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Original article

Evaluation of Quality and Antibacterial Activity of Four Brands of Ciprofloxacin Tablets Marketed in Libya

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ABSTRACT

Ciprofloxacin is one of fluoroquinolones antibiotics used in treatment for infections of the urinary tract, skin and soft-tissues, and lower respiratory tract. There are many brands of ciprofloxacin tablets available in pharmacies of Albaiyda city and the aim of this study was to evaluate quality of four available brands of ciprofloxacin tablets by quality control parameters and to test their antibacterial activity. Four leading brands of ciprofloxacin tablet each with a label claim 500 mg were purchased from the various retail pharmacies of Albaiyda city and evaluated by in vitro quality control tests for tablet according to pharmacopeia (BP/ USP) that include evaluation of uniformity of weight and weight variation, friability, hardness, and disintegration time. The second evaluation was the antibacterial activity of the four brands against Klebsiella pneumonia, Staphylococcus aureus, and Escherichia coli by well diffusion susceptibility method. Weight variation for four brands of ciprofloxacin ranged from 0.507% to ,0.753%, the highest variation was found in Brand A, and the lowest weight variation was observed in Brand B and all brands comply with specification. Friability of all brands was below 1% which means that all brands have passed the test and met the specification, and the brand which most likely to be friable between brands is Brand B (0.64%) and the least likely to be friable is Brand C (0 %). The results indicated that all brands of ciprofloxacin tablets were not in the limit of hardness test and the highest hardness value was for Brand C (276 N), and the lowest hardness value was for Brand A (114.2 N). Disintegration time for four brands was under 5 minutes and all brands were complied with the both BP and USP specifications. larger zone of inhibition (ZI) for ciprofloxacin brands against Klebsiella pneumonia was found in Brand C (26.19mm) indicating that it has the highest activity and larger ZI for ciprofloxacin brands against Staphylococcus aureus was found in Brand D (40.40mm) and larger ZI for ciprofloxacin brands against Escherichia coli was also found in Brand D (21.21mm) indicating that it has the highest activity against both types of bacteria. From this study it was demonstrated that all four brands of ciprofloxacin tablet marketed in Libya comply with BP and USP specification for quality control test of uniformity of weight and weight variation, friability, and disintegration time, except that in hardness test in the four brands were found out the limit but this test is non compendial test and all the brands have similar antibacterial effect except Brand C which has slightly better microbiological activity against Klebsiella pneumonia and Brand D which is more effective against Staphylococcus aureus, and Escherichia coli.

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INTRODUCTION

Ciprofloxacin is one of fluoroquinolones antibiotics [1]. In 1981 it was discovered by Bayer, Germany and in 1987 The Food and Drug Administration (FDA) approved it as first oral broad-spectrum antibiotic [2]. It is one of the most

important drugs required for the basic health care system and it is present in the World Health Organization's (WHO) list of essential drugs [3].

Ciprofloxacin mechanism of action is primarily by inhibition of bacterial DNA gyrase. It is effective after oral administration, with potent antibacterial activity against most Gram-negative, and many Gram-positive bacteria. Ciprofloxacin is an effective treatment for infections of the urinary tract, skin and soft-tissues, lower respiratory tract, and bone and joints, and for prophylaxis in transurethral surgery [4]. Substandard and counterfeit drugs are a major cause of problems in health and confidence of patients [5]. According to WHO approximately 10% of the global pharmaceuticals market consists of counterfeit drugs, this estimation increases to 25% in developing countries, and can exceed 50% in some countries [6]. It is also estimated by FDA that up to 25% of the drugs consumed in poor countries are substandard or counterfeit [7].

A study of WHO result in 28% of antibiotic and 20–90% of antimalarial drugs were not corresponding to quality specification [8]. Drug product must comply with standards to be a quality drug. The main properties for the quality of any drug in its dosage form are its safety, efficacy, and patient acceptability and compliance [9]. The quality of pharmaceutical products must be reliable and reproducible from batch to batch [10]. Test of products during and after manufacturing at various intervals during their shelf-life is necessary to o ensure the quality of drug products [11]. Also, quality control is the part of Good Manufacture Practice (GMP) which gives all procedures of sampling, specifications, testing, documentation and release and will ensure that the necessary and relevant tests are actually carried out and no products released for sale or supply until their quality has been examined to be comply with standards [12]. Quality control evaluation involves weight variation test, test of content, friability test, hardness test, disintegration test and dissolution test [13]. Misuse of antimicrobial agents and use of sub-standard and counterfeit drugs are major causes of drug resistance among communities [14].The aim of this study is to evaluate quality of four available brands of ciprofloxacin by quality control parameters and to test their antibacterial activity against *Klebsiella pneumonia*, *Staphylococcus aureus*, and *Escherichia coli* by well diffusion susceptibility method.

MATERIALS AND METHODS

Drug samples and materials

Four commercially available leading brands of ciprofloxacin tablet each with a label claim 500 mg were purchased from the various retail pharmacies of Albayda city in may /2022 and they were coded as Brand A, Brand B, Brand C, and Brand D as in table 1.

Table 1. Description of four brands of ciprofloxacin tablets.

Brand code	Brand name	Country of origin	Strength in mg	Batch number	Expiry date
A	Sifloks	Tunisia	500	21002	10/2025
B	Ciprofloxacin	UK	500	C 1521006Z	8/2025
C	Ciprocin	Egypt	500	2104692	6/2024
D	Marocen	Serbia	500	125FFC	5/2024

For antibacterial activity test we use the following materials: HCL 25%, Purified Water, Mueller Hinton Agar powder (CM0337B), antibiotic standard disks, Mercury thermometer, Erlenmeyer flask {250ml and 500ml}, Petri dishes, Sterile Swabs, Tweezers. For quality control evaluation testes drugs in table 1 were used and distilled water was used for disintegration test.

Instruments

Electronic balance (SAETORIUS), Friability tester (Model: TAR 220, ERWEKA GMBH), Tablet hardness tester (Model: TBH 220 D, ERWEKA GMBH), Disintegration tester (Model: ZT 122, Serial No: 121831.0968, ERWEKA GMBH), Water bath (Model: TW20 GB, JULABO) Autoclave (Model: YX280, SHANGHAL SANSHEN MEDICAL EQUIPMENT CO, LTD), Dry heat sterilization (Serial No: 40673577, Thermo electron corporation), Refrigerator (Serial No: 7100007, Model: RCUR16X1, Electrolux).

Quality control testes

Uniformity of weight and weight variation test

According to the USP weight variation test was run by weighting 20 tablets for each of the four brands individually using an electronic balance, then calculating the average weights and comparing the individual tablet weights to the average. The difference in the two weights was used to calculate weight variation by using the following formula**:**

Weight variation = $(Iw - Aw)/Aw \times 100\%$, where, *Iw*is Individual weight of the tablet and *Aw* is Average weight of the tablet [9].

Friability test

For this test twenty tablets from each of the four brands were weighed and placed in the friabilator and then operated at 25 rpm for 4 minutes, the tablets were then dedusted using brush and weighed. The difference in the two weights was used to calculate friability by using the following formula:

Friability = $(Iw - Fw)/Iw \times 100\%$, where, *Iw* is total initial weight of the tablets and

Fw is total final weight of the tablets [9].

Hardness test:

For this test hardness tester was used. Ten tablets from each of the four brands were tested. Tablet was placed vertically on the Hardness tester and the load was then applied along the radial axis of the tablet. The weight or load required for breaking the tablet was measured [9].

Disintegration test

For this test ERWEKA disintegration tester was used to measure disintegration time for tablets, six tablets from each brand were employed for this test and one tablet was placed in each tube, the basket rack was positioned in a vessel containing 700 ml of distilled water maintained at 37 ± 2 °C, so that the tablets remained below the surface of the liquid on their upward movement. A motor driven device was used to move the basket assembly containing the tablets up and down at a frequency of 30strokes per minute, and the apparatus was operated for 30 min [9].

Antibacterial activity test

Microorganisms' isolates

Antimicrobial activity of different ciprofloxacin samples was tested against three different bacterial isolates obtained from local private medical analysis laboratories. All the existing cultures of microorganisms were refreshed by streaking them using a sterile inoculation loop on plates filled with nutrient agar medium in a laminar flow hood. Following this, the plates were incubated at a temperature of 37ºC for a duration of 24 hours.

Culture media

The study utilized nutrient agar medium to cultivate and promote the growth of all microorganisms under investigation. For the purpose of shaking incubation and standardization of these microorganisms, nutrient broth was employed [15].

Well diffusion susceptibility method

Nutrient agar medium plates were inoculated with fresh microbial cultures. Four wells, each with a diameter of 8 mm, were created in the agar media using a sterilized test tube. Subsequently, ciprofloxacin extract, in volumes of 1µl containing a concentration of 6.25 µg/ml, was introduced into the wells. Additionally, DMSO, in a quantity of 24 µl per well, was added to one well for the positive control, while another well was used for the negative control. The plates, now inoculated, were then placed in an incubator set at a temperature of 37ºC for a duration of 24 hours. Following this incubation period, the zones of inhibition were measured in millimeters. Three replicates were prepared for each microorganism.

Antibacterial activity of reference drugs

Ciprofloxacin was subjected to examination at concentrations achieved by taking 0.1 grams of each tablet and dissolving it in 100 milliliters of aseptic distilled water to acquire a concentration of 1000µg/ml, subsequently followed by sequential dilutions to attain concentrations of 6.25 µg/ml. This agent was assessed against standard bacteria, namely, *Klebsiella pneumonia*, *Staphylococcus aureus*, and *Escherichia coli*.

Negative controls

Distilled water (DW) underwent examination in comparison to the reference bacteria, specifically *Klebsiella pneumonia, Staphylococcus aureus, and Escherichia coli*. Approximately all of the assessed generic ciprofloxacin displayed in-vitro antimicrobial bioequivalence to the reference medication.

RESULTS

Quality control testes

Uniformity of weight and weight variation test

The results of weight variation test for four brands of ciprofloxacin were found as following; Brand A (0.753%), Brand B (0.507%), Brand C (0.699%), and Brand D (0.533%) as shown in table 2, among all brands, the highest variation was found in Brand A, and the lowest weight variation was observed in Brand B. According to specification the tablet complies with weight variation test if not more than 2 of individual weights deviate from average weight by more than 5 %, and based on this all tablets were tested and results of individual tablet weight show that all brands comply with specification.

Average weights also for four brands were listed in table 2 and it was noted that the highest weight was for Brand D and the lowest was for Brand C.

Table 2. Average weight, standard deviation from average weight, weight variation means, and standard deviation of four brands of ciprofloxacin tablets.

Brands	Average weight (g), SD	Weight variation mean (%), SD
A	0.753495 ± 0.006926	0.753157 ± 0.497727
B	0.7718 ± 0.005435	0.507904 ± 0.473615
C	0.69375 ± 0.005937	0.699099 ± 0.466846
D	0.77949 ± 0.005075	0.533426 ± 0.352588

Friability test

Results of friability for four brands of ciprofloxacin were as following; Brand A (0.019%), Brand B (0.64%), Brand C (0 %), and Brand D (0.0318%), which means that the brand which most likely to be friable between brands is Brand B and the least likely to be friable is Brand C as listed in table 3. Friability of all brands was below 1% and they comply with specification.

Table 3. Average hardness (N), standard deviation, friability percent (%), disintegration time (min), and standard deviation of four brands of ciprofloxacin tablets.

Brands	Friability %	Hardness (N), SD	Disintegration time (min), SD
A	0.019792	114.2± 14.96514	4.463333±0.603015
B	0.641026	177.3 ±8.628763	0.581667±0.264304
C	0	276 ± 28.53458	4.876667±0.866226

Hardness test

From table 3 the obtained values of hardness for four brands of ciprofloxacin were found as Brand A (114.2 N), Brand B (177.3 N), Brand C (276 N), and Brand D (166.5 N), it was clear that the highest hardness value was for Brand C and the lowest hardness value was for Brand A.

Disintegration test

Disintegration time for four brands listed in table 3 and was obtained as following Brand A (4.46 min), Brand B (0.58 min), Brand C (4.87 min), and Brand D (1.365min), the highest disintegration time was for Brand C and the lowest disintegration time was for Brand B. All brands comply with disintegration test specifications.

Antibacterial activity test

Different types of bacteria are selected to cover most common gram positive and negative bacteria including (*Escherichia coli, Staphylococcus aureus, and Klebsiella pneumonia*). Table 4 describes all the results obtained from well diffusion agar test.

Table 4. Results of zone of inhibition for ciprofloxacin brands against (Klebsiella pneumonia, Staphylococcus aureus, and Escherichia coli).

Mean diameter of growth inhibition zone	Brand A	Brand B	Brand C	Brand D
Klebsiella pneumonia	25.26	25.25	26.19	25.25
Staphylococcus aureus	39.39	39.39	39.39	40.40
Escherichia coli	19	18.18	20.19	21.21

Key: MDIZ (mm) = Mean diameter of growth inhibition zone in mm. Interpretation of results: MDIZ (mm):>18 mm: Sensitive, 14 to 18 mm: Intermediate: <14 mm: Resistant. (-): No inhibition zone. The highly activity of brands were written in bold*

DISCUSSION

The quality of pharmaceuticals is under great risks in developing countries which is because some factors like uses of substandard raw material and lacks of facility that is why it is necessary to check the quality of pharmaceutical products. Pharmacopeial testing check on product properties according to standard specification [16].

Quality control study is important evaluation for tablet dosage forms using different quality control parameters (weight variation, hardens, friability, and disintegration time) these parameters were tested to determine the differences between various brands of ciprofloxacin tablets that are available in the Libya drug market. Uniformity of weight serve as indicator of good manufacturing practice (GMP) as well as amount of the active pharmaceutical ingredients, and that is important for reproducibility and mass production of any product [13].

Average weights for four brands as listed in table 2 were Brand A (0.753g ± 0.006), Brand B (0.771g ± 0.005), Brand C (0.693g ± 0.005), and Brand D (0.779g ± 0.005), and it was noted that the highest weight was for Brand D and the lowest was for Brand C as given in figure 1.The results of weight variation test for four brands of ciprofloxacin were found as following; Brand A (0.753%), Brand B (0.507%), Brand C (0.699%), and Brand D (0.533%) as shown in table 2, among all brands, the highest variation was found in Brand A, and the lowest weight variation was observed in Brand B as shown in figure 2. The highest variation was (0.753%), Therefore, all the four brands tested in this study complied with the specification for uniformity of weight which states that for tablets weighing more than 324 mg, weight of not more than 2 tablets should not differ from the average weight by more than 5% [17]. Thus, all brands met the specification of weight uniformity test. In the study of quality evaluation of ten brands of ciprofloxacin tablets available in Bangladesh, Uddin et al., also reported similar results [16].

The loss due to abrasion in packaging, handling and shipping is a measure of the tablet friability. It is another measure of the tablet strength and this well effect on pharmaceutical elegance and patient acceptance[13] [16]**.**Values of friability for four brands of ciprofloxacin as shown in table 3 and figure 3were Brand A (0.019%), Brand B (0.64%), Brand C (0 %), and Brand D (0.0318%)**,** the friability was less than (0.64%).The pharmacopoeia states that the friability value of tablets should be less than 1% and as such all the brands of ciprofloxacin had passed this friability specification[18].Also, this showed that all the brands could withstand abrasion without loss of tablet integrity. Alyahawi and Alsaifi in study of quality control assessment of different brands of ciprofloxacin 500 mg tablets in Yemen showed that all brands pass the pharmacopeial specification for friability[13].

The test for hardness is non-compendial test [13]. The hardness of the tablets plays important role in the ability of the tablets to resist chipping, abrasion and breakage under conditions of handling, transportation and storage [19]. Hardness, which may call crushing strength of the tablet is used for adjustments of the pressure in the tablet press [20]. hardness can influence also other parameters such as disintegration [21]. The average values of hardness for four brands of ciprofloxacin as shown in table 3 were found as Brand A (114.2 N), Brand B (177.3 N), Brand C (276 N), and Brand D (166.5 N), it was clear that the highest hardness value was for Brand C and the lowest hardness value was for Brand A as it illustrated in figure 4. The results indicated that all brands of ciprofloxacin tablets were not in the limit range of 4 to 10 Kg/cm² (49.03- 98.07 N) [20]. Hardness of our brands were greater than 114 N. Tablet hardness may be caused by the difference in properties of excipients that used in the manufacture of the different brands [16]**.** Alyahawi and Alsaifiin study of quality control assessment of different brands of ciprofloxacin tablets in Yemen showed that all brands were not in the limit range of hardness test [13].

Drug must be in solution form before absorption of it takes place inside the body. The first important step toward solution for tablets is the breakdown of the tablet into smaller particles or granules, that is known as disintegration [22]. Disintegration process is related directly to dissolution and bioavailability of a drug [23]**.** Disintegration time of tablet is important physicochemical property, and it is the time required for tablets to disintegrate into particles. It is measured by disintegration test [13]. Results of disintegration time for four brands are listed in table 3 and were obtained as following; Brand A (4.46 min), Brand B (0.58 min), Brand C (4.87 min), and Brand D (1.365 min), the highest disintegration time was for Brand C and the lowest disintegration time was for Brand B as clarified in figure 5.

Disintegration time for four brands were under 5 minutes. BP states that the disintegration time is not more than 15 minutes for uncoated tablets, while USP specification for disintegration time is not more than 30 minutes for both uncoated and film coated tablets. According to this all brands were complied with the both BP and USP specifications. The rapid disintegration time that observed in all brands might be attributed to type and amount of disintegrant used in their formulation. Similar findings were reported by Alyahawi and Alsaifi[13]. Uddin et al. also in their study reported that the disintegration time for ten brands of ciprofloxacin tablet met USP specifications [16].

The existence of Sub-standard antimicrobial agents poses a significant concern for the overall well-being of the general public, as it potentially leads to the discouraging impact on patients and the hindrance of progress in combating antimicrobial resistance [24].

The rise in the quantity of generic pharmaceutical products originating from various origins has positioned individuals engaged in the healthcare sector in a situation where they must choose one out of several seemingly identical options. Some of them are counterfeit drugs that may contain wrong ingredients or insufficient active ingredients. Unfortunately, counterfeiting of medicines is a widespread issue globally and is becoming more sophisticated and organized. The World Health Organization (WHO) states that each year, 700,000 individuals from Africa succumb to mortality as a result of the consuming of spurious anti-malarial or antitubercular medications, with a majority of these medications being imported from China and India. Counterfeit medications can also impede health by inducing a state of tolerance among users towards presently efficacious drugs, ultimately transforming them into antimicrobial agents that lack efficacy [25,26]. The brands A, B, and C have demonstrated no notable distinction in comparison to brand D, which exhibits marginally greater efficacy, particularly against *Staphylococcus aureus* and *Escherichia coli* (40.40 and 21.21 respectively). These findings imply that brand D possesses superior microbiological quality metrics and standards. Furthermore, perhaps, the procedures and methods used by suppliers for these antibiotics are proper in terms of storage and transportation. On the other hand, suppliers' wise selection of pharmaceutical companies that adhere to good quality systems and effective materials.

CONCLUSION

From the present study, it was demonstrated that all four brands of ciprofloxacin tablet marketed in Libya comply with BP and USP specification for quality control test of uniformity of weight and weight variation, friability, and disintegration time, except that in hardness test where four brands were found out the limit but this test is non compendial test. Regarding the antibacterial activity, all the brands have similar antibacterial effect except Brand C which has slightly better microbiological activity against *Klebsiella pneumonia* and Brand D which is more effective against *Staphylococcus aureus, and Escherichia coli.* Studies like this evaluation are important to solve the problem of counterfeit and substandard drugs especially in developing countries and to improve health care services.

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الجودة والنشاط المضاد للبكتيريا لأربعة ماركات من أقراص السيبروفلوكساسين المسوقة في ليبيا

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قسم الصيدلانيات، كلية الصيدلة، جامعة عمر المختار، البيضاء، ليبيا

الملخص

سيبروفلوكساسين هو أحد المضادات الحيوية الفلوروكينولونات ، وهو معتمد من قبل إدارة الغذاء والدواء، والذي يستخدم في علاج التهابات المسالك البولية والجلد والأنسجة الرخوة والجهاز التنفسي السفلي. وهو موجود في قائمة منظمة الصحة العالمية للأدوية الأساسية. هناك العديد من العلامات التجارية لأقراص سيبروفلوكساسين المتوفرة في صيدليات مدينة البيضاء والهدف من هذه الدراسة هو تقييم جودة أربع علامات تجارية متاحة من أقراص سيبروفلوكساسين من خلال معايير مراقبة الجودة واختبار نشاطها المضاد للبكتيريا. تم شراء أربع علامات تجارية رائدة متاحة تجاريا من أقراص سيبروفلوكساسين لكل منها مع مطالبة ملصق 500 مجم من صيدليات البيع بالتجزئة المختلفة في مدينة البيضاء وتم تقييمها من خلال اختبارات مراقبة الجودة في المختبر للأقراص وفقا لدستور الأدوية (BP / USP) والتي تشمل تقييم توحيد الوزن واختلاف الوزن ، والتفتيت ، والصلابة ، ووقت التفكك. كان التقييم الثاني هو النشاط المضاد للبكتيريا للعلامات التجارية الأربع ضد *الالتهاب الرئوي الكلبسيلة والمكورات العنقودية الذهبية* والإشريكية القولونية *بطريقة* حساسية الانتشار بشكل جيد. تراوح اختلاف الوزن لأربع علامات تجارية من سيبروفلوكساسين من 0.507٪ إلى 0.753٪ ، وتم العثور على أعلى تباين في العلامة التجارية أ ، ولوحظ أدنى اختلاف في الوزن في العلامة التجارية ب وجميع العلامات التجارية تتوافق مع المواصفات. كانت قابلية تفتيت جميع العلامات التجارية أقل من 1٪ مما يعني أن جميع العلامات التجارية قد اجتازت الاختبار واستوفت المواصفات ، والعلامة التجارية التي من المرجح أن تكون قابلة للتفتيت بين العلامات التجارية هي العلامة التجارية (0.64٪) B والأقل احتمالا أن تكون قابلة للتفتيت هي العلامة التجارية (0٪) C. أشارت النتائج إلى أن جميع ماركات أقراص سيبروفلوكساسين لم تكن في حدود اختبار الصلابة وكانت أعلى قيمة صلابة للعلامة التجارية (276 N) C ، وأقل قيمة صلابة كانت للعلامة التجارية (114.2 N) A. كان وقت التفكك لأربع علامات تجارية أقل من 5 دقائق وتم الامتثال لجميع العلامات التجارية لمواصفات BP و USP. تم العثور على منطقة تثبيط أكبر لماركات سيبروفلوكساسين ضد الالتهاب الرئوي الكلبسيلة في العلامة التجارية C (26.19 مم) مما يشير إلى أنه يحتوي على أعلى نشاط وتم العثور على منطقة تثبيط أكبر لماركات سيبروفلوكساسين ضد المكورات العنقودية الذهبية في تم العثور أيضا على العلامة التجارية D (40.40 مم) ومنطقة تثبيط أكبر لماركات سيبروفلوكساسين ضد الإشريكية القولونية في العلامة التجارية D (21.21 مم)) مما يشير إلى أن لديها أعلى نشاط ضد كلا النوعين من البكتيريا. من هذه الدراسة تبين أن جميع العلامات التجارية الأربعة لأقراص سيبروفلوكساسين التي يتم تسويقها في ليبيا تتوافق مع مواصفات BP و USP لاختبار مراقبة الجودة لتوحيد الوزن واختلاف الوزن والتفتيت ووقت التفكك ، باستثناء أنه في اختبار الصلابة في العلامات التجارية الأربع تم العثور على الحد الأقصى ولكن هذا الاختبار غير اختبار شامل وجميع العلامات التجارية لها تأثير مضاد للجراثيم مماثل باستثناء العلامة التجارية C التي لديها نشاط ميكروبيولوجي أفضل قليلا ضد *الالتهاب الرئوي Klebsiella* والعلامة التجارية D وهو أكثر فعالية ضد *المكورات العنقودية الذهبية ، والإشريكية القولونية.*

.الكلمات الدالة .قرص سيبروفلوكساسين ، مراقبة الجودة ، الصلابة ، التفتيت ، التفكك ، النشاط المضاد للبكتيريا