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Evaluation of the quality of 500mg paracetamol tablets dispensed in the formal sector of the city of Ndjamena

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Abstract

Introduction. Ensuring the quality of medications, whether they are produced locally or imported, is an essential pillar of any healthcare system. Quality control tests ensure that products comply with pharmaceutical standards and thus protect patients from the risks of adverse effects or therapeutic failure.

In Chad, the circulation of counterfeit medications persists even within the official supply chain, amplifying the threats to public health. This work aims to evaluate the quality of 500 mg paracetamol tablets marketed in the formal circuits of the city of N'Djamena.

Materials and methods. We conducted an experimental study lasting 6 months using as a reference the standards of the European Pharmacopeia 8.0 IV th edition and the American 37NF32. The samples from different batches were selected using a non-random method in the city of N'Djamena. The pharmacotechnical tests conducted concerned labeling, visual inspection, hardness, disintegration, friability, mass, and dimensions. The physicochemical tests focused on the identification and quantification of the active ingredients.

Results. Three (3) come from Africa, which is a rate of 15%, eight (8) come from Asia, which is a rate of 40%, and nine (9) come from Europe, which is a rate of 45%. The non-conformities found were: hardness (65%), friability (15%), labeling 7 lots (40%), approval (15%), and principal dosage. The compliant parameters were Disintegration, mass uniformity, principal identification, and sizing.

Conclusion. Out of all the batches analyzed, 16% were declared non-compliant and 84% were compliant with the analyzes. These non-conformities can be due to a manufacturing defect, the failure of the quality assurance system, and sometimes intentional malpractice by certain laboratories. All these non-conformities expose the population to therapeutic failures, deaths, worsening of existing pathology, therapeutic adherence problems, and the emergence of fever resistance phenomena.

Keywords: Evaluation; Paracetamol; Quality; Tablet; Formal Sector

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1. Introduction

The World Health Organization (WHO) defines the quality of a drug as all the factors that guarantee its safety and efficacy, from manufacturing to marketing. According to this definition, one in ten medicines circulating in resource-limited countries is substandard or falsified (1). These countries are mainly located in Africa, Asia, and South America, where the absence of local pharmaceutical industries makes populations dependent on imports (5).

In 2013, American researchers analyzed 17,000 samples of drugs used to treat tropical diseases and found that nearly 41% did not meet the required quality standards (3).

The Food and Drug Administration (FDA) estimates that approximately 10% of drugs sold on the global market are counterfeit; this figure rises to 80% in some African countries. The FDA also concludes that 25% of drugs consumed in the poorest countries are fake and that these products result in a price reduction of approximately 45% for donors (5).

A recent WHO alert (7) highlighted the counterfeit drug COMBIART (a combination of artemether and lumefantrine) in Chad, Côte d'Ivoire, and Mali (8).

The lack of robust quality assurance systems in these countries exposes populations to increased health risks (6).

In Asia, particularly in China, it is estimated that 200,000 to 300,000 people die each year due to poor-quality medicines; between 30% and 50% of medicines sold in pharmacies are of inferior quality (2).

In Yaoundé and Niamey, a study conducted in 2007 revealed non-compliance rates of 50% and 58% respectively in a study on antimalarial drugs (4).

In Chad, counterfeit medicines continue to circulate even in the official supply chain, thereby increasing the risks to public health (27).

Although several studies have examined the quality of medicines in Chad, few focus specifically on paracetamol, one of the most commonly prescribed analgesics by clinicians (9).

With this in mind, our study aims to assess the quality of paracetamol in the form of 500 mg tablets sold through formal channels in the city of N'Djamena.

The results will enable the creation of a reliable database and guide public policies aimed at strengthening pharmaceutical quality control in Chad.

2. Methodology

2.1. Study framework and period

This is a comparative experimental study conducted between July 2022 and January 2023. Samples were taken from pharmaceutical establishments in the city of N'Djamena. The analysis was carried out in two specialized laboratories: the National Laboratory for Drug Quality Control, located in N'Djamena (Chad), and the Food Quality Control Laboratory, based in Douala (Cameroon). These two sites were used to examine the quality of the paracetamol tablets collected.

2.2. Duration of the study

Sample collection took place over two months (July–August).

The experimental analyses, followed by statistical processing, lasted four months (September 2022–January 2022). The study thus covered a total period of six consecutive months.

2.3. Methods and materials

2.3.1. Target

The study focused on 500 mg paracetamol tablets sold through legal channels in the city of N'Djamena.

2.3.2. Sample selection criteria

Only medicines with paracetamol as the sole active ingredient, sold in tablet form, were included in the study.

All combination medicines and all other dosage forms (capsules, effervescent tablets, suspensions, etc.) were systematically excluded to ensure the homogeneity of the sample population.

2.3.3. Sampling

Sampling was carried out using a non-random method, consisting of selecting paracetamol-based painkillers marketed in tablet form in the formal distribution channels of the city of N'Djamena. We prioritized the diversity of batches available on the market at the time of the study in order to obtain a minimum of 120 tablets per batch, in accordance with the requirements stipulated by the European Pharmacopoeia 8.0 (4th edition) and the US Pharmacopoeia 37NF32 **(11,12).**

2.4. Sample analysis techniques

2.4.1. Labeling control

Principle: This consisted of verifying that all information concerning the name of the drug, the international nonproprietary name (INN), the active ingredient dosage, the pharmaceutical form, the name and address of the manufacturer, the batch assigned by the manufacturer, the expiry date and date of manufacture, and storage data was indicated on the drug label (11).

2.4.2. Visual inspection

Principle: This involved checking the physical appearance of the tablets. Tablets should generally be uniform in appearance (color, odor, shape, appearance, breakability) and comply with the specifications in the manufacturer's dossier. They should not be damaged, and the surface should be smooth (11).

2.4.3. Mass uniformity test

Principle: This involved checking that the individual weights of a specified number of tablets taken from the batch were within a narrow range around the average weight of the tablets in the sample taken (11).

Procedure: Take 20 tablets at random;

Weigh each tablet on a precision scale accurate to 0.0001g. The individual mass of no more than two (02) of the twenty (20) units may deviate from the average mass by a percentage higher than that indicated in the following table, but the mass of no unit may deviate by more than twice that percentage.

Pharmaceutical forms weight	**Average weight**	**Limit deviation and percentage of average weight**
Uncoated tablets and	80 mg or more	10
Film-coated tablets	More than 80 mg and less than 250 mg	7.5
	250 mg or more Film-coated tablets	5

Source: European Pharmacopoeia 6 (2008). Volume 1

2.5. Disintegration test

Principle: This test determined the tablets' ability to disintegrate in a liquid medium within a specified time and under well-defined experimental conditions. This test is part of the tests to check the “in vitro availability” of the active ingredient contained in the tablets (11).

Procedure: randomly select 6 tablets; place 1 tablet per tube; check the temperature: 37°C +/- 2; adjust the volume of the immersion liquid, start disintegration.

Disintegration is achieved when there is no residue on the grid; if there is any residue, it consists only of a soft mass with no palpable core; only fragments of the coating remain on the grid. Record the disintegration time. According to the standard, the disintegration time for an uncoated tablet is less than or equal to 15 minutes (11).

2.6. Friability test

Principle: this consisted of subjecting tablets to a regular drop force for a given time in order to assess the loss of mass of these tablets (11).

Procedure: take 12 tablets; remove any dust; weigh them (Mi) using a weighing pan; place them in the friability tester for a period of time t, rotating them in a cylinder while checking that the tablets fall evenly, and weigh them again (Mf) after removing any dust. The maximum mass loss considered acceptable is 1%.

2.7. Hardness or breaking strength test

2.7.1. Principle

The hardness of a tablet is determined by measuring the intensity of the force applied diametrically to it to cause it to break by crushing **(14).**

2.7.2. Procedure

Randomly select 10 tablets, measure the hardness of the 10 tablets with the durometer, taking care to remove all tablet debris before each measurement, calculate the average hardness Dmc, identify the maximum hardness obtained (Dmax) and the minimum hardness obtained (Dmin), calculate the upper control limit: LCS = Dmc x 1.1, calculate the lower control limit: LCI = Dmc x 0.9. The tablets are compliant if none of the hardness values obtained is greater than the calculated LCS and less than the calculated LCI.

Protocol for identifying and measuring the active ingredient

2.7.3. Identification

The active ingredient paracetamol was identified by thin-layer chromatography in the presence of 2mg/ml or 10mg/5ml. (NaOH 0.1 M) (extraction solvent), and 14 mL methanol, 4 mL concentrated ammonia (development solvents) **(12).**

2.8. Assay of the active ingredient

2.8.1. Principle

This test is designed to determine whether 500mg paracetamol tablets actually contain 500mg of paracetamol using UV/Visible spectrophotometry **(13).**

Take 20 tablets, crush them thoroughly in a mortar, and weigh out a precise amount (equivalent to approximately 75mg of paracetamol).

Place in a 100 ml flask, add 25 ml of 0.1 M NaOH solution, 50 ml of distilled water, shake for 15 min in an ultrasonic bath and make up to volume with distilled water.

Filter using filter paper, discarding the first ml of filtrate, then take 10 ml of filtrate, place it in a 100 ml flask, make up to volume with distilled water, then filter, take 5 ml of filtrate, place it in a 50 ml flask, make up to volume with distilled water, and determine the absorbance at a wavelength of 257 nm.

2.9. Administrative authorization for research

Authorization to carry out this work was obtained from the Dean's Office of the Faculty of Medicine and Biomedical Sciences at the University of Yaoundé I. The anonymity of the sellers in the formal circuit and of the manufacturing laboratories (as indicated on the label) of the drugs collected was preserved.

2.10. Statistical analysis of data

Data entry: Microsoft Excel 2013 Processing: SPSS software version 20.0. The results were presented in terms of numbers and frequencies. The Phi test was used to identify associations between variables. Reduced deviation test: binomial distribution score used to compare proportions (compliance rates).

3. Results

3.1. Paracetamol tablets collected

The drug samples consisted of 20 batches of paracetamol tablets, with a minimum of 120 tablets per batch.

3.2. Distribution of samples

Three (3) came from Africa, representing 15% of the total, eight (8) came from Asia, representing 40%, and nine (9) came from Europe, representing 45%.

3.3. Approval of samples

Of the 20 batches, seventeen (85%) had valid marketing authorization and three (15%) did not. This could explain the non-compliance with current regulations, which may result in the consumption of products of dubious quality by the population.

3.4. Labeling and organoleptic characteristics control

Eight non-compliant batches were identified, representing 40% non-compliance compared to 60% compliance.

Visual observations of the tablets show that all of our samples are white in color, round in shape with flat edges, and have a bare appearance. It should also be noted that most of the paracetamol samples taken had a break line on one of the two sides.

3.5. Visual inspection

All 20 sample batches (100%) analyzed were compliant with the visual inspection, i.e., 100%.

3.6. Uniformity of dimensions

We note that the values obtained are all conclusive; the thickness of the 20 tablets is within the recommended range and does not exceed the standard [4.08 to 4.68 mm].

3.7. Hardness test

Thirteen batches of samples did not comply with the hardness requirement, i.e., 65%. These 10 samples had tablets with hardness values below the LCI (lower control limit).

4. Discussion

Twenty batches were analyzed as part of our study; of these, 16.84% were found to be non-compliant with the specifications of the various pharmacopoeias in force. This rate is lower than that reported by Awono et al. (26.29%) in Cameroon in 2021 **(15),** who assessed the pharmaco-technical quality of paracetamol on the legal and illegal markets in the Ébolowa region (southern Cameroon): public health issues. This discrepancy in results can be explained by the smaller size of our sample compared to the study by Awono et al.

4.1. Pharmaceutical testing

4.1.1. Labeling control

With regard to labeling non-compliance, we identified 07 batches, or 20.14%. This rate is lower than that reported by Awono et al., who found 25% non-compliance in their study on the pharmaco-technical evaluation of paracetamol in the legal and illegal markets of Ébolowa (Southern Region of Cameroon). It is also lower than the result obtained by Diop et al. **(16),** who detected one case of counterfeit paracetamol generics in the illicit market in Senegal.

Faulty labeling indicates a failure to comply with good manufacturing practices and can lead to poor therapeutic compliance, poisoning, deterioration of the dosage form, and a lack of product traceability.

4.1.2. Based on organoleptic characteristics

Of the 20 batches analyzed, 100% were found to comply with the established criteria. This result contrasts with the study conducted by Diop et al. **(17)** in Senegal, where 23% of batches were found to be non-compliant when analyzed for the organoleptic characteristics of paracetamol.

4.2. Based on hardness

4.2.1. Mass uniformity

No batches were reported as non-compliant. This finding is consistent with the study conducted by KOUONANG (20), which detected no non-compliance, and differs from the results obtained by DJIM-MADJIM (1.1%) (22) and MBADINGA (1%) in 2008 in Mali **(21)** in their analyses of the quality control of amodiaquine and quinine.

A lack of mass uniformity indicates poor distribution of the active ingredient, which can result in under- or over-dosing of certain tablets.

4.2.2. Based on the disintegration test

The disintegration test assesses the ability of tablets to disintegrate under temperature and pH conditions corresponding to in vivo conditions. All batches comply with disintegration tests. This result was contrary to that of Diop et al. **(17),** who found a non-compliance rate of 6.25%. This reassures the bioavailability of the tablets in the batches studied, which may have a good percentage.

4.2.3. Friability test

Regarding friability, 15% were non-compliant. This result was higher than that of DANZABE, which found 11.1% non-compliance (23). Poor friability may be due to a manufacturing problem.

4.2.4. Identification of the active ingredient

The results of the active ingredient identification test show that all the tablets analyzed did indeed contain paracetamol. It passed the test 100%. This result is similar to that found by Awono et al. (15) in a study on the pharmaco-technical evaluation of paracetamol in the legal and illegal markets of Ébolowa (southern region of Cameroon) in 2021. However, this result differs from that found by Ousmane SIDIBE in 2011, (24) who detected 7.04% of non-compliance cases in a study on the quality control of antimalarial drugs in seven (07) administrative regions of Mali.

4.2.5. Dosage of the active ingredient

With regard to dosage, we found a non-compliance rate of 16%, which exceeds that reported by NGUENANG (6.67%) (25) in a study conducted in 2017 in Yaoundé on quinine sulfate tablets sold in pharmacies. Conversely, this result is lower than that obtained by ReMeD in 1997 (26), who found a non-compliance rate of 24% for the quality of cotrimoxazole in Cambodia and Africa. This disparity can be explained by manufacturing defects, counterfeiting, or poor workmanship in certain laboratories.

Under-dosing of this drug exposes the population to treatment failure, worsening of the underlying disease, and compliance issues.

5. Conclusion

Our study focused on evaluating the quality of 500 mg paracetamol tablets dispensed in the formal sector in the city of N'Djamena. A t otal of 20 samples were analyzed, 82.77% of which were compliant and 17.23% non-compliant. These non-compliances are probably due to manufacturing problems, non-compliance with pharmaceutical regulations, and inadequate storage conditions. These data suggest that contamination and counterfeiting are not yet fully under control in Chad.

The consequences for public health are manifold: risk of therapeutic failure, worsening of pathologies, and loss of confidence in pharmaceutical systems. By highlighting these shortcomings, our study makes a modest but significant contribution to alerting and raising awareness among health authorities and to the implementation of targeted corrective measures (strengthening quality control, improving storage conditions, and awareness campaigns).

Compliance with ethical standards

Disclosure of conflict of interest

Authors have declared that no competing interests exist.

Authors' contributions

DF and ABH carried out the study; AMAH, HMB and TJ participated in data collection and laboratory experiments; DF, HMB,ADA and AMAH analyzed the data; ABH, SYA,AC and DF drafted the manuscript; ABH, AC and DF read and corrected the manuscript; AC and NN supervised the work; all authors read and approved the final manuscript

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