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RESEARCH ARTICLE

A COMPARATIVE QUALITY STUDY OF SELECTED AUTHORIZED AND SMUGGLED MEDICINES IN ADEN, YEMEN

Eman Abdo Ali[1,*], Olfat Saleh Ahmed[1] and Hala Shokri[1]

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

***Corresponding author: Eman Abdo Ali; E-mail: abdo.ali.eman@gmail.com**

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Abstract

In Yemen, most of the medicines are imported. Drugs that enter the country by legal means undergo some tests by Supreme Board for Drugs and Medical Appliances (SBDMA) to evaluate the quality of the product. However, some medicines enter the country illegally (smuggling) and this makes them bypass the evaluation of their quality by the SBDMA. This work was carried out to determine the physical quality control parameters of authorized and smuggled drug products marketed in Aden pharmacies. The authorized and smuggled brands of cefuroxime (CEF), atorvastatin (ATR), and carvedilol (CAR) tablets available in Aden pharmacies were selected. The tablets were evaluated for their physical properties and quality control parameters including weight variation, hardness, friability, and disintegration test. The level of drug content also was evaluated using UV spectroscopy. The physical assessment showed that the authorized and smuggled brands of the same products were uniform in shape, color, packing, and labeling information except for the registration number and manufacture date which were present only on the authorized brands. The three authorized and smuggled brands of CEF, ATR, and CAR complied with the official specifications for weight version, diameter, thickness and hardness, friability, and disintegration tests except for the hardness value of ATR. All authorized brands agreed with the label claims whereas some smuggled brands contained the appropriate active ingredients but did not contain the right amounts.

Keywords: Authorized, Smuggled, Quality Control, Cefuroxime, Atorvastatin, Carvedilol.

Introduction

In the current era of globalization, the safety, effectiveness, and quality of medications are important considerations when choosing the best course of drug therapy [1]. As a result of poverty in Yemen, the majority of people are unable to receive basic medical care and medicines for chronic diseases [2]. Moreover, risk factors that are not adequately managed by administering counterfeit medications, such as high blood pressure, high blood sugar, or high serum lipids, could have serious impacts on people's health [3].

In Yemen, most of the medicines are imported [4]. During transportation, pharmaceutical items must be delivered in such a way that their integrity is not compromised and storage conditions are controlled. Drugs that enter the country by legal means undergo some tests by SBDMA to evaluate the quality of the product. However, some medicines enter the country illegally (smuggling) and this makes them bypass the evaluation of their quality by the SBDMA [5].

Quality control of medications and pharmaceutical formulations includes all steps taken, such as specification setting, sampling, testing, and analytical authorization to guarantee that starting material, intermediate, packaging materials, and final completed pharmaceutical products identify the strength and purity of the drug. A pharmaceutical dosage form's safety and effectiveness can be guaranteed when its quality is stable.

To evalute a tablet, weight variation, content uniformity, thickness, hardness, friability, disintegration, and dissolution should be taken into consideration [6].

Marketing authorizations granted under the "centralized procedure" allow the marketing authorization holder to market the medicine and make it available to patients and healthcare professionals throughout the EU based on a single marketing authorization. Such authorization is

granted by the European Commission following the scientific assessment of the application by the European Medicines Agency [7]

Pharmaceutical legislation primarily aims to ensure that high-quality, safe, and efficient medications are made available, and to provide correct information about them. Drug rules, pharmacy acts, and laws all cover these requirements. The Medicine regulatory authority (MRA) is the enforcing body [8]

Smuggling is a more attractive alternative due to the delays and difficulties that the agents face in obtaining registration and licenses as well as the possibility of tax evasion. There are several reports of how many smuggled medications are discovered in pharmacies.When private pharmacies were investigated by Shabwa Governorate, Behan District, the district council (local heads of department), and the police, discovered that 70% of the drugs were smuggled and 20% of the drugs had no price printed on the package and the remaining 10% were legally imported through an agent, however, their prices had changed. Pharmacists and agents spoken to in Sana'a estimated that between 50 and 80% of drugs are smuggled. Smuggled products are outside any system of quality assurance [9].

According to SBDMA, a society for consumer protection that monitors the use of 192 fake medicines, 176 different drugs are smuggled into Yemen, 46 of which are fake.15 Medicines of doubtful quality, origin, and expiry date are smuggled into the country through illegal channels and pose a serious threat to public health. These medicines are exposed to moisture and light during transport, which affects their quality. Sometimes these medicines become quite popular and the demand for them increases, as in the case of phenolphthalein laxative tablets, which are illegal in Yemen but continue to be sold [10].

Huge amounts of fake drugs flood Yemeni markets and pose serious health threats. Many Yemeni patients have become victims of fake drugs that are not appropriate for human use. Faking medicines generally begin with the most sought-after and rare drug types and then further expanded to other therapeutic categories. Faking medicines can only be identified by their side effects on the patients. There is no control over these drugs' safety, quality, and effectiveness; SBDMA statistics indicate the presence of 46 different fake drugs on the Yemeni market [10].

Many new pharmaceuticals are regularly placed on the market and it is becoming increasingly difficult to track the safety of each drug, which has led to the inflow of falsified or non-standard medicine. Therefore, this study intended to assess and compare the quality of some authorized and smuggled marketed products available in Aden pharmacies.

Materials & Methods

Chemicals

Authorized and smuggled brands of cefuroxime (CEF), atorvastatin (ATR), and carvedilol (CAR) tablets available in Aden pharmacies were selected for this study. Hydrochloric acid (UNI-CHEM – Serbia), methanol (LOBA CHEMIE – India), and distal water are used as solvents.

Instruments

The absorbance of the solution of the tablets was determined using a UV-Vis spectrophotometer (Lasany®, advanced microprocessor UV-VIS-L1-295). Electronic balance (A&D Company Ltd, Japan, HR-250) was used for weighing. The hardness of individual tablets was tested using a Monsanto hardness tester. Friability was evaluated using a friability tester (Campbell Electronics – India) and a micrometer tester (DIN-863/II) was used to determine the dimension of the tablets. A disintegration tester (erweka zt-41, ERWEKA – Germany) was used for the disintegration testing of the products.

Method

Sample Collection

Three different drug products were chosen and assessed, including CEF tablets, 500 mg, ATR tablets, 10 mg, and CAR tablets, 6.25 mg, based on the availability of the medication as an authorized (A) and a smuggled (S) form local pharmacies in Aden city. A comparative quality study was done between authorized and smuggled brands of each type of selected drug product. All the selected samples were tablet dosage form and coded as illustrated in Table 1:

Table 1: Codes of selected drug products

Code	Brand Name
CEF.A	Cefuroxime axetil (Authorized)
CEF. S	Cefuroxime axetil (Smuggled)
ATR. A	Atorvastatin calcium (Authorized)
ATR. S	Atorvastatin calcium (Smuggled)
CAR. A	Carvedilol (Authorized)
CAR. S	Carvedilol (Smuggled)

Physical Assessment

The packaging and labeling of the selected brands were examined carefully to check the required information such as manufacturers' addresses and dates, batch numbers, expiry dates, and amount of active ingredients, registration numbers of both authorized and smuggled brands. Tablet color, and shape, were also determined carefully.

Quality Control Tests:

Weight Uniformity

Tablets (10) from each of the brands were weighed together using an electronic balance and the average weight of a tablet was determined. The tablets were weighed individually and the deviations of the weights of each tablet from the average weight of a tablet were calculated and the results were compared to the standards in the USP [11]. The deviation was calculated according to the following equations (1):

$$\text{Deviation} = \frac{\text{limit }\%}{100} \times \text{average weight of tablet} \quad (1)$$

According to USP, not more than 2 of the individual weights should deviate from the average weight by more than the percentage deviation (Table 2), and non should deviate by more than twice that percentage [12].

Table 2: Limits of weight variation uniformity test according to USP

Weight of Tablet	Limit
130mg or less	10%
130mg to 324mg	7.5%
More than 324 mg	5%

Thickness and diameter

Tablet diameter and thickness were determined with a micrometer. An average of ten tablets from each drug sample was taken. It is expressed in terms of a millimeter. The thickness of a tablet should be controlled within ±5% variation of a standard value depending on the size of the tablet [13].

Hardness Test

Six tablets from each brand were placed in the middle and perpendicular to the Monsanto hardness tester. When the device was started, the equipment was made to gradually apply force onto the tablet until the tablet split, and the force at which the splitting occurred was recorded. The recommended value for tablet hardness is 4-8 kg/cm^2 [14] and 9-15 kg/cm^2 was considered acceptable for film-coated tablets [15].

Friability

The friability of tablets is determined by using a friabilator for 100 revolutions. The friabilator is operated at 25 rpm for 4 min. Ten tablets from each batch are selected randomly and weight. The tablets were subject to the combined effect of abrasion and shock in a plastic chamber in each revolution. The tablets were removed, de-dusted, and weighed again. The Friability of tablets less than 1% is considered acceptable [16]. The % friability was then calculated by the following equation (2) [17].

$$\%\, friability = \frac{intial\ weight - final\ weight}{intial\ weight} \times 100 \quad (2)$$

Disintegration Test

Six tablets were randomly selected from each brand for this test. These selected tablets were placed individually in each of the six cylindrical tubes of the basket rack of the disintegration apparatus using distal water for all selected brands and maintained at 37 °C until no particle remained on the basket of the system. The disintegration time(DT) was taken to be the time at which no granule of any tablet was left on the mesh [18].

Assay Method:

Procedure for preparing calibration curve

Different aliquots of CEF, ATR, and CAR in the range 0.2 - 1 ml were transferred from the stock solution into a series of 10 ml volumetric flasks and the volume was made up to the mark with selected solvent to get concentrations 2, 4, 6, 8, and 10 µg/ml, respectively.

Determination of drug content

Ten tablets from each brand were weighed accurately. An amount of the powered tablet equivalent to 10mg of CEF, ATR, and CAR was weighed and transferred to a 100 ml volumetric flask, dissolved in 20 ml selected solvent (HCL for CEF and methanol for ATR and CAR) by shaking manually for 10 min. The volume was adjusted with the same solvent up to the mark to give final strength (100 µg/ml) .Appropriate volume of 0.6 ml of sample was transferred into 10 volumetric flasks, and diluted to give a concentration of 6 µg/ml [15, 16, 19].

Results & Discussion

Physical Assessment.

Physical characteristics of the tablets, packing, labeling information, and the price for the different brands are represented in Tables 3 and 4 respectively. The results showed that there was a difference in prices in Aden pharmacies between authorized and smuggled brands. The three smuggled brands were cheaper than the authorized of the same product. All authorized brands (CEF.A, ATR. A, and CAR. A) had labels containing registration number, manufacturing, and expiry date, while all smuggled brands (CEF.S, ATR. S, and CAR. S) have expiry dates only.

All tablets were white oblong in shape and packed in Aluminum foil except the brand's CAR. A and CAR.S which were off-white, round, and with blister package. All show no defects on the tablets. Tablets from (CEF. A and CEF. S), (ATR. A and ATR. S), and (CAR. A and CAR. S) were uniform in color, and shape, Figure 1.

Table 3: Physical characteristics of the tablets of the selected brands.

Brand code	Country of origin	Shape	Color	Coated	Package	Price /pack(YR)
CEF. A	Turkey	Oblong	White	Film Coated	Aluminum foil	6000
CEF. S	Turkey	Oblong	White	Film Coated	Aluminum foil	4000
ATR. A	Turkey	Oblong	White	Film Coated	Aluminum foil	6000
ATR. S	Turkey	Oblong	White	Film Coated	Aluminum foil	3000
CAR. A	Turkey	Round	Off-White	Uncoated	Blister pack	5500
CAR. S	Turkey	Round	Off-White	Uncoated	Blister pack	3600

Table 4: Packing and labeling information for the different brands

Product Code	Regis. No.	Strength (mg/tablet)	Active ingredient	Batch No.	Storage condition	Date	
						Manuf.	Expiry
CEF. A	√	√	√	√	√	√	√
CEF. S	X	√	√	√	√	X	√
ATR. A	√	√	√	√	√	√	√
ATR. S	X	√	√	√	√	X	√
CAR. A	√	√	√	√	√	√	√
CAR. S	X	√	√	√	√	X	√

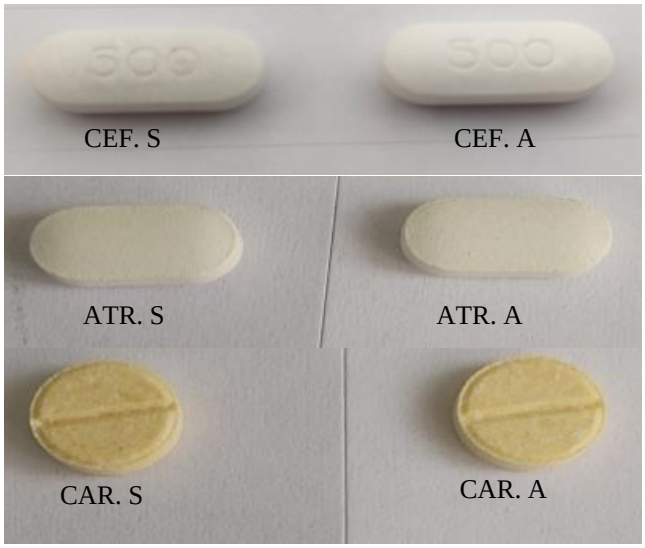


Fig. 1: Tablet appearance of selected authorized and smuggled products.

Tablet weight uniformity

The weight uniformity test was intended to ensure that each tablet contains the same amount and dosage of drugs or active ingredients [16]. Deviations can affect the dose of drug ingredients per tablet. According to USP, not more than 2 of the individual weights should deviate from the average weight by more than the percentage deviation and non should deviate by more than twice that percentage. Therefore, the result showed that all the selected brands passed the test. Moreover, there was no difference between the weight of tablets for the authorized and smuggled brands from each selected product (Table 5).

Table 5: Tablet Uniformity of Weight Test Results (mg)

Parameters	CEF		ATR		COR	
	A	S	A	S	A.	S
Average wt.	914	929	154	157	101	102
Deviation	By ±5%		By ±7.5%		By ±10%	
	46	46	12	12	10	10
Upper limit	960	976	166	168	111	112
Lower limit	868	883	143	145	91	92
No. of tablets deviating	-	-	-	One	-	-
Inference	pass	pass	pass	pass	pass	Pass

Tablet Thickness and Diameter

The size and shape of the tablet depend on the diameter and thickness of the tablet. The results of the thickness and diameter of the samples tablets were represented in Table 6. It is observed that the standard deviations for diameter and thickness were small (less than 5%,), so the size and shape of tablets of each brand are consistent. There was no significant difference between the thickness and diameter of tablets for the authorized and smuggled brands of each selected product.

Tablet Hardness

Tablet preparations should have a certain hardness to be able to withstand a variety of mechanical shocks during manufacturing, packaging, and transportation. The hardness of the CEF. A tablet was 14.75 and for CEF. S was 10.76, meaning that both brands passed the hardness test for coated tablets according to BP[15], while the hardness of the ATR A was 4.60 and ATR. S was 4.05, meaning that both brands failed the hardness test. The difference in the hardness between authorized products and smuggled products may also be due to the differences in granulation methods, binders, and lubricants used in the tablet manufacturing process by each manufacturer [12]. The hardness of the CAR. A was 4.05 and for CAR. S was 4.40, meaning that both brands passed the hardness test for uncoated tablets.

Tablet Friability

The USP states that the friability value of tablets should be less than 1%. As such, CAR. A and CAR.S showed less friability percentage and had passed the friability specification (Table 6). The tablets from CEF.A, CEF.S, ATR.A and ATR.S brands had no loss in their weight after the test.

Disintegration Test

According to USP for film-coated tablets, each test tablet should completely be destroyed within a maximum of 30 minutes and 15 minutes as disintegration time for uncoated tablets [20]. Therefore, the results showed that the disintegration time for (CEF. A and CEF. S), and (ATR. A and ATR. S) was within 30 minutes and hence passed the disintegration test and for CAR. A and CAR. S brands were found to be within specified limits of USP (Table 6).

The difference in the disintegration time of the tablets between CEF. A and CEF. S brands were minor although there were differences between their hardness value. The differences could be attributed to differences in excipients used in the manufacture of the tablets as well as differences in the manufacturing process. [15] , however, the difference in the disintegration time of the tablets from (CAR. A and CAR. S) and (ATR. A and ATR. S) brands were proportional to their results of the hardness test.

A summary of the quality tests for the authorized and smuggled CEF, ATR, and CAR brands was illustrated in Figures 2,3, and 4 respectively.

Table 6: Quality controls tests for the selected brands

Sample		Diameter (mm ± SD)	Thickness (mm± SD)	Hardness (kg/cm^2)	Friability (% loss)	Disintegration (Time/min.)
CEF. A		19.59±0.01	5.84±0.04	14.75±0.37	0	**0.30±1.80**
CEF. S		19.70±0.01	5.88±0.02	10.76±2.25	0	**0.29 ±2.99**
ATR.A		10.18±0.25	3.41±0.03	4.60±0.36	0	**2.16±0.11**
ATR. S		10.07±0.03	3.27±0.24	4.05±0.23	0	**1.20±0.11**
CAR. A		7.08±0.02	2.12±0.03	4.05±0.24	0.02	**3.44±0.32**
CAR.S		7.08±0.04	2.12±0.04	4.40±0.57	0.07	**3.78±0.43**
Criteria	**Film coated**	SD ≤ 5%	SD ≤ 5%	9 – 15kg/cm^2	<1%	**30min.**
	uncoated			4-8 kg/cm^2		**15 min.**

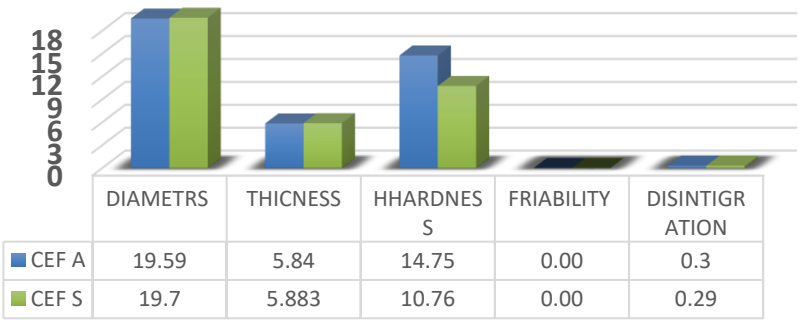
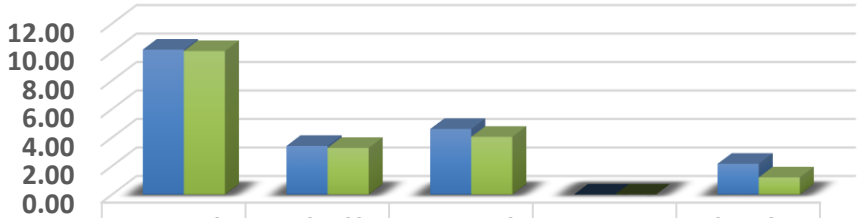
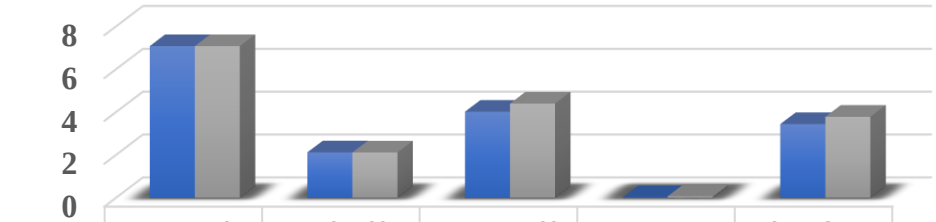


Fig. 2: Quality controls test of CEF.A and CEF.S brands



	DIAMETRS	THICNESS	HHARDNESS	FRIABILITY	DISINTIGRATION
ATR. A	10.18	3.41	4.60	0.00	2.16
ATR. S	10.07	3.27	4.05	0.00	1.20

Fig. 3: Quality controls test of ATR.A and ATR.S brands



	DIAMETRS	THICNESS	HHARDNESS	FRIABILITY	DISINTIGRATION
CAR. A	7.08	2.12	4.02	0.02	3.44
CAR. S	7.079	2.116	4.40	0.07	3.78

Fig. 4: Quality controls test of CAR.A and CAR.S brands

Determination of Maximum Wavelength:

The study of the spectrum revealed that CEF, ATR, and CAR show a well-defined λ max at 281 nm for CEF using 0.1M HCl, 246 nm, and 248 for ATR and CAR respectively using methanol as solvent (Figures. 5,6, and 7 respectively).

Calibration curve

The calibration curve were established from five calibration solutions over the 2-10µg/ml concentration range by plotting absorption vs. concentrations. The calibration curves were done in duplicate. The result are linear and the correlation coefficient (R^2) are 0.9998, 0.9999 and 0.9999 for CEF, ATR, and CAR respectively.

Stright line equation for CEF:

$y=0.0761x + 0.013$

$R^2=0.9998$

Stright line equation for ATR:

$y=0.099x – 0.0036$

$R^2=0.9999$

Stright line equation for CAR:

$y=0.0996x + 0.0107$

$R^2=0.9999$

Determination of drug content

The results of the determination of drug levels for the authorized and smuggled branded tablets are represented in Table 7. The results showed that the authorized brands of CEF and ATR agreed with the label claims whereas, smudged brands of CEF and ATR tablets contained the appropriate active ingredients but did not contain the right amounts. The CAR. A and CAR.S tablets contained the right amounts of active ingredients and were in good agreement with the label claims according to the USP specification.

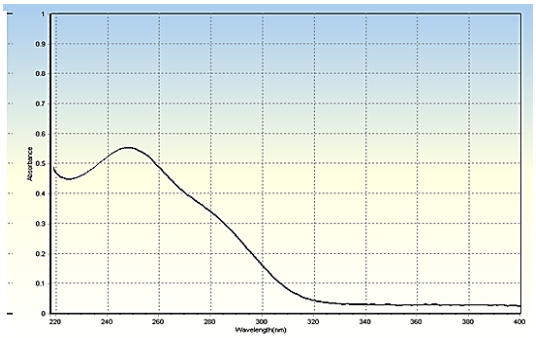


Fig. 5: UV spectrum of cefuroxime

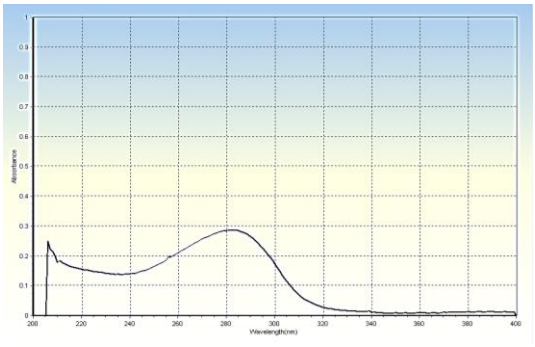


Fig. 6: UV spectrum of Atorvastatin

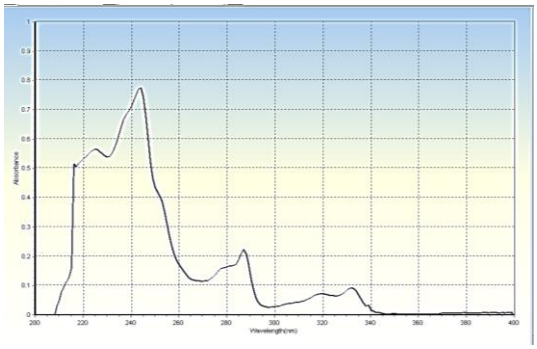


Fig. 7: UV spectrum of Carvedilol

Table 7: Content of atorvastatin in ATR.A and ATR.S brands

Sample	Label claim (mg/tablet)	Amount found mg/tablet	potency	Criteria (USP)
CEF. A	500	500.80±0.63	100.16 ±0.13	90–110%
CEF. S	500	404.62±1.10	80.92 ±1.33	
ATR. A	10	9.65±0.01	96.52±0.61	
ATR. S	10	8.09±0.06	80.94±0.61	
CAR. A	6.25	6.20±0.07	99.18 ±1.13	
CAR. S	6.25	5.84±0.08	93.44 ±1.33	

Conclusion

The authorized and smuggled brands of various drug products are available in Aden pharmacies. This study intended to evaluate the quality of different marketed authorized and smuggled products: CEF, ATR and CAR brands tablets available in Aden pharmacies. Physical assessment of the authorized and smuggled brands of the same product were uniforms in shape, color, packing, and labeling information except for the registration number and product date were present only on the authorized brands. All authorized brands used in this study agreed with the label claims whereas some smuggled brands (CEF ,ATR)contained the appropriate active ingredients but did not contain the right amounts.

Recommendation

Consumers should be educated by health authorities and healthcare providers, about the potential danger that consuming illegal drugs could cause. Other brands not covered in this study could as well undergo a similar evaluation.

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مقالة بحثية

دراسة مقارنة بين جودة الأدوية المرخصة والمهربة في عدن، اليمن

أيمان عبده علي[1]*، ألفت صالح أحمد[1] و هالة شكري[1]

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

* الباحث الممثّل: أيمان عبده علي؛ البريد الالكتروني: abdo.ali.eman@gmail.com

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المُلخّص

في اليمن، يتم استيراد معظم الأدوية. تخضع الأدوية التي تدخل البلاد بالوسائل القانونية لبعض الاختبارات من قبل المجلس الأعلى للأدوية والأجهزة الطبية (SBDMA) لتقييم جودة المنتج. ومع ذلك، فإن بعض الأدوية تدخل البلاد بشكل غير قانوني (التهريب) وهذا يجعلها تتجاوز تقييم جودتها من قبل (SBDMA). تم تنفيذ هذا العمل لتحديد معايير مراقبة الجودة المادية لمنتجات الأدوية المصرح بها والمهربة التي يتم تسويقها في صيدليات عدن. تم اختيار العلامات التجارية المعتمدة والمهربة من أقراص سيفوروكسيم وأتورفاستاتين وكارفيديلول المتوفرة في صيدليات عدن. تم تقييم الأقراص لخصائصها الفيزيائية ومقاييس مراقبة الجودة بما في ذلك تباين الوزن والصلابة والتفتيت واختبار التفكك. كما تم تقييم مستوى محتوى الدواء باستخدام التحليل الطيفي للأشعة فوق البنفسجية. أظهر التقييم المادي أن العلامات التجارية المصرح بها والمهربة لنفس المنتجات كانت موحدة في الشكل، اللون، التعبئة ومعلومات الملصقات باستثناء رقم التسجيل وتاريخ التصنيع اللذين كانا موجودين فقط على العلامات التجارية المعتمدة. امتثلت العلامات التجارية الثلاث المعتمدة والمهربة (CEF) و (ATR) و (CAR) للمواصفات الرسمية لإصدار الوزن والقطر والسماكة والصلابة والتفتيت والتفكك باستثناء قيمة صلابة (ATR). وافقت جميع العلامات التجارية المعتمدة على مطالبات الملصق بينما احتوت بعض العلامات التجارية المهربة على المكونات النشطة المناسبة ولكنها لم تحتوي على الكميات الصحيحة.

الكلمات المفتاحية: مرخص، مهرب، مراقبة الجودة، سيفوركسيم، أتورفاستاتين، كارفيديلول.

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