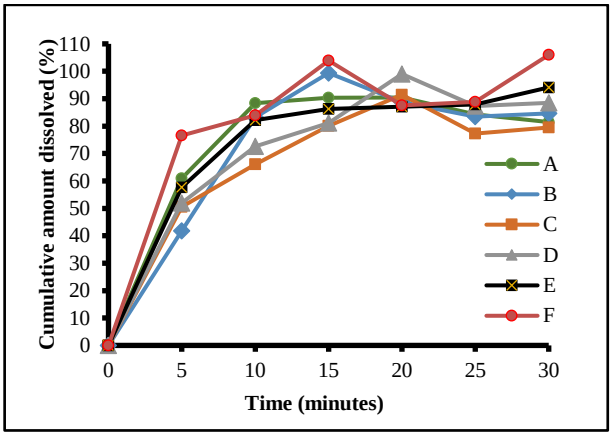

Fig. 5: The dissolution profiles of levocetirizine dihydrochloride from the six brands film coated tablets.

Table 5: The dissolution rate of levocetirizine dihydrochloride from six brands, The dissimilarity f_1 and similarity f_2 Factors.

Time (minutes)	Cumulative amount dissolved (% ±S.D)					
	A	B	C	D	E	F
5	60.96 ±0.92	41.81 ±0.44	50.56 ±1.60	51.92 ±0.56	57.70 ±1.27	76.53 ±2.79
10	88.37 ±1.29	83.17 ±0.40	66.09 ±0.0.52	72.60 ±3.31	82.21 ±0.86	83.95 ±2.06
15	90.35 ±1.41	99.38 ±0.28	80.05 ±0.81	81.13 ±3.81	86.26 ±0.90	103.83 ±0.90
20	90.42 ±1.71	88.72 ±0.22	91.43 ±1.25	99.00 ±4.52	87.05 ±0.63	87.58 ±1.34
25	84.33 ±1.68	83.45 ±0.15	77.32 ±0.28	87.30 ±1.80	87.91 ±0.50	88.78 ±0.32
30	81.51 ±1.49	84.58 ±0.32	79.44 ±0.38	88.48 ±1.16	94.11 ±1.14	105.96 ±0.07
f_1	-	7.87	10.70	11.47	6.67	13.15
f_2	-	52.10	47.28	50.90	59.32	43.66

SD: standard deviation

Conclusion

According to the study of physicochemical parameters, the results revealed that the six brands met the acceptable criteria. Furthermore, all tested brands exhibited dissolution of more than 80% within 15 minutes. The comparison of the dissolution profile by calculating the difference factor (f_1) and similar factor (f_2) indicated that only four of the six brands are interchangeable. The quality and equivalence of the various brands of drugs must be carefully surveyed and monitored in order to guarantee that they are sold for the successful management of diseases.

Conflict of interest

The authors declare no conflicts of interest.

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Author information

ORCID

Sana Saleh Al-Kubati: 0000-0003-3355-7705

مقالة بحثية

تقييم الجودة والتكافؤ لبعض العلامات التجارية للأقراص المغلفة لدواء الليفوسيتيزين داي هيدروكلورايد المباعة في عدن، اليمن

سناء صالح القباطي[1،*]، ألفت صالح أحمد[1] و رندا محمد سيف[1]

[1] قسم الصيدلانيات، كلية الصيدلة، جامعة عدن، اليمن

*** الباحث الممثّل: سناء صالح القباطي؛ البريد الالكتروني: ss.alkubati@pharm.adenuniv.com**

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المُلخّص

ان الأدوية الجنيسة هي أقل تكلفة من الأدوية الاصلية، وأصبح انتشارها يمثل مشكلة في البلدان منخفضة الدخل. حيث يجب أن تكون متكافئة علاجيًا وصيدلانيًا مع الدواء ذو المنشأ الاصلي. ان الليفوسيتيزين داي هيدروكلورايد هو دواء فعال للتخفيف من اعراض الشرى المزمن والتهاب الأنف التحسسي الدائم والحساسية الموسمية. حيث كشف تقصينا حول هذا الدواء في الصيدليات الخاصة في عدن، اليمن، أنه يُباع تحت اسم 28 علامة تجارية من دول مختلفة المنشأ. لهذا السبب، من الصعب على المهنيين الطبيين والمرضى الذين يستخدمون هذا الدواء دون وصفة طبية اختيار منتج دوائي آمن وفعال ومناسب من حيث التكلفة. لقد قمنا بتقييم جودة وتكافؤ ست علامات تجارية من أقراص الليفوسيتيرين داي هيدروكلوريد والمغلفة بطبقة رقيقة من بلدان مختلفة المنشأ وحددت برموز A و B و C و D و E و F، وباستخدام العلامة التجارية A كمنتج مرجعي. ولقد تم تقييم الطريقة التحليلية للأشعة فوق البنفسجية لتحديد كمية الدواء من الأقراص. حيث اشارت النتائج أنها صحيحة ودقيقة. كما تم تقييم الأقراص من حيث الوزن والسمك والصلابة والتفتيت ومحتوى الدواء في كل قرص وكذلك معدل الذوبان. ومن أجل مقارنة معدل ذوبان الدواء لكل علامة تجارية مع العلامة التجارية المرجعي، تم استخدام عامل الاختلاف (f_1) وعامل التشابه (f_2). حققت نتائج المعلمات الفيزيائية الكيميائية الحدود المقبولة لجميع العلامات التجارية الست، كما وأظهرت جميع العلامات التجارية الست معدل الذوبان في غضون 15 دقيقة، بقيم تتراوح من 80.05 ±0.81 to 103.83 ±0.90 والتي تقع ضمن القيمة الموصي بها البالغة 80٪ خلال 30 دقيقة لأشكال الجرعات الصلبة الفموية المخصصة للذوبان الفوري. ووفقًا لنتائج f_1 و f_2، كانت العلامات التجارية B و D و E فقط مشابهة مع العلامة التجارية A ويمكن استخدامهم بالتبادل. في الختام، أربع من العلامات التجارية الست قابلة للتبديل مع العلامة التجارية المرجعي. من أجل الصحة العامة عالية الجودة، هناك حاجة إلى تحليل شامل ومراقبة مستمرة للتأكد من جودة وتكافؤ الأدوية التي يتم تسويقها تحت العلامات التجارية المختلفة.

الكلمات المفتاحية: الليفوسيتيزين داي هيدروكلورايد، **الجودة، التكافؤ**، عامل الاختلاف (f_1)، عامل التشابه (f_2).

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