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Quality of Essential Medicines from Different Sources in Enugu and Anambra, Nigeria

Julia Gabel,[1] Micha Lächele,[1] Katharina Sander,[1] Gesa Gnegel,[1] Nkiru Sunny-Abarikwu,[2] Rita Ezinwanne Ohazulike,[2] Juliet Ngene,[2] Jane Frances Chioke,[2] Christine Häfele-Abah,[3] and Lutz Heide[1]*

[1]*Pharmaceutical Institute, Eberhard Karls University Tübingen, Tübingen, Germany;* [2]*Faith-Based Central Medical Foundation (FBCMF), Enugu, Nigeria;* [3]*German Institute for Medical Mission (Difaem), Tübingen, Germany*

Abstract. This study investigated the quality of 13 essential medicines in the states of Enugu and Anambra, Nigeria. A total of 260 samples were purchased from licensed pharmaceutical manufacturers and wholesalers and from vendors in pharmaceutical markets with unclear licensing status. Samples were analyzed for identity, content, and dissolution according to the United States Pharmacopeia (USP) 42 monographs. Forty-five samples of this study could be examined for authenticity with the Mobile Authentication Service scheme of the Nigerian National Agency for Food and Drug Administration and Control. Out of all samples, 25.4% did not comply with the USP 42 specifications. Strikingly, 21 out of 22 dexamethasone tablet samples (95%) were out of specification (OOS). Nine out of 19 glibenclamide samples (47%) failed dissolution testing, and 7 out of 17 cotrimoxazole samples (41%) failed assay testing. Medicines against noncommunicable diseases showed a slightly higher percentage of OOS samples than anti-infectives (21.2% versus 17.6%). The rates of OOS samples were similar in medicines stated to be produced in Nigeria, India, and China but were very different between individual manufacturers from each of these countries of origin. Therefore, prequalification of products, manufacturers, and suppliers are very important for quality assurance in medicine procurement. Unexpectedly, the total proportions of OOS samples were similar from licensed vendors (25.2%) and from markets (25.5%). Four samples (1.5%), all collected in markets, were clearly falsified and did not contain the declared active pharmaceutical ingredients. The proportion of falsified medicines was found to be lower than frequently reported in the media for Nigeria.

INTRODUCTION

The United Nations demand in their Sustainable Development Goals "access to safe, effective, quality and affordable essential medicines" for all.[1] However, the achievement of this goal is compromised by the frequent occurrence of substandard and falsified (SF) medicines. As defined by the WHO,[2] falsified medicines are "medical products that deliberately/fraudulently misrepresent their identity, composition or source." Substandard medicines are "authorized medical products that fail to meet either their quality standards or their specifications, or both." Substandard and falsified medicines can lead to increased mortality and morbidity but also to economic loss and increased poverty.[2] Furthermore, underdosed anti-infectives can contribute to the emergence of antimicrobial resistance.[3]

Especially low- and middle-income countries (LMICs) suffer from SF medicines. A systematic review by the WHO from 2017[2] estimated a prevalence of 10.5% SF medicines in LMICs. A more recent meta-analysis by Ozawa et al.[4] estimated an overall prevalence of 12.4% of SF medicines in all LMICs and 18.9% in African countries. Another review calculated a prevalence of even 25%.[5] However, all these reviews state that the reported prevalence rates are very heterogeneous between individual studies and that more consistent data on the quality of medicines are urgently required. Such data could support policymakers on the best use of resources to tackle the problem of SF medicines and to implement the three-pronged strategy of prevention, detection, and response suggested by the WHO.[6]

Heterogeneous findings on the prevalence of SF medicines have also been reported from Nigeria. Table 1 summarizes the results of the 11 most important studies published since 2001. These studies investigated different types of medicines and used high-performance liquid chromatography (HPLC) for analysis. The reported percentages of samples not containing the declared active pharmaceutical ingredient (API) ranged from 0% to 4%. Importantly, the reported percentages of substandard samples, showing incorrect amounts or insufficient dissolution of the API, ranged from 1.3% to 74%, with a median value of 29% that markedly exceeds the overall estimate for LMICs in the WHO review mentioned above.[2]

Several other studies[7–9] investigated medicine quality in Nigeria using the Global Pharma Health Fund (GPHF)-Minilab, which is based on thin-layer chromatography (TLC).[10] However, as GPHF-Minilab analysis has a lower sensitivity than HPLC analysis for the detection of substandard medicines,[11] their results cannot be compared with those of the above-mentioned studies. A few further medicine quality studies included only small sample numbers from Nigeria.[12–19]

The Nigerian national medicine regulatory agency (National Agency for Food and Drug Administration and Control [NAFDAC]) has conducted medicine quality surveys in collaboration with the United States Pharmacopeia (USP), but the methods and results of these studies have not been published in full scientific detail. The study by NAFDAC included in Table 1 was summarized in a NAFDAC newsletter in 2019.[20] In that survey, analysis of all samples was carried out with the GPHF-Minilab. Samples failing Minilab analysis, as well as a certain percentage of samples passing Minilab analysis, were subjected to confirmatory assay testing using HPLC.

The above-mentioned studies clearly demonstrate that in Nigeria, as in other LMICs, quality assurance in drug procurement is extremely important for achieving "access to quality medicines for all" as demanded in the Sustainable Development Goals of the United Nations. In Nigeria, as in most other African countries, faith-based organizations

* Address correspondence to Lutz Heide, Pharmaceutical Institute, Eberhard Karls University Tübingen, Auf der Morgenstelle 8, 72076 Tübingen, Germany. E-mail: heide@uni-tuebingen.de

TABLE 1
Previous studies on SF medicines in Nigeria

Study	Type of Investigated Medicines	Parameters Investigated (Specifications Used)	No. of Samples Investigated	No. (%) of Falsified Samples Not Containing the Stated API(s)	No. (%) of Substandard Samples	Comment
Taylor et al. (2001)[71]	Anti-infectives	Assay (BP)	581	6 (1.0)	273 (47)	Somewhat unusually, most of the substandard samples were reported to contain an excessive amount of API.
Onwujekwe et al. (2009)[72]	Antimalarials	Dissolution profile; API amount* (USP)	225	9 (4.0)	51 (23)	Abstract and text state "37% did not meet USP specification"; however, this is a calculation error.
WHO (2011)[43]	Antimalarials	Assay; dissolution (USP, Ph. Int.)	61†	2 (3.3)†	29 (48)†	15 samples (25%) showed deviations classified as "extreme" based on the criteria also used in the present study (see "Definitions of medicine quality"). Related substances and uniformity of mass of dosage units were investigated as well.
Ebenezer (2015)[73]	Metformin	Assay (BP)	179	0 (0)	7 (3.9)	The study compared the originator product Glucophage® (Merck KGaA, Darmstadt, Germany) with generic medicines. All originator samples were in specifications.
WHO (2016)[74]	Medicines for maternal health	Assay (USP, BP, Ph. Int.)	17†	0 (0)†	5 (29)†	
Kaur et al. (2016)[75]	Artemisinin-based combinations	Assay (limits 85–115%)	3,024	(1.2)	(6.6)	Only percentages, not numbers of SF medicines, are given. Assay tolerance limits are wider than those of USP and may lead to a 3-fold-lower prevalence estimate compared with that of studies using USP specifications.[39]
Anyakora et al. (2018)[76]	Medicines for maternal health	Assay (USP)	Oxytocin, 159; misoprostol,166	Oxytocin, 1 (0.6); misoprostol, 0 (0)	Oxytocin, 117 (74); misoprostol, 56 (34)	Also investigated magnesium sulfate and calcium gluconate injections, reporting 6.8% and 2.4% of substandard samples, respectively.
Lawal et al. (2019)[77]	Oral antibiotics	Assay (USP, BP)	112	3 (2.7)	40 (36)	
Redfern et al. (2019)[78]	Amlodipine, lisinopril	Assay (USP)	361	0 (0)	101 (28)	
Ndichu et al. (2019)[79]	Nifedipine	Assay (Ph. Int.)	102	0 (0)	30 (29)	
NAFDAC (2019)[20]	Antimalarials	GPHF-Minilab; assay (USP?)	907	0 (0)	12 (1.3)	All samples were analyzed with GPHF-Minilab. Samples failing Minilab analysis, as well as a certain percentage of samples passing Minilab analysis, were analyzed by HPLC, probably according to USP.

API = active pharmaceutical ingredient; BP = British Pharmacopoeia; HPLC = high-performance liquid chromatography; Ph. Int. = International Pharmacopoeia; SF = substandard and falsified; USP = United States Pharmacopeia.
* Onwujekwe et al. (2009)[72] calculated the API amount from the dissolution testing experiment.
† Several countries were investigated in these studies, but the numbers shown here are for Nigeria only.

provide an important part of the health services to the population, including pharmaceutical services.[21–23] Many faith-based drug supply organizations are members of the Ecumenical Pharmaceutical Network (EPN).[21] The EPN describes itself as an "independent, non-profit, Christian organization committed to provide quality-assured pharmaceutical services".[24] In Nigeria, one of the EPN member organizations is the Faith-Based Central Medical Foundation (FBCMF), based in the state of Enugu. The FBCMF procures medicines within Nigeria and supplies them primarily to faith-based health facilities in Enugu and neighboring states. The EPN gives great importance to pharmaceutical quality assurance, and the FBCMF has been an active member of the "Difaem-EPN Minilab Network" since 2017, employing the GPHF-Minilab[10] for local medicine quality screening.[9,25,26]

The present study was undertaken to assist the FBCMF and other stakeholders in Nigeria in the further improvement of their quality assurance in drug procurement. As explained in Materials and Methods, 13 essential medicines important in the FBCMF's medicine supply operation were chosen, comprising both medicines against infectious diseases and medicines against noncommunicable diseases (NCDs). Because the sampling for the present study was conducted during the COVID-19 pandemic, two medicines with alleged or real relevance for the treatment of COVID-19 were included, i.e., chloroquine and dexamethasone, respectively. All these medicines were purchased in Nigeria from a total of 62 different commercial sources, including licensed manufacturers and wholesalers as well as pharmaceutical "markets" of unclear licensing status. The quality of the medicines was investigated locally by FBCMF staff using the GPHF-Minilab and at Tübingen University, Germany, according to the USP for the content and dissolution of the APIs. The registration numbers of the medicines were compared with Nigeria's Registered Drug Product Database (the "NAFDAC Greenbook").[27] Medicines carrying a personal identification number (PIN) code of NAFDAC's Mobile Authentication Service (MAS) scheme[28] were tested for the authenticity information provided by this scheme using short messaging service (SMS) messaging in Nigeria.

The quality of the investigated medicines was found to be very different between different types of medicines and between different manufacturers, and these results may be useful for the further improvement of pharmaceutical quality assurance by the FBCMF and other stakeholders in Nigeria and elsewhere.

MATERIALS AND METHODS

Study design and ethical approval. The study design is based on the guidelines on the conduct of surveys of the quality of medicines published by the WHO in 2016[29] and the Medicine Quality Assessment Reporting Guidelines.[30] The study protocol was submitted to the Enugu State Commissioner of Health, and permission for this study was granted on January 30, 2021.

Included medicines. Thirteen medicines were included in this study (Table 2). The medicines were selected based on their compliance with several or all of the following criteria: 1) inclusion in the Nigeria Essential Medicines List 2020[31]; 2) availability of a monograph in the USP 42 for compendial analysis; 3) availability of a monograph for their analysis with the GPHF-Minilab,[32] including the possibility for their detection by TLC using ultraviolet (UV) light (254 nm); 4) economic importance in the medicine procurement and distribution by the FBCMF; 5) inclusion in a previous study of our group in Cameroon and the Democratic Republic of the Congo (DRC),[11] to allow a comparison of results; and 6) alleged or true relevance for the treatment of COVID-19.[33,34] Based on advice by the FBCMF, the most common dosage forms and strengths were selected to be preferably sampled. If the medicine was not available in the form of tablets at a sampling site, capsules could be sampled, and vice versa. If the preferred strength was not available, a different strength could be sampled but only adult dosages. Injectables and oral dosage forms could not be substituted for each other.

Sample size calculation. In a previous study in Cameroon and the DRC,[11] 12.3% of the medicine samples from health facilities in the formal sector had been found to be noncompliant with pharmacopeial specifications, in contrast to 28.2% of the samples from informal vendors. Using these proportions, the minimum sample size required to observe a significant difference between these groups with 95% confidence and a power of 80% was calculated as 97 samples per group, applying the formula[35]

$$n=(Z_{\frac{\alpha}{2}}+Z_{\beta})^2\times(p_1(1-p_1)+p_2(1-p_2))/(p_1-p_2)^2$$

where n is the minimum sample size required, $Z_{\alpha/2}$ is the critical value of the normal distribution at $\alpha/2$, i.e., 1.96 for a 95% confidence level ($\alpha = 0.05$), Z_{β} is the critical value of the normal distribution at β, i.e., 0.84 for a power of 80% ($\beta = 0.2$), and p_1 and p_2 are the expected sample proportions of the two groups, i.e., 12.3% and 28.2%, respectively.

It was therefore decided to attempt collection of 10 samples of each of the 13 medicines from licensed manufacturers and wholesalers and another 10 samples each from pharmaceutical "markets" with unclear licensing status, resulting in a theoretical number of 130 samples per group.

Number of units purchased for each sample. For each sample, if possible, 100 tablets/capsules, or 20 vials in the case of ceftriaxone injections, were purchased. If the medicine was sold only in packages larger than 100 tablets/capsules or 20 vials, the entire package was purchased to obtain the original packaging, provided the expense for a single sample did not exceed 20,000₦ (approximately $50). If only a smaller amount than 100 tablets/capsules or 20 vials was available, this smaller amount was collected, but not fewer than 30 tablets/capsules or five vials per sample.

Sampling sites and sample collection. Medicines were collected from two types of sources: 1) licensed pharmaceutical manufacturers and wholesalers (hereafter referred to as licensed vendors) and 2) vendors in pharmaceutical markets of Onitsha and Enugu with unclear licensing status (hereafter referred to as markets).

As part of its medicine procurement and distribution operation, the FBCMF keeps a list of licensed vendors. For the present study, the 74 vendors on the list at that time were contacted by the FBCMF staff using WhatsApp for the procurement of the 13 medicine types listed in Table 2, without mentioning the intended medicine quality testing. Medicines were subsequently bought from those suppliers who could

most readily deliver the requested items. Most licensed vendors were able to offer only one or a few of the 13 medicine types requested.

The market in Onitsha (Anambra State) is well known as one of the largest cluster of market vendors of medicines in Nigeria.[36–38] These vendors operate in professional-looking premises, but their status of licensing is unclear. A similar but much smaller market is located in Enugu town (Enugu State). Even private hospitals and pharmacies frequently buy medicines from these markets.[36] Occasionally, the FBCMF also needs to purchase medicines from these markets, especially when a certain product is unavailable from the licensed vendors. For the present study, four FBCMF staff members visited Onitsha and Enugu pharmaceutical markets to purchase the study medications, again without mentioning the intended medicine quality testing. No questions were asked by the market vendors about the reasons for the purchase. The FBCMF staff members selected the market vendors for this study based on convenience, first visiting the largest market vendors in Onitsha market and subsequently neighboring ones. Sample collection was carried out first in the Onitsha market and subsequently in the Enugu pharmaceutical market.

Especially the larger market vendors were able to offer several of the 13 medicine types requested and often more than one brand of each type of medicine. All available brands were purchased until the desired number of samples was reached. Because several FBCMF staff members were carrying out the purchases in parallel, the targeted number of 10 samples per medicine type was exceeded in several cases (Table 2).

A first round of sample collection was conducted from July to August 2021. Because the targeted number of samples had not yet been reached from the licensed vendors, a second round of sample collection was carried out from February to June 2022.

When samples were procured from the licensed suppliers, payment of the samples was conducted in accordance with the standard procedures of the FBCMF. For the Onitsha and Enugu pharmaceutical markets, the collected medicines were paid for in cash by the investigators.

Sample handling and shipment. Samples were collected in their original containers whenever possible. Otherwise, they were collected in light- and air-tight screw-cap plastic containers carried by the investigators. Containers that were not full were filled up with clean cotton wool to minimize mechanical damage to the tablets/capsules during transport. Upon collection, each sample was labeled immediately with a unique code number using preprinted adhesive sample labels. As soon as possible after sample collection, each sample was photographed from all sides.

All obtained samples were transported to the air-conditioned medicine storage rooms of the FBCMF without delay, where they were stored at 20°C. For each sample, 25 tablets or capsules (or five vials in the case of ceftriaxone injections) were kept by the FBCMF for on-site GPHF-Minilab analysis. The remaining samples were shipped by commercial courier service to Tübingen University in November 2021 for samples from the first round of sample collection and in June 2022 for samples from the second round. Upon their arrival at Tübingen University, they were stored in an air-conditioned room at 21°C until analysis.

Chemical analysis. Compendial analysis for identity and quantity (i.e., assay) of the APIs was carried out at the Pharmaceutical Institute of Tübingen University according to the USP 42 monographs, in accordance with the recommendation by Hauk et al.[39] High-performance liquid chromatography was performed with an Agilent 1260 Infinity II system and an Agilent 1100 system (Agilent Technologies, Santa Clara, CA). Columns for HPLC analysis were obtained from A. Maisch HPLC GmbH (Ammerbuch-Entringen, Germany), and certified pharmaceutical secondary standards were obtained from Sigma-Aldrich (St. Louis, MO). For furosemide tablets, the HPLC column and solvent system described in the British Pharmacopoeia 2022 were used.

TABLE 2
Overview of medicines included in this study

API	Preferred Dosage Form	Preferred Strength (mg)	No. of Samples Collected from Vendors in Pharmaceutical Markets with Unclear Licensing Status	No. of Samples Collected from Licensed Pharmaceutical Manufacturers and Wholesalers
Atenolol†	Tablet	50	10	4
Ceftriaxone sodium	Powder for injection	1000	11	12
Cefuroxime axetil	Tablet	250	13	11
Chloroquine phosphate (or sulfate)	Tablet	250 (or 200)	10	6
Ciprofloxacin hydrochloride†	Tablet	500	14	12
Dexamethasone	Tablet	4*	14	8
Fluconazole	Capsule‡	150	12	10
Furosemide†	Tablet	40	12	2
Glibenclamide†	Tablet	5	9	10
Hydrochlorothiazide†	Tablet	25	11	5
Metformin hydrochloride†	Tablet	500	12	10
Metronidazole†	Tablet	200§	11	14
Cotrimoxazole†	Tablet	480	10	7
Total			149	111
Grand total			260	

API = active pharmaceutical ingredient.
* None of the dexamethasone samples could be obtained in the form of 4 mg tablets. Rather, 18 samples were obtained as 0.5 mg tablets, and four samples were obtained as 1 mg tablets.
† Medicine types also included in a previous study of our group in Cameroon and the DRC.[11]
‡ Seven fluconazole samples could be obtained as capsules, and the other 15 could be obtained as tablets.
§ Twenty-two metronidazole samples could be obtained as 200 mg tablets, and the other three could be obtained as 400 mg tablets.

For dissolution testing, the analytical procedures described in the respective monographs of USP 42 were followed, using a PTWS 610 dissolution tester (Pharma Test Apparatebau AG, Heinburg, Germany) and an Agilent 708-DS dissolution apparatus (Agilent Technologies). Quantification of the dissolved APIs was carried out using the HPLC systems described above or by UV spectroscopy (for cefuroxime axetil, chloroquine, and furosemide) using a Perkin Elmer Lambda 25 UV/Vis spectrometer. The USP published in 2021 its intent to revise the method for dissolution testing of dexamethasone tablets,[40] and this revised method was followed. One metformin sample represented sustained-release tablets, and the respective USP dissolution specifications (Supplemental Table S1) were observed for that sample. For stage S_1 of dissolution testing, the number of units tested and the lower limits for average and minimum dissolution rates (Supplemental Table S1) followed the method for small-scale dissolution screening published by Rahman et al.[41] As described by Rahman et al.,[41] for samples failing stage S_1, any subsequent stage S_2 dissolution testing followed USP 42 specifications, both for the total number of units tested and for the lower limits for average and minimum dissolution. No stage S_3 testing was carried out.

Dissolution testing was not carried out for the 23 ceftriaxone samples, as these represented powders for injection, and not for the seven fluconazole capsule samples because no dissolution testing method for fluconazole capsules is specified in the USP 42. Furthermore, for one ciprofloxacin sample, not enough tablets were available for dissolution testing.

Content uniformity was not assessed in the present study because of the limited resources available.

Definitions of medicine quality. In this study, the current definitions of SF medicines by the WHO were used,[42] together with additional criteria suggested by Hauk et al.[39] and by Ozawa et al.[4] As proposed in the WHO QAMSA study[43] and applied in a previous study by our group in Cameroon and the DRC,[11] samples deviating from USP specifications were further divided into those showing moderate deviations from the pharmacopeial limits and those showing extreme deviations. Extreme deviations were defined as deviations of more than 20% from the stated amount of API in assay analysis and/or average dissolution rates of the API of the tested units falling more than 25% below the pharmacopeial threshold (i.e., falling below the pharmacopeial *Q* value minus 25%).

Statistical calculations. Calculations and statistical analyses were conducted using Excel 2019 (included in Microsoft 365; Microsoft Corp., Redmond, WA). For calculation of significant differences between proportions, MedCalc® (MedCalc Software Ltd., Ostend, Belgium) was used.[44]

Information of national authorities and stakeholders. The Enugu State Commissioner of Health (Nigeria), the NAFDAC, and the WHO Global Surveillance and Monitoring System for SF medical products were informed about the results of the study.

RESULTS

Overview of collected medicines. Two hundred fifty-seven medicine samples were purchased from 62 commercial sources. However, visual inspection showed that three purchased samples included blisters of two different batches, instead of representing a uniform sample. These different batches were subsequently treated as separate samples and analyzed for their quality individually. Therefore, the total number of investigated samples was 260. The number of samples collected from licensed vendors and from markets for every API is depicted in Table 2. Nearly all samples could be obtained in the preferred dosage form and strength; exceptions are noted in the footnotes of Table 2.

Nearly all collected samples were generic products, either sold under their international nonproprietary names ("unbranded generics") or sold under a brand name decided by the marketing authorization holder ("branded generics"). Only three out of the 260 samples (1%) represented originator products; all three were found to comply with pharmacopeial specifications. No expired products were encountered during sample collection.

The 260 samples collected in this study were manufactured by 89 different manufacturers located in eight different countries. As illustrated in Figure 1, 45.4% of the samples were stated to be manufactured in India, 38.5% in Nigeria, and 10.8% in China. In contrast, only 1.9% of the samples were stated to be manufactured in Europe (United Kingdom, France, and Spain) and 1.2% in Southeast Asia (Malaysia and Thailand). For nine samples, a marketing authorization holder but no manufacturer was stated; however, for three of these, representing the same brand, the country of manufacture was stated (India). All nine were found to comply with pharmacopeial specifications.

Detailed information on all samples, with their stated manufacturers and countries of manufacture, is given in Supplemental Table S2.

Falsified medicines. Within the 260 investigated samples, four (1.5%) did not contain the stated API(s) (Figure 2A to D). All four samples had been obtained in markets, not from licensed vendors. One of them was labeled as containing

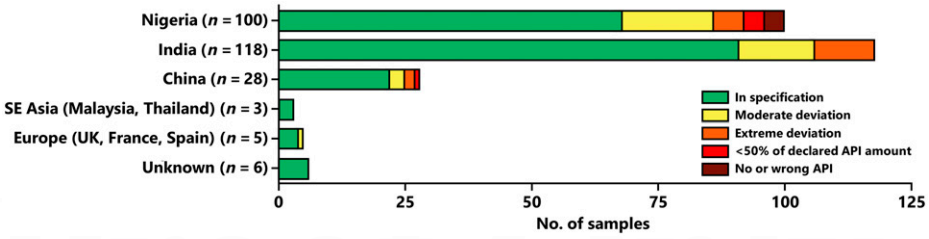


FIGURE 1. Number of samples stated to be manufactured in different countries and results of their compendial quality testing. See the legend for Figure 5 for definitions of quality categories. The four discovered falsified medicines (containing no active pharmaceutical ingredient [API] or a wrong API) were stated to be manufactured in Nigeria, but this statement might be incorrect.

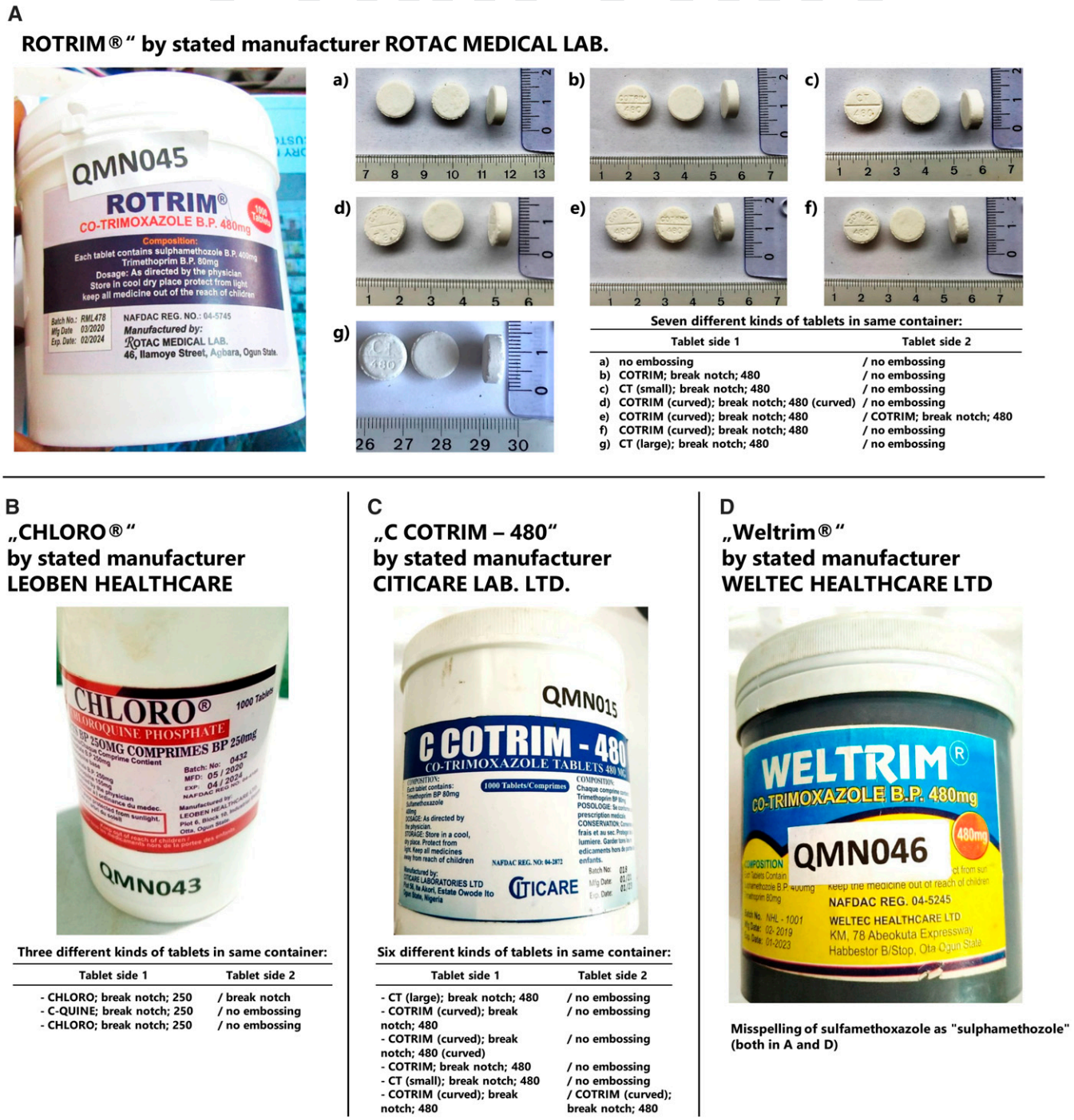


FIGURE 2. Four falsified medicines discovered in this study. Products A, B, and C contained different kinds of tablets, with different embossings and thicknesses, in the same container. None of these contained any active pharmaceutical ingredient. Product D contained paracetamol (27 mg per tablet) instead of the labeled ingredients sulfamethoxazole and trimethoprim.

chloroquine phosphate 250 mg, and the other three were labeled as containing sulfamethoxazole/trimethoprim 400/80 mg. All four represented remarkably crude falsifications: the samples depicted in Figure 2A, B, and C contained several different kinds of tablets with different embossings and different thicknesses within the same bulk container. On the labels of the samples depicted in Figure 2A and D, the API sulfamethoxazole was misspelled as "sulphamethozole." Although all four product labels showed a NAFDAC registration number, three of these could not be found in Nigeria's Registered Drug Product Database,[27] and the fourth one belonged to a completely different product in the database. The names of the four stated manufacturers could not be found either in an internet search or in Nigeria's Registered Drug Product Database.[27] Apparently, the stated manufacturers do not exist. Notably, the name of one of these manufacturers, Citicare

Laboratories Ltd. (Figure 2C), has been detected previously on falsified medicines in Nigeria.[20]

High-performance liquid chromatography analysis showed that three of these products did not contain any detectable amount of API. In contrast, the product labeled "Weltrim" (Figure 2D) was found not to contain sulfamethoxazole and trimethoprim but instead paracetamol (27 mg per tablet), identified by HPLC, TLC, and UV analysis in comparison with an authentic paracetamol reference standard. Falsified medicines containing low amounts of paracetamol have also been found in previous studies.[11,33]

Two further samples were found to carry a remarkably misspelled logo, depicted in Supplemental Figure S1 and stating "WHO GMP CERTIFIED QALITY [sic] PRODUCT". Although the WHO has published guidelines for the issuance of good manufacturing practice (GMP) certifications by national authorities, the WHO itself does not issue such certificates. Both samples represented the same batch and brand of "Eden Fluconazole 150 mg Capsules" (stated manufacturer, Impulse Pharma Pvt. Ltd., India). The stated NAFDAC registration number (C4-0072) could not be verified in Nigeria's Registered Drug Product Database,[27] but the marketing authorization holder, Eden U.K Pharmaceutical Ltd., Nigeria, was represented in that database with several other products. Both samples complied with USP specifications for the content of the API (dissolution was not tested for fluconazole capsules; see Materials and Methods). It was therefore decided to consider these two samples not as falsified but as "in specification."

Analysis of the quantity of the APIs. All 260 collected samples were subjected to assay analysis (i.e., quantification of API content). Figure 3A shows the result for each sample as a percentage of the API amount stated on the label. The USP specifies compliance limits for each API, as depicted in Figure 3A and summarized in Supplemental Table S1. Within the investigated medicines, these limits ranged from 90% to 115% of the declared amount for ceftriaxone injections up to 95% to 105% for metformin tablets. Among all 260 samples, 212 (81.5%) showed an API amount within the USP specifications. Twenty-seven samples (10.4%) showed a moderate deviation (i.e., deviations not exceeding ±20% of the stated amount). Twenty-one samples (8.1%) showed an extreme deviation, i.e., a deviation of more than 20% of the stated amount. The latter 21 samples comprised 12 samples containing between 50% and 79.9% of the stated API amount, 5 samples containing less than 50% of the stated API amount, and 4 samples not containing the stated APIs at all.

Samples not containing the stated APIs at all were considered falsified (see above). In accordance with the suggestion by Hauk et al.[39] and Ozawa et al.,[4] samples containing less than 50% of the stated API amount, without evidence that their low content may have been due to API degradation, were considered "probably falsified" because it does not appear likely that such deviations can occur without fraudulent intent.

Photos of the five probably falsified samples are depicted in Supplemental Figure S2A to E. The product shown in that figure (stated name, "SA'A QUINE," chloroquine phosphate tablets) was found to contain only 13.1% of the stated API amount. Notably, for this product, the batch numbers and expiry dates on the secondary packaging were different from those on the blisters, and even different ones appeared on different blisters.

The two samples shown in Supplemental Figure S2B and C (stated names, "Poletrim" and "Zimatrim") were labeled to contain sulfamethoxazole/trimethoprim 400/80 mg but contained only 22.4% and 23.9% of the declared amount of trimethoprim, respectively. The first of these two samples furthermore contained only 50.1% of the declared amount of sulfamethoxazole, whereas the latter one contained the correct amount of that API.

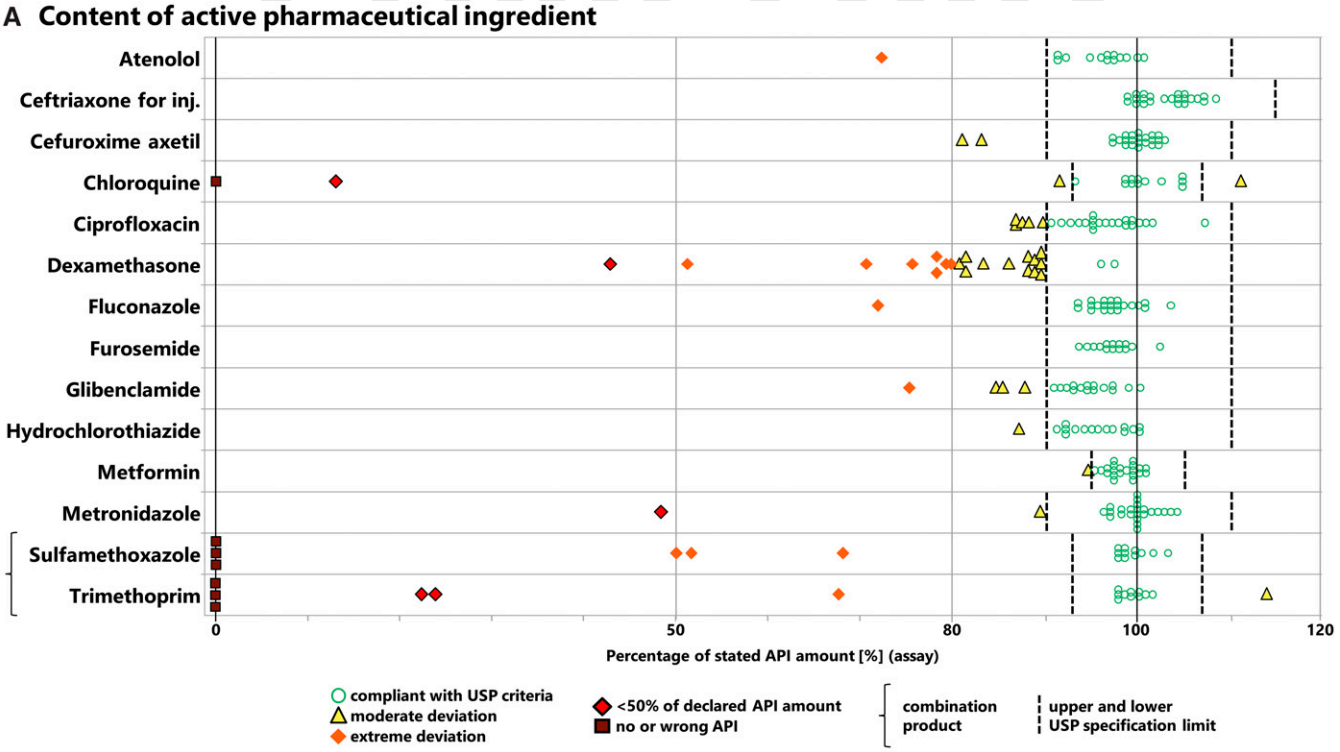
A fourth product was labeled "Zunagyl" (Supplemental Figure S2D) and contained only 48.4% of the declared amount of metronidazole. The tablets of this product exhibited an unpleasant odor. All four above-mentioned products were stated to be produced by Nigerian manufacturers listed in NAFDAC's List of Inspected Local Pharmaceutical Manufacturing Facilities,[45] but only two of these were still listed in Nigeria's Registered Drug Product Database[27] in September 2023.

A fifth product, labeled "Destrax" (Supplemental Figure S2E), was a dexamethasone tablet product stated to be manufactured in China. It contained only 42.9% of the stated amount of the API.

Among the 260 samples, there were 22 cases in which two samples of the same brand and batch had been collected, and in an additional three cases, even three samples of the same batch had been collected. As expected, in most of these cases (i.e., in 22 out of 25 cases), the different samples of the same batch showed very similar assay results: the assay values of the individual samples deviated from the mean assay value for the respective batch by ±0.9% on average. However, there were three notable exceptions. First, three samples of chloroquine phosphate tablets with the stated name "Quimal" (stated manufacturer, Dana Pharmaceuticals Limited, Nigeria; stated batch number, QT145) showed assay results of 98.9%, 98.8%, and 111.4% of the stated API amount. The excessive API content of the latter sample was also confirmed in the dissolution testing. This amount exceeds the pharmacopeial limit of 107% (Supplemental Table S1), and the unequal contents of samples of the same batch indicates serious violations of GMP.

Similarly, two samples of glibenclamide tablets with the stated name "Tionil" (stated manufacturer, Merit Organics Ltd., India; stated batch number, T32002) showed very different assay results, i.e., 94.7% and 75.4% of the stated API amount. Both samples also failed in dissolution testing, the latter sample showing a dissolution of only 42.7% of the stated API amount.

Finally, two samples of chloroquine phosphate tablets named "Albequine" (stated manufacturer, Alben Healthcare Ind. Ltd., Nigeria; stated batch number, 017) showed assay results of 99.3% and 91.7% of the declared amount, respectively; the latter value is below the pharmacopeial limit of 93.0%. This latter sample was found to contain, within the same blister packs, both white tablets and tablets with brown spots. A subsequent separate assay analysis of these two types of tablets resulted in 100.6% and 81.9% of the stated API amount, respectively. Both investigated samples of this batch failed in dissolution testing. It cannot be excluded that the observed brown spots are the result of microbial contamination.[46,47]



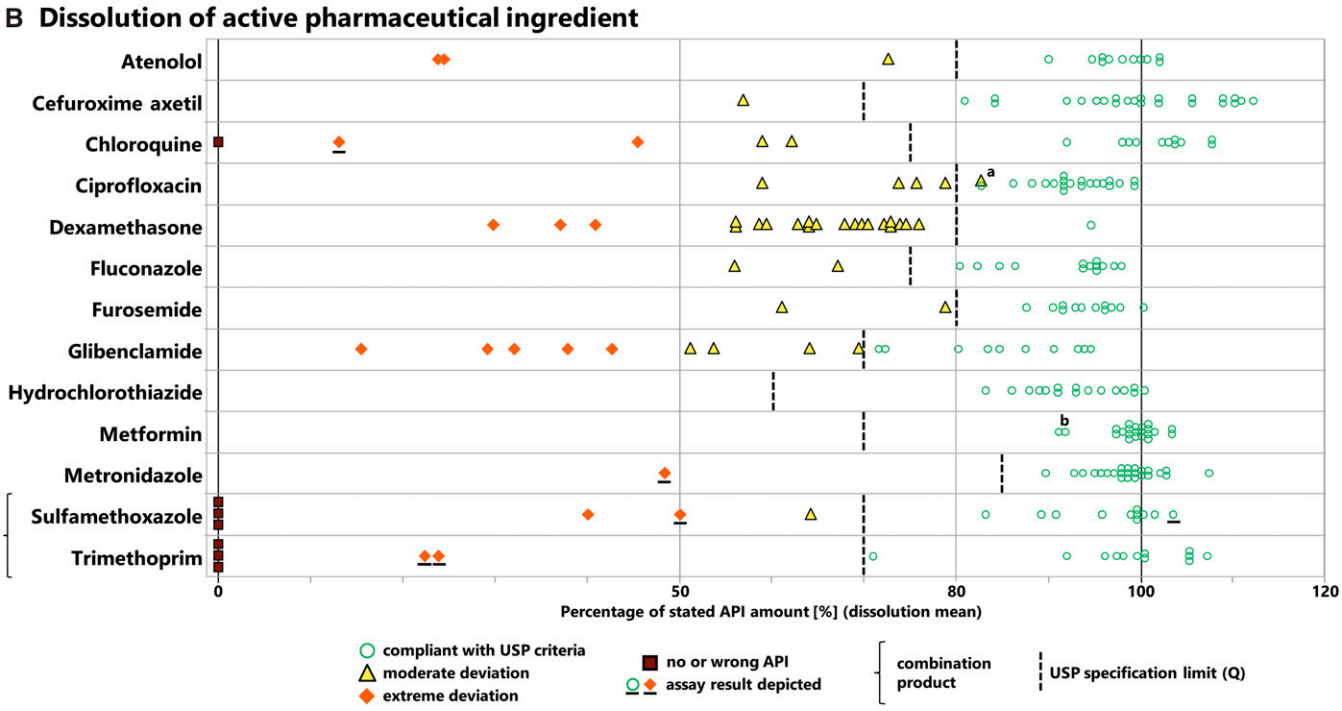


FIGURE 3. Content and dissolution of the active pharmaceutical ingredient (API) determined for each sample, expressed as a percentage of the stated API amount. (**A**) Content of the API. (**B**) Dissolution of the API. The specification limits of the United States Pharmacopeia (USP) (*Q* values in case of dissolution) are depicted. [a]For this ciprofloxacin sample, individual tablets showed a dissolution of less than *Q* minus 15%. Thereby, this sample deviates from USP specifications, even though its mean dissolution is above the pharmacopeial *Q* value of 80%. [b]This metformin sample was formulated as an extended-release tablet. Therefore, dissolution testing was carried out and evaluated according to the USP monograph for metformin extended-release tablets (see Supplemental Table S1). Dissolution testing was not carried out for four samples that already showed in assay analysis contents of chloroquine, metronidazole, or trimethoprim lower than *Q* minus 25% (see text). Their API contents are depicted in Figure 3B with underlined symbols.

Analysis of the dissolution of the APIs. Of the 260 collected samples, 229 were eligible for dissolution testing as described in Materials and Methods. Two hundred twenty-one of those 229 samples were subjected to dissolution testing, and Figure 3B shows the result for each sample. The USP specifies a compliance limit (*Q* value) for each API, as depicted in Figure 3B and summarized in Supplemental Table S1. Within the investigated medicines, these limits ranged from a dissolution of ≥60% of the declared API amount for hydrochlorothiazide tablets to ≥85% for, e.g., metronidazole tablets.

Among the 221 investigated samples, 173 (78.3%) showed an API dissolution complying with the USP specifications. Thirty-six samples (16.3%) showed a moderate deviation (i.e., an average dissolution between *Q* and *Q* minus 25%). Twelve samples (5.4%) showed an extreme deviation (i.e., an amount of the dissolved API more than 25% lower than the pharmacopeial *Q* value).

Dissolution testing was not carried out for the four falsified medicines that did not contain the declared APIs. Furthermore, it was decided not to carry out dissolution testing for one chloroquine, one metronidazole, and two sulfamethoxazole/trimethoprim samples, because for these samples, the above-described assay testing had already shown an API content that was more than 25% lower than the pharmacopeial *Q* value. Their API contents are depicted in Figure 3B with underlined symbols. Inclusion of these samples into the above calculation increases the number of samples not complying with the USP dissolution specifications to a total of 56 out of 229 samples (24.5%).

As already observed for the assay values, different samples of the same batch showed similar dissolution results. However, there was one notable exception (beyond the cases with different assay results in the same batch, described above): two samples of glibenclamide tablets with the stated name "Glanil" (stated manufacturer, Nigerian-German Chemicals Plc; stated batch number, FPD070421) showed very different dissolution results, i.e., 64.1% and 32.1% of the stated amount of the API, respectively. Both values are below the pharmacopeial *Q* value of 70%. Notably, on the blisters of the second sample, the name of the API was misspelled as "gilbenclamide," whereas the spelling was correct on the blisters of the first sample, carrying the same batch number. Three further batches of this "Glanil" brand were investigated in this study, all of them failing dissolution testing, with only 29.2%, 37.9%, and 51.2% of the API being dissolved. One of these samples (stated batch number, FPD070321) also showed the misspelling "gilbenclamide" on the blister. These observations indicate severe shortcomings in the manufacturing of this product.

Samples representing the same brand (albeit different batches) showed mostly consistent results regarding compliance or noncompliance with dissolution testing. However, six brands were found where some batches passed dissolution testing and others did not. The most prominent examples were five samples of "Eden Atenolol" (stated manufacturer, Impulse Pharma Pvt. Ltd., India), showing dissolution rates of 96.3%, 95.9%, 94.7%, 24.5%, and 23.8%, respectively; the last two values represent extreme deviations from the pharmacopeial *Q* value of 80%. Furthermore, two samples of "Biocipro" (stated manufacturer, McCoy Pharma Pvt. Ltd., India) showed dissolution rates of 91.8% and 59.0%, respectively; the latter value falls below the pharmacopeial *Q* value for ciprofloxacin of 80%.

Combined results of compendial analysis. If the results of assay and dissolution testing are combined, 194 of all 260 analyzed samples (74.6%) complied with USP specifications. Thirty-seven samples (14.2%) showed moderate deviations, and 29 samples (11.2%) showed extreme deviations (Figure 4). The latter group comprised five samples (1.9%) that were considered "probably falsified" because their API content was below 50% of the stated amount and four samples (1.5%) that were considered "falsified" because they did not contain any of the stated APIs at all.

Out of the 260 samples, 48 (18.5%) were already found to be out of specification (OOS) by assay testing. However, 18 samples (6.9%) were found to be OOS only by subsequent dissolution testing. This shows that an omission of

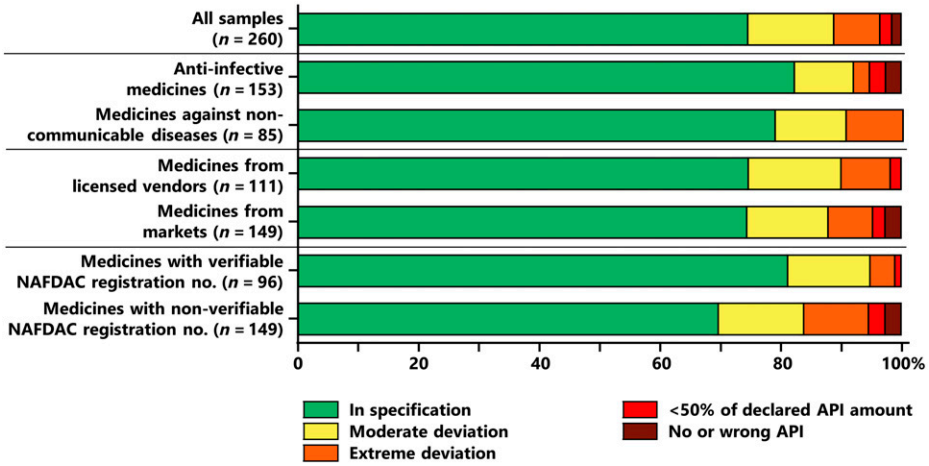


FIGURE 4. Results of compendial analysis for different therapeutic groups, for different sources of medicines, and for medicines with verifiable and nonverifiable National Agency for Food and Drug Administration and Control (NAFDAC) registration numbers (see text). Dexamethasone can be used in the treatment of both COVID-19 and noncommunicable diseases and was therefore excluded from the comparison of anti-infective medicines with medicines against noncommunicable diseases. See the legend for Figure 5 for definitions of quality categories.

dissolution testing in medicine quality studies leads to a quite substantial underestimation of the prevalence of substandard medicines.

As shown in Figure 4, medicines against NCDs showed a slightly higher percentage of OOS samples than anti-infective medicines (21.2% versus 17.6%, respectively). Dexamethasone had been excluded from this comparison because it can be used in the treatment of both COVID-19 and NCDs. Contrary to our expectations, medicines obtained from licensed vendors showed an overall proportion of OOS samples similar to that of medicines obtained from markets (25.2% and 25.5%, respectively). However, the four falsified medicines that did not contain the declared APIs were all obtained from markets.

Results of compendial analysis for the different APIs. As summarized in Figure 5, the results were very different for the different investigated APIs. No or relatively few quality problems were found for ceftriaxone injections or for metformin, hydrochlorothiazide, metronidazole, and fluconazole tablets (or capsules). Serious quality problems were found for chloroquine and cotrimoxazole tablets; similar observations for the two latter APIs have been made in previous studies,[9,26,33,48] for chloroquine especially after it had been (incorrectly) alleged to be effective in the treatment of COVID-19.[33] Furthermore, more than half of the investigated glibenclamide samples were found to be OOS, mostly due to dissolution failures. Although shortcomings of glibenclamide tablets in dissolution testing have been reported previously,[11,49] the extent of this problem observed in the present study was unexpected.

Recall of substandard dexamethasone tablets in Nigeria. Among all medicines investigated in this study, the most striking result was found for dexamethasone tablets (Figure 5). Out of 22 samples, 21 did not comply with pharmacopeial specifications, with 20 of these already failing in assay testing. As we had never found such a high proportion of failures before, this observation prompted us to reconfirm the accuracy of our analytical method by an interlaboratory comparison. Three of the dexamethasone samples were sent to the WHO-prequalified medicine quality control laboratory of the Mission for Essential Drugs and Supplies (MEDS) in Nairobi, Kenya, without communicating the already obtained analytical results. The samples were analyzed by MEDS for their API content according to the USP. The assay values determined by MEDS and by Tübingen University were in very good agreement: they deviated from the mean assay value for the respective sample on average by ±1.2%, with MEDS reporting for two samples a lower content and for one sample a higher content than that reported by Tübingen University.

According to the labels, the 22 dexamethasone samples had been produced by 14 different manufacturers: 10 from India, three from Nigeria, and one from China. Notably, the two samples that complied with assay specifications had been produced in Nigeria.

As shown in Figure 3A, seven of the dexamethasone samples failed the pharmacopeial specifications for assay only by a narrow margin. However, all of these seven samples failed the pharmacopeial specifications for dissolution very clearly: all of them showed dissolution values below 74%, and five of them showed dissolution values even below 65% (*Q* value, 80%).

Six of the dexamethasone samples were found to contain small amounts of the preservatives methylparaben and/or propylparaben. Although there is no clinical evidence of adverse effects in humans related to parabens, the

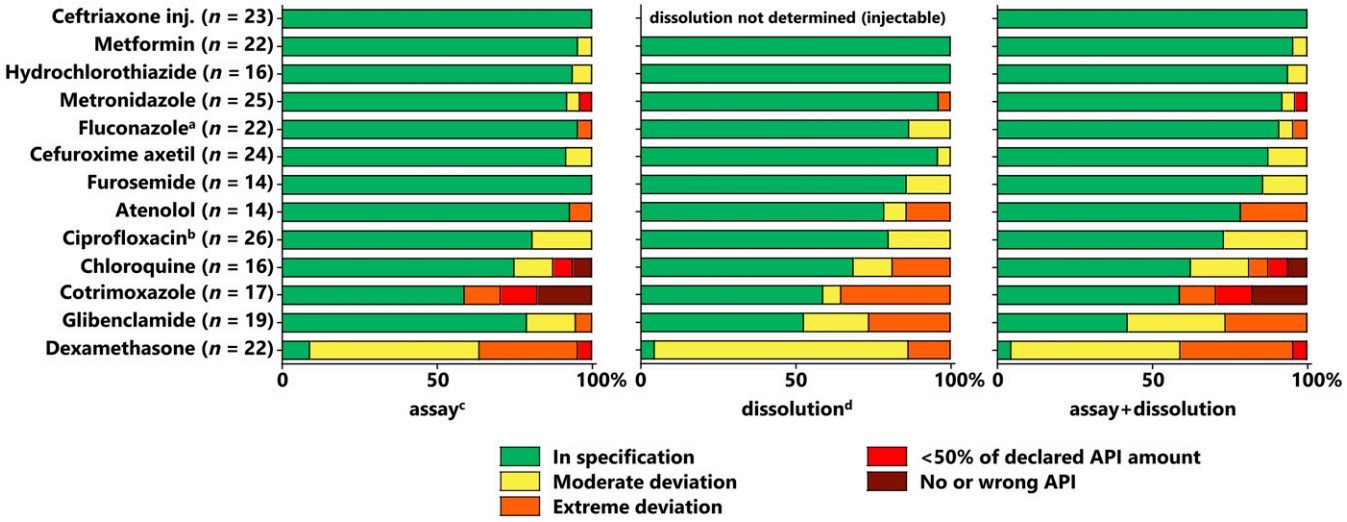


FIGURE 5. Results of compendial analysis for the investigated active pharmaceutical ingredients (APIs). [a]Only 15 of 22 fluconazole samples were tested for dissolution, since 7 samples were collected as capsules and no dissolution testing method for fluconazole capsules is specified in the United States Pharmacopeia (USP). [b]Only 25 of 26 ciprofloxacin samples were tested for dissolution, because not enough dosage units were available for one of the samples. [c]For assay values, the following five categories were used[4,39,43]: 1) containing no or wrong APIs (i.e., "falsified"); 2) containing less than 50% of the declared API amount, without evidence that their low content was due to API degradation (i.e., "probably falsified"); 3) other samples deviating by more than 20% from the declared API amount (i.e., "extreme deviation"); 4) deviations from USP assay specifications by not more than 20% of the declared API amount (i.e., "moderate deviation"); 5) in specification. [d]For dissolution values, average dissolution values lower than *Q* minus 25% were considered "extreme deviations"; dissolution values below USP specifications but not lower than *Q* minus 25% on average were considered "moderate deviations".[43] The categories "falsified" and "probably falsified" were not used, as these categories were based on assay results alone.

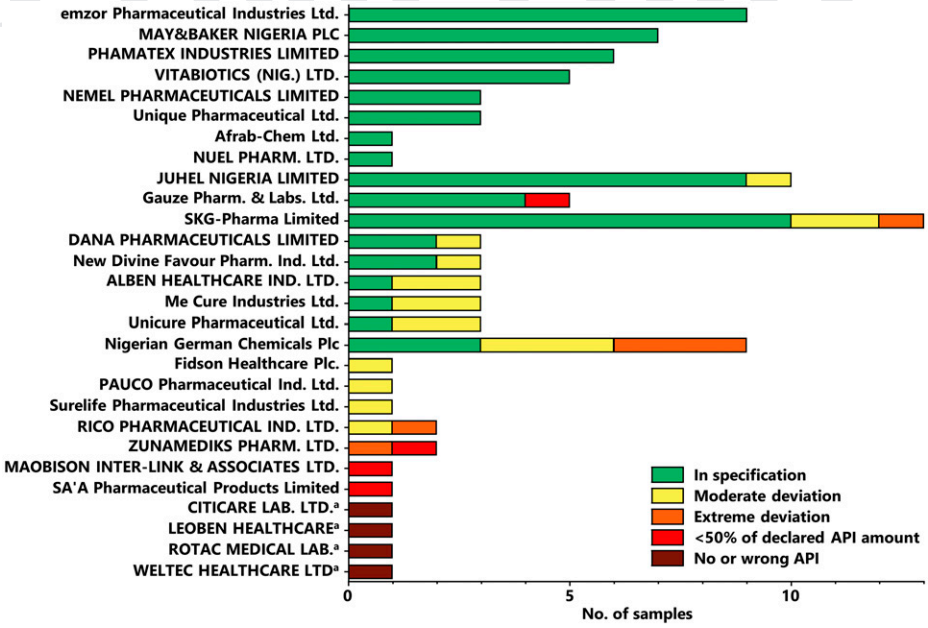


FIGURE 6. Results of compendial analysis for different stated manufacturers from Nigeria. See the legend for Figure 5 for definitions of quality categories. [a]The names of the four stated manufacturers of falsified medicines could not be found by an internet search nor in Nigeria's Registered Drug Product Database.[27] Apparently, these four manufacturers do not exist.

European Medicines Agency states that the use of these substances should be avoided wherever possible.[50]

In view of the importance of the above-mentioned findings on dexamethasone tablets, they were communicated to the WHO on September 16, 2022, and subsequently by the WHO to the NAFDAC. Probably based on this report, the NAFDAC recalled these substandard dexamethasone products through a public alert on October 8, 2022,[51] in a swift and decisive reaction.

Results of compendial analysis for different manufacturers. Figure 6 shows the results of the compendial testing for the 28 stated manufacturers from Nigeria. For eight manufacturers (together representing 35 samples), all their investigated medicines complied with pharmacopeial specifications. On the other hand, for 11 stated manufacturers (together representing 13 samples), none of the tested samples complied with specifications. Therefore, careful manufacturer selection is important for quality assurance in medicine procurement, although larger numbers of samples from each manufacturer need to be investigated. The data in Figure 6 indicate a tendency that larger manufacturers, supplying a higher number of samples, provided medicines with better quality than manufacturers supplying only one single sample. An exception is the stated manufacturer Nigerian-German Chemicals Plc who supplied nine samples, but six of these (66.7%) failed pharmacopeial specifications.

As with Figure 6, Supplemental Figures S3, S4, and S5 show the results of compendial testing for the stated manufacturers from India, China, and other countries, respectively.

Confirmation of NAFDAC registration status of the collected medicines. For any medicine marketed in Nigeria, displaying a NAFDAC registration number on the packaging is an obligatory requirement.[52] Among the 260 samples collected in this study, only 15 (representing six different APIs and 11 different brands) did not carry a NAFDAC registration number. All of them had been collected in markets. All of them were stated to be manufactured outside of Nigeria, or the manufacturer was not stated at all (only the marketing authorization holder). Twelve of these 15 samples complied with pharmacopeial specifications, and three showed moderate deviations. Therefore, according to the current WHO definitions,[2,42] these products are not to be considered as falsified but as nonregistered medical products. In a similar medicine quality study in Malawi,[53] only 61% of the collected medicine samples were registered by the national medicines regulatory authority (NMRA); in comparison, the proportion of samples carrying a NAFDAC registration number in the present study (93%) is remarkably high.

Two hundred forty-five samples collected in this study did carry a NAFDAC registration number. On the African continent, NAFDAC is among the leading NMRAs regarding the online provision of information on the registration status of medicines, through Nigeria's Registered Drug Product Database, also called the NAFDAC Greenbook.[27] For 96 samples, the registration numbers given on the product labels could be correctly verified in the NAFDAC Greenbook. The registration numbers stated on the product labels were, according to the NAFDAC Greenbook, given to products of different APIs and brands only for three collected samples. One of these three was a falsified cotrimoxazole sample, mentioned above. The other two were stated to represent the brand "Aphantix" (furosemide tablets; stated manufacturer, Mancare Pharmaceuticals Pvt. Ltd., India; stated NAFDAC registration number, 04-9146). Both had been collected in markets, and both complied with pharmacopeial specifications for assay and dissolution. It cannot be decided whether they carried an incorrect registration number simply because of an unintended mistake or had been produced and marketed with fraudulent intent.

For 146 samples, the registration number stated on the label could not be found in the NAFDAC Greenbook. It is

possible that their registration status had expired and had yet to be renewed. On the other hand, we noticed that some of these registration numbers were added correctly during the time of our data analysis, possibly indicating ongoing work of the NAFDAC on the completion of that database. (In the present study, the final comparison of observed registration numbers to the database was carried out in September 2023.)

Of the 96 samples with a verifiable registration number, 18.8% were OOS (95% CI, 11.1–29.6%). In contrast, of the 149 samples with a nonverifiable or incorrect registration number, 30.2% were OOS (95% CI, 22.0–40.4%; $P = 0.046$). Although this difference is statistically significant, our data show that the presence of a verifiable NAFDAC registration number does not exclude the risk of that medicine being substandard or even extremely substandard, as shown in Figure 4. The percentages of samples with nonverifiable registration numbers were similar in products from licensed vendors (59.5%) and from markets (61.9%).

MAS scheme. The NAFDAC took a pioneering step by instituting a medicine package serialization project called the Mobile Authentication Service (MAS) scheme, explained in detail in a NAFDAC guideline of 2018.[28] For products of antiprotozoal and antibacterial APIs listed in that guideline, each medicine package manufactured in or imported into Nigeria is to be labeled by the marketing authorization holder (or by the manufacturer) with a unique PIN code (Figure 7A and B). The PIN is hidden by an opaque covering that can be scratched off by the consumer. The consumer can send this PIN toll-free via SMS to a telephone number displayed next to the PIN (Figure 7A and B) belonging to one of the five service providers contracted by the NAFDAC for this scheme.[28] The consumer then receives an automatic response in the form of a text message (SMS). Besides the information about whether the sample is a genuine product, the message should contain at least the name, the NAFDAC registration number, the batch number and expiry date of the product, and a helpline telephone number for further information and for the reporting of nonverifiable products.[28] This is a unique and interesting scheme, and the present study provided an opportunity to gather some data on its current functionality.

According to the NAFDAC guideline, six of the anti-infective APIs investigated in this study were expected to be included in the MAS scheme. As shown in Table 3, only for three of those APIs MAS PINs were indeed found, and in each case only for part of the respective samples. The overall coverage by the MAS scheme for samples of the six anti-infective APIs was 29.0% (Table 3). Several samples of fluconazole and metformin also carried MAS PINs, although these APIs are not mentioned in the guideline of 2018. Unexpectedly, by far most of the medicines carrying a MAS PIN had been manufactured abroad and hardly any in Nigeria (Table 3).

In total, out of the 260 samples collected in this study, 46 carried a MAS PIN (Table 3). Of those, 45 showed the contact numbers of the NAFDAC-approved service providers M-Pedigree (28 samples), Sproxil (15 samples), UBQ-t/Kezzler (one sample), and PharmaSecure (one sample). One further sample carried a PIN of the service provider Chekkit, which is not named in the NAFDAC guideline and was therefore excluded from further investigation. Compendial

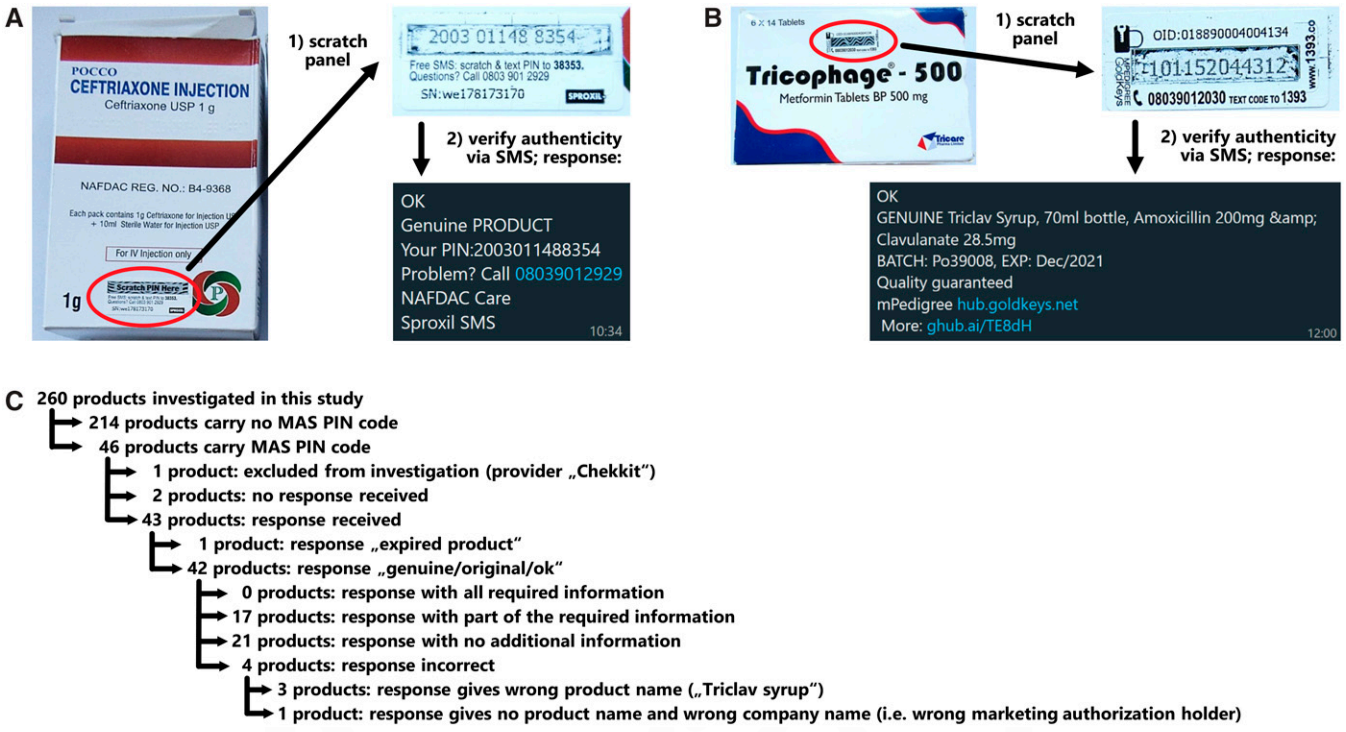


FIGURE 7. (**A**) SMS verification of a Mobile Authentication Service (MAS) PIN code resulting in a correct but incomplete response; see text for National Agency for Food and Drug Administration and Control (NAFDAC) requirements for a complete response. (**B**) SMS verification of a MAS PIN code resulting in an incorrect response (i.e., a wrong product name). (**C**) Summary of all results of MAS PIN code testing.

TABLE 3
Medicine samples carrying NAFDAC MAS scheme PIN codes

	Samples Manufactured in Nigeria			Imported Samples			All Samples		
		With PIN			With PIN			With PIN	
APIs	Total (*n*)	*n*	%	Total (*n*)	*n*	%	Total (*n*)	*n*	%
Listed in NAFDAC MAS guideline									
Chloroquine	16	0	0	0	0	–	16	0	0
Cotrimoxazole	17	0	0	0	0	–	17	0	0
Metronidazole	25	0	0	0	0	–	25	0	0
Ceftriaxone injection	0	0	–	23	7	30	23	7	30
Cefuroxime axetil	0	0	–	24	17	71	24	17	71
Ciprofloxacin	6	2	33	20	12	60	26	14	54
Total	64	2	3	67	36	54	131	38	29
Not listed in NAFDAC MAS guideline									
Fluconazole	2	0	0	20	2	10	22	2	9
Metformin	9	2	22	13	4	31	22	6	27
Grand total	75	4	5	100	42	42	175	46	26

MAS = Mobile Authentication Service; NAFDAC = National Agency for Food and Drug Administration and Control; PIN = personal identification number.

analysis showed that this sample complied with USP specifications.

None of the 45 investigated MAS PINs had been scratched free prior to the investigation in this study. They were now scratched free, and the PIN that appeared was forwarded to the respective service providers by SMS, using a mobile phone in Nigeria. The answers received are summarized in Figure 7C and are shown in full detail in Supplemental Table S3. Only for two samples was no response received. Among the 43 received responses, one stated (correctly) that the product in question was expired at the time of this testing (June 2023). All other 42 responses gave confirmation that the sample in question was a genuine product. Compendial analysis in this study had shown that 39 of these samples were in specification, and three (7.1%) showed moderate deviations.

Unexpectedly, not a single one of the SMS responses provided the complete obligatory information specified by the NAFDAC guideline.[28] In 21 cases, the only information was the claim that the product was genuine, with no mention of the product name, NAFDAC registration number, or batch number or expiry date (see Figure 7A as example). Among the cases where at least some of the obligatory information was given, the information was incorrect in the case of four samples. Three products of the Indian manufacturer Baroque Pharmaceuticals Pvt. Ltd., representing cefuroxime axetil, metformin, and fluconazole tablets, respectively, were incorrectly stated to represent "Triclav Syrup" (Figure 7B), a brand of amoxicillin/clavulanic acid that is currently not listed in the NAFDAC Greenbook. For one further sample, the SMS response did not specify the product name but stated a marketing authorization holder that, however, was different from the one stated on the product label (Supplemental Table S3).

Among the 43 PINs for which SMS responses were received, the average response time was 38 seconds, the shortest for the provider M-Pedigree (14 seconds) and the longest for the provider Pharmasecure (79 seconds).

The NAFDAC guideline[28] specifies that the MAS PINs must be for one-time use only. If the same PIN is sent to the service provider repeatedly, the expected answer is "PIN used," which is important since otherwise a single valid PIN could be copied from a genuine package and be attached to multiple falsified medicine packages. In the present study, 16 of the above investigated MAS PINs were sent to the respective service provider for a second time. In eight cases, the correct response "PIN used" was received. However, in four cases the unmodified previous response was received, claiming that the product was genuine. In four further cases, no response at all was received within a predecided waiting time of 5 minutes.

As mentioned above, chemical analysis in the course of this study identified 9 out of the 260 samples as falsified or probably falsified. However, none of these nine products carried a MAS PIN code, and they could therefore not be examined for SMS responses within the MAS scheme.

DISCUSSION

The key aim of the present study was to assist the FBCMF and similar stakeholders in Nigeria in their future decision-making and resource management for quality assurance in medicine procurement. For this purpose, selected types of medicines were purchased from different sources and analyzed for the content and dissolution of the APIs. Overall, 260 samples were investigated, and 25.4% of these were found to be OOS in assay, dissolution, or both. In comparison, a systematic review by the WHO in 2017,[2] which summarized the results of 100 medicine quality studies, reported that the average prevalence of SF medicines in LMICs was 10.5% when all included studies were considered, and 15.6% when only studies using HPLC for analysis were considered (as with the present study) but not studies using less sensitive detection methods like the GPHF-Minilab.[10]

Our own group conducted a study in Cameroon and the DRC[11] with analytical methodology very similar to that in the present investigation. Eight of the medicine types (APIs and formulations) included in that previous study were also included in the present study (Table 2), allowing a direct comparison of the results. When only these eight medicine types were considered, the percentages of samples with moderate deviations from USP specifications were very similar in the two studies (11.8% and 11.9%, respectively). However, the rate of samples with extreme deviations (including falsified and probably falsified medicines) in the present study in Nigeria was 10.5% (95% CI, 6.0–17.0%), three times higher than the rate of 3.1% (95% CI, 1.4–5.8%)

observed in the study in Cameroon and the DRC ($P = 0.001$). Likewise, the rate of falsified and probably falsified samples among these eight medicine types was 3.9% (95% CI, 1.4–8.5%) in the present study, significantly higher than the rate of 0.3% (95% CI, 0.01–1.9%) observed in Cameroon and the DRC ($P = 0.004$). All the above comparisons, however, should be interpreted with caution, because the present study was not designed as a prevalence study with randomized selection of the sampling sites and was carried out only in a limited region of Nigeria.

Although the number of SF medicines detected in this study is concerning, it is markedly lower than frequently speculated in the lay press and in some scholarly publications.[54,55] For example, in a survey among 541 health professionals in Nigeria, the proportion of "fake" medicines on the Nigerian market was estimated to be 49% on average.[56] A Nigerian official of the National Drug Law Enforcement Agency was even quoted by the press as stating that in Nigeria, 70% of all the drugs on the market would be "fake."[57,58] A much lower percentage of falsified medicines was found in the present study, and this is in agreement with the results of previous scientific studies in Nigeria (see Introduction). More systematic research with appropriate methodology is desirable and could complement the present communications by the NAFDAC[57] to curb unfounded, exaggerated speculations about the proportion of falsified and substandard medicines in Nigeria.

The sample collection for the present study was carried out during the COVID-19 pandemic. This pandemic resulted in a sudden increase in demand for medicines with alleged or true relevance for COVID-19 therapy, creating an opportunity for criminals to market falsified versions of such medicines.[59] Indeed, falsified chloroquine tablets were found in the present study, similar to observations made previously in other African countries.[33,48] Especially, and as a new observation, an extremely high rate of poor-quality dexamethasone tablets was detected, most of these imported from India and China. This finding calls for a thorough investigation of the quality of dexamethasone products in other countries as well. The swift recall of the substandard dexamethasone tablets by the NAFDAC[51] confirms that effective structures are in place to implement such recalls in Nigeria.

In medicine quality studies in the past, anti-infective medicines tended to be overrepresented in comparison with medicines against NCDs.[2] In this study, we found a slightly higher percentage of medicines against NCDs than against anti-infectives to be OOS, and similar findings were made in our previous study in Cameroon and the DRC.[11] Mortality from NCDs is already high in sub-Saharan Africa and is still rising,[60] and a more extensive inclusion of medicines against NCDs in future medicine quality studies is desirable.

Unexpectedly, and in contrast to findings from other countries,[11,61] the proportions of OOS samples were found to be similar in markets and in licensed vendors in the present study. However, no clearly falsified medicines were found from licensed vendors. It should be noted that the "open drug markets"[36,54] in Onitsha and Enugu are not simple roadside market stalls like in some neighboring African countries but are shops with a professional appearance, often very well stocked with many types of medicines. Our data show that simple adherence to licensed vendors is not sufficient to exclude substandard medicines from medicine procurement. As shown in Figure 1, the replacement of imported medicines by locally produced ones is also not sufficient, as the proportions of OOS samples are similar in medicines from Nigeria, India, and China.

The MAS scheme by the NAFDAC is currently intended to cover only the most important anti-infective medicines.[28] However, even for these medicines, 71% of the samples collected in this study did not carry a MAS PIN code (65% in licensed vendors and 77% in markets). In addition, some technical shortcomings and mistakes have been observed, similar to previous reports.[62] Therefore, the verification of MAS PIN codes appears to be of limited value in quality assurance at present.[62–65]

Preferential procurement of medicines prequalified by the WHO Medicine Prequalification Program[66,67] would certainly be useful if such medicines were available and affordable in Nigeria. However, of the 13 types of medicines investigated in this study, only four are included in that program (ceftriaxone, ciprofloxacin, cotrimoxazole, and dexamethasone), and each of them only with a small number of commercial products. Therefore, none of the 260 samples collected in this study represented a WHO-prequalified product. A substantial expansion of this WHO program is probably necessary to make it useful for procurement agencies in Nigeria.

As part of its quality assurance, the FBCMF carries out visual inspection of procured medicines[68] and chemical investigation using the GPHF-Minilab.[10] Similar to previous studies,[26] the present study found visual inspection to be a valuable tool for the identification of falsified medicines (see Results). Also, screening analysis with the GPHF-Minilab was found to reliably detect falsified medicines with no or wrong APIs (data not shown), as also reported in previous studies.[11] However, the GPHF-Minilab detects medicines of insufficient amount or dissolution of the API only with low sensitivity,[11] and simple, inexpensive screening technologies that can reliably detect substandard medicines do not yet exist.[25] The FBCMF has access to compendial medicine quality analysis through its membership in the EPN, which includes the WHO-prequalified medicine quality control laboratory of MEDS, Kenya,[26] but this can be used for only a limited number of samples. Therefore, a comprehensive quality assurance system is required, based on WHO's Model Quality Assurance System for Procurement Agencies[69] and including prequalification of products, manufacturers, and suppliers as a key component. Another key component is visual inspection of all procured medicines as well as laboratory analysis of selected medicines using both screening methods like the GPHF-Minilab and, as far as possible, compendial analysis as done in the present study. Collaborations within large networks like EPN may greatly facilitate such quality assurance in medicine procurement.

CONCLUSION

Even in the presence of a strong and dedicated national medicine regulatory authority like the NAFDAC, which has recently reached WHO Maturity Level 3,[70] ensuring the quality of medicines in Nigeria remains a challenge. Contrary to common belief, the largest problem is not the occurrence of falsified medicines sold with criminal intent under fake product and fake manufacturer names but the high prevalence of substandard medicines, arising from insufficient resources,

insufficient competence, and insufficient diligence in their manufacturing. This applies equally to medicines manufactured in Nigeria and to imported ones. Accordingly, a solution of this problem cannot be found by law enforcement measures alone but requires an evolutionary approach including continuous training and supervision efforts and involving many stakeholders. One part of these efforts must be a systematic prequalification of products and manufacturers in medicine procurement by private, nongovernmental, and governmental organizations.

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Authors' addresses: Julia Gabel, Micha Lächele, Katharina Sander, Gesa Gnegel, Lutz Heide, Pharmaceutical Institute, Eberhard Karls University, Tuebingen, Germany, E-mails: julia.gabel@uni-tuebingen.de, micha-benjamin.laechele@uni-tuebingen.de, katharina.sander@student.uni-tuebingen.de, gesa.gnegel@uni-tuebingen.de, and heide@uni-tuebingen.de. Nkiru Sunny-Abarikwu, Rita Ezinwanne Ohazulike, Juliet Ngene, Jane Frances Chioke, Faith-Based Central Medical Foundation (FBCMF), Enugu, Nigeria, E-mails: pharmenkay@gmail.com, sr.ezinwanne@gmail.com, nnejul@yahoo.com, and srjanefrances@yahoo.com. Christine Häfele-Abah, German Institute for Medical Mission (Difaem), Tübingen, Germany, E-mail: haefele@difaem.de.

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Supplementary Material for

Quality of Essential Medicines from Different Sources in Enugu and Anambra, Nigeria

Julia Gabel,[1] Micha Lächele,[1] Katharina Sander,[1] Gesa Gnegel,[1] Nkiru Sunny-Abarikwu,[2] Rita Ezinwanne Ohazulike,[2] Juliet Ngene,[2] Jane F. Chioke,[2] Christine Häfele-Abah,[3] Lutz Heide[1]*

[1]Pharmaceutical Institute, Eberhard Karls University Tuebingen, Tuebingen, Germany; [2]Faith-Based Central Medical Foundation (FBCMF), Enugu, Nigeria; [3]German Institute for Medical Mission (Difaem), Tuebingen, Germany

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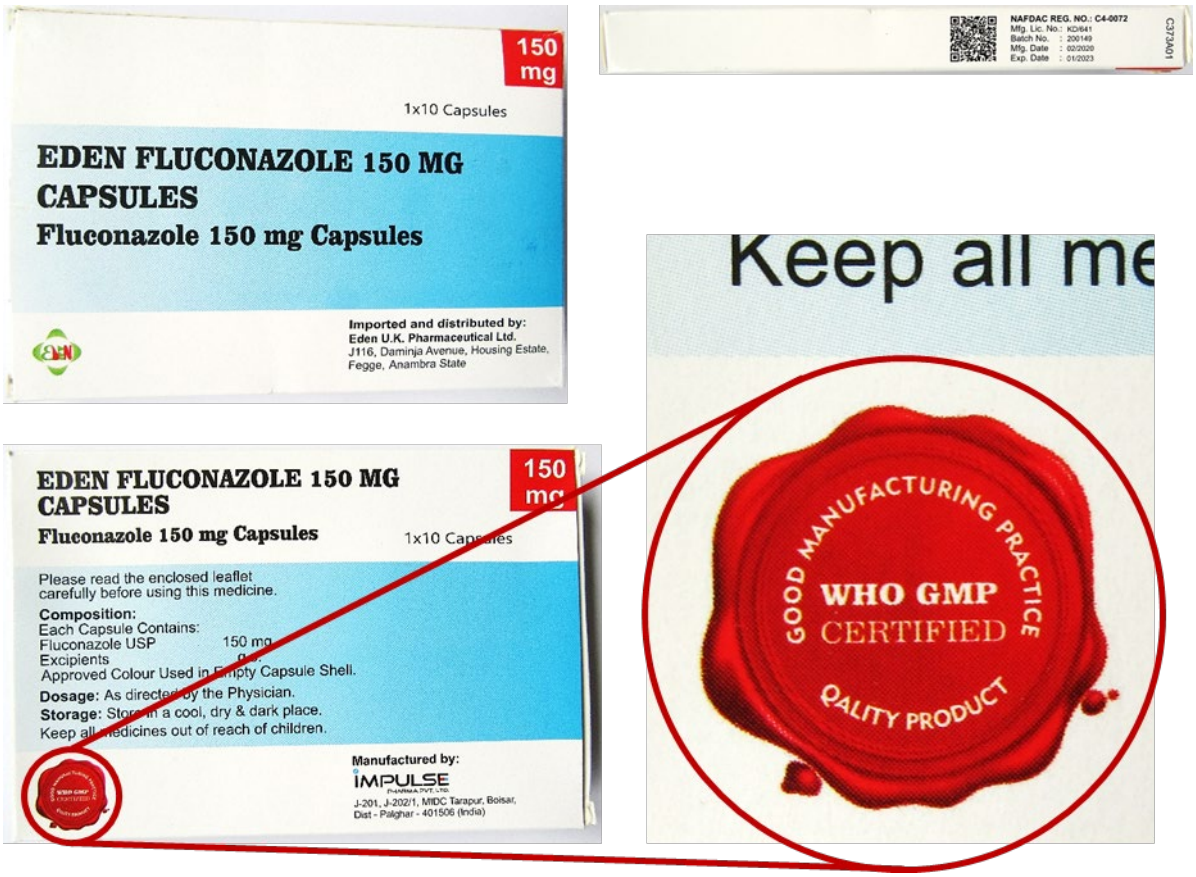
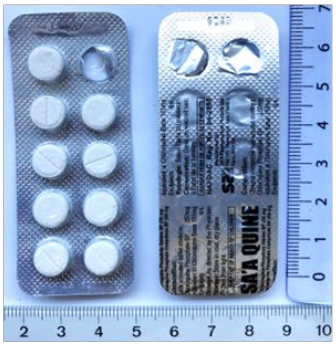


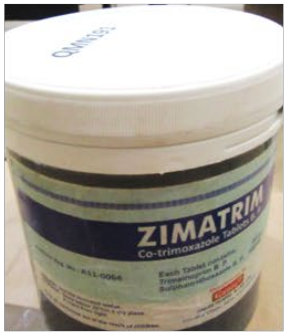
Supplementary Figure S1. "Eden Fluconazole 150mg Capsules", carrying a misspelled "WHO" logo. Note the spelling „QALITY" instead of „QUALITY". While WHO has published guidelines for the issuance of GMP certifications by national authorities, WHO itself does not issue such certificates. Nevertheless, the sample complied with USP specifications for the content of the API.

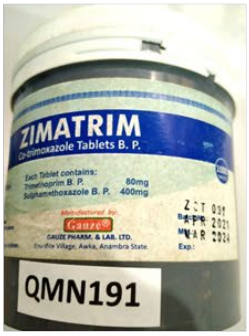
A) „SA'A QUINE" (chloroquine phosphate) by stated manufacturer SA'A Pharmaceutical Products Limited; 13.1% of stated API content



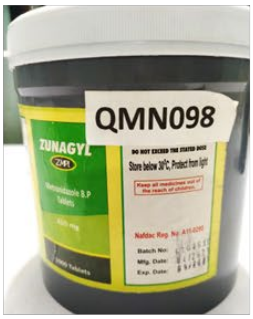
B) „POLETRIM" (sulfamethoxazole/ trimethoprim) by stated manufacturer MAOBISON INTER-LINK & ASSOCIATES LTD; 50.1%/22.4% of stated API content

C) „ZIMATRIM"(sulfamethoxazole/ trimethoprim) by stated manufacturer Gauze Pharm. & Labs. Ltd.; 103.5%/23.9% of stated API content



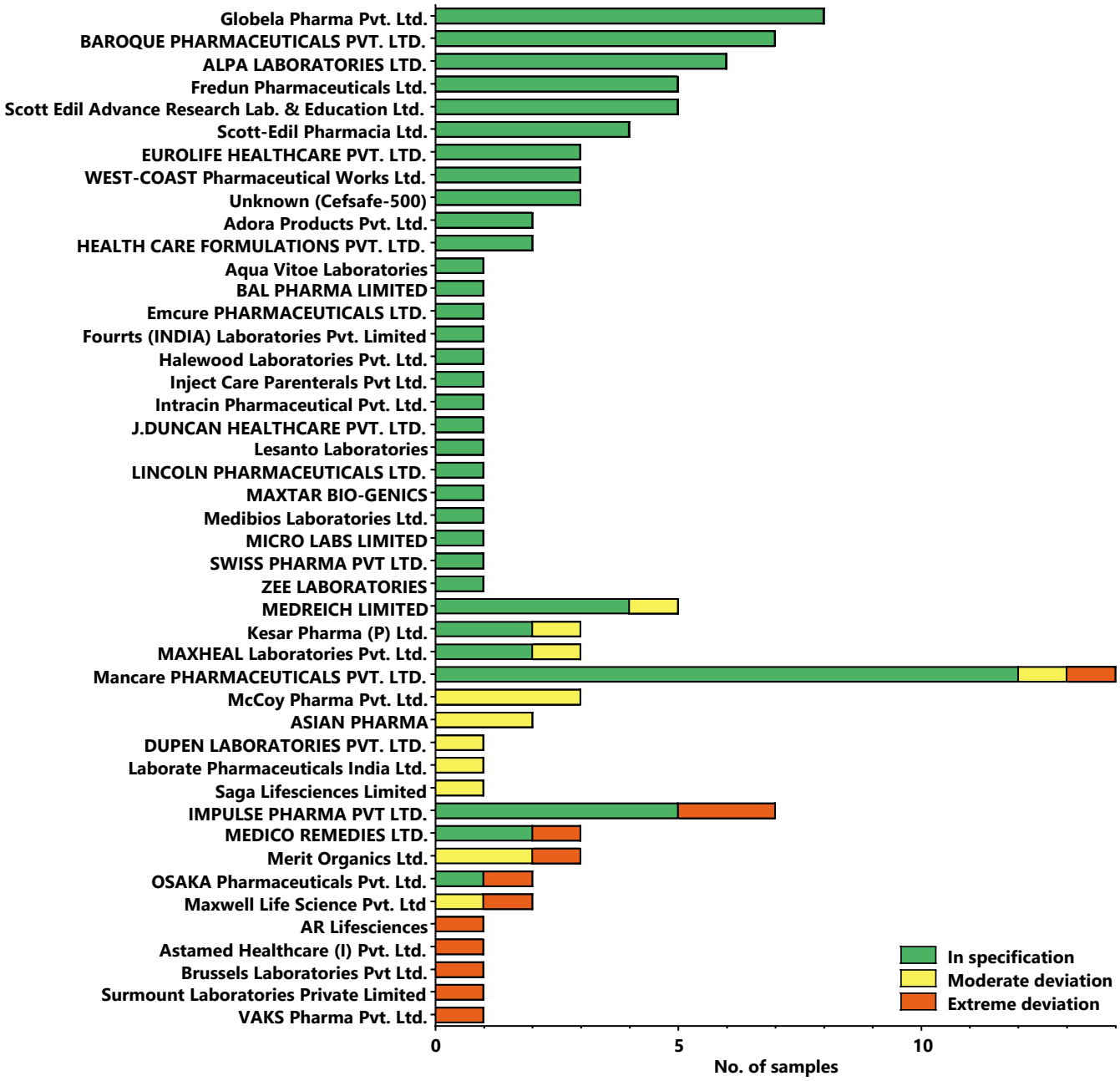


D) „ZUNAGYL" (metronidazole) by stated manufacturer ZUNAMEDIKS PHARM. LTD.; 48.4% of stated API content

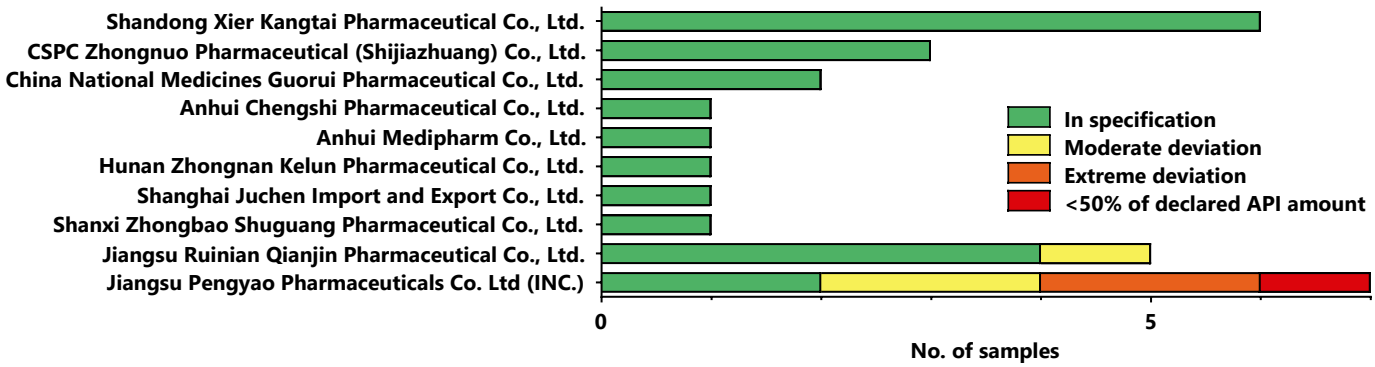


E) „Destrax" (dexamethasone) by stated manufacturer Jiangsu Pengyao Pharmaceuticals Co. Ltd.; 42.9% of stated API content

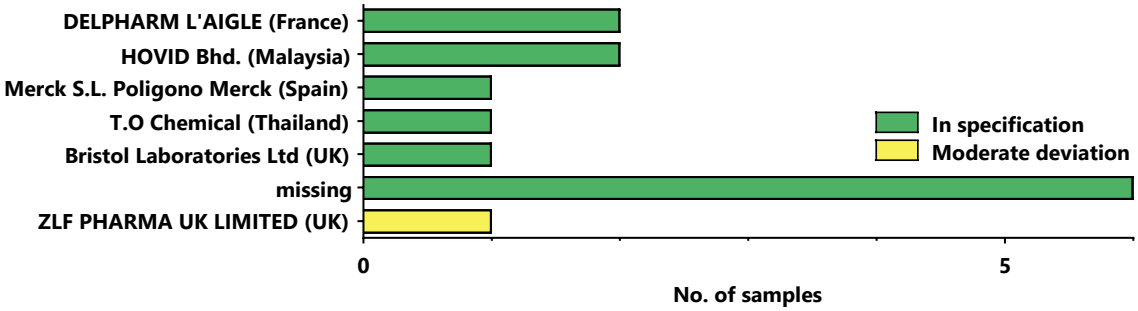
Supplementary Figure S2. Five medicine samples containing less than 50% of the stated API, without evidence that their low content was due to API degradation, therefore considered as probably falsified medicines.



Supplementary Figure S3. Results of compendial analysis for different stated manufacturers from India.



Supplementary Figure S4. Results of compendial analysis for different stated manufacturers from China.



Supplementary Figure S5. Results of compendial analysis for different stated manufacturers from further countries.

Supplementary Table S1. Specifications for assay and dissolution analysis for each investigated active pharmaceutical ingredient.

Active pharmaceutical ingredient (API)	Dosage form tested	USP 42 specification for content of the API (=assay) [% of declared content)	USP 42 specification for dissolution of the API (Q value) [% of declared content]	Specification by Rahman et al. 2021[§] for stage S_1 dissolution testing	
				Average dissolution rate of n=3 units[#]	Minimum dissolution rate found in n=3 units[#]
Atenolol	tablet	90.0-110.0	≥80	≥86	≥82
Ceftriaxone sodium	powder for injection	90.0-115.0	-	-	-
Cefuroxime axetil	tablet	90.0-110.0	≥70*	≥76	≥72
Chloroquine phosphate and sulphate	tablet	93.0-107.0	≥75	≥81	≥77
Ciprofloxacin hydrochloride	tablet	90.0-110.0	≥80	≥86	≥82
Dexamethasone	tablet	90.0-110.0	≥80[&]	≥86	≥82
Fluconazole	tablet	90.0-110.0	≥75	≥81	≥77
Furosemide	tablet	90.0-110.0	≥80	≥86	≥82
Glibenclamide	tablet	90.0-110.0	≥70	≥76	≥72
Hydrochlorothiazide	tablet	90.0-110.0	≥60	≥66	≥62
Metformin hydrochloride	tablet	95.0-105.0	≥70	≥76	≥72
Metformin hydrochloride	extended-release tablet	90.0-110.0	≥85[$]	≥91	≥87
Metronidazole	tablet	90.0-110.0	≥85	≥91	≥87
Co-trimoxazole	tablet	93.0-107.0	≥70	≥76	≥72

[§] Rahman et al. 2021. Small-scale dissolution test screening tool to select potentially substandard and falsified (SF) medicines requiring full pharmacopoeial analysis. Sci Rep 11: 12145.

[#] If one or both of these limits were not met, stage S_2 testing was carried out according to the United States Pharmacopeia (USP).

* USP specification for dissolution after 45 min. USP specification for dissolution after 15 min: Q ≥50%.

[$] USP specification for dissolution after 10 hrs. USP specification for dissolution after 1hr: Q ≥20%; after 3 hrs: Q ≥45%.

[&] United States Pharmacopeia, 2021. Dexamethasone Tablets - Notice of Intent to Revise. Available at: https://www.uspnf.com/sites/default/files/usp_pdf/EN/USPNF/revisions/dexamethasone-tabs-pending-nitr-20210730.pdf. Accessed November 15, 2023.

Supplementary Table S2: List of all samples investigated in this study

Note: Many medicines were purchased not directly from their manufacturer but from other commercial sources. For those medicines it cannot be verified whether the manufacturers' storage recommendations have been complied with from the time of manufacture until the time of sample collection. Changes in medicines quality may have occurred due to inappropriate transport and storage conditions, and therefore non-compliance with USP specifications is not necessarily due to substandard manufacturing or packaging. However, the results listed below reflect the quality in which health facilities, and ultimately patients, would receive these medicines.

* Co-trimoxazole comprises sulfamethoxazole and trimethoprim.

[§] Source A) Licensed pharmaceutical manufacturers and wholesalers ; Source B) Vendors in pharmaceutical markets of Onitsha and Enugu with unclear licensing status.

[#] For definitions of medicine quality refer to the main manuscript. USP 42 criteria was applied.

No.	Stated product name	Stated active pharmaceutical ingredient	Stated manufacturer	Stated manufacturing country	Source[§]	NAFDAC-Reg. No	Verification of NAFDAC-Reg. No possible in Nigeria's Registered Drug Product Database (Sep. 2023)	Batchnumber	Applied method for quantification of dissolution testing	Assessment of assay results[#]	Assessment of dissolution results[#]	Assessement of assay AND dissolution results[#]	Sample ID
1	Harvad Cefuroxime tablets	Cefuroxime axetil	ALPA LABORATORIES LTD.	India	B	B4-7976	verified	TC0009	UV/Vis	in specification	in specification	in specification	QMN 001
2	Cefsafe-500	Cefuroxime axetil	missing	India	B	C4-0252	verified	HH108B21	UV/Vis	in specification	in specification	in specification	QMN 002
3	Oxispa 500	Cefuroxime axetil	Zee Laboratories	India	B	A4-4096	verified	ZET1408	UV/Vis	in specification	in specification	in specification	QMN 003
4	Cefuroxime Deno	Cefuroxime axetil	Scott-Edil Advance Research Laboratories & Education Ltd.	India	B	C4-0958	not found	1130Z007	UV/Vis	in specification	in specification	in specification	QMN 004
5	Ciprofloxacin 500 mg	Ciprofloxacin	Shanghai Juchen Import and Exports Co. Ltd.	China	B	missing	-	200203	HPLC	in specification	in specification	in specification	QMN 005
6	Ugolife Ciprofloxacin-500	Ciprofloxacin	Kesar Pharma (P) Ltd.	India	B	B4-7467	not found	T20466	HPLC	in specification	in specification	in specification	QMN 006
7	Biocipro	Ciprofloxacin	McCoy Pharma Pvt. Ltd.	India	B	B4-2452	not found	MP9422	HPLC	moderate deviation	in specification	moderate deviation	QMN 007
8	Ciprofloxacin 500	Ciprofloxacin	Jiangsu Pengyao Pharmaceutical Co. Ltd. (INC.)	China	B	B4-5947	verified	201257	HPLC	in specification	in specification	in specification	QMN 008
9	Biophage 500	Metformin	SKG-Pharma Limited	Nigeria	B	A4-6597	verified	2126	HPLC	in specification	in specification	in specification	QMN 009
10	Gluformin	Metformin	Nigerian-German Chemicals Plc	Nigeria	B	04-6426	verified	FPB080321	HPLC	in specification	in specification	in specification	QMN 010
11	Metformin	Metformin	Fredun Pharmaceuticals Ltd.	India	B	B4-0944	not found	FK0002	HPLC	in specification	in specification	in specification	QMN 011
12	Transglobe's Metformin	Metformin	EUROLIFE HEALTHCARE PVT. LTD.	India	B	A4-4274	not found	TMN005	HPLC	in specification	in specification	in specification	QMN 012
13	AD-Fluconazole	Fluconazole	Globela Pharma Pvt. Ltd.	India	B	B4-1543	not found	20GT047	HPLC	in specification	in specification	in specification	QMN 013
14	Nkoyo Fluconazole	Fluconazole	Mancare PHARMACEUTICALS PVT. LTD.	India	B	A4-0421	not found	TUL45	HPLC	in specification	in specification	in specification	QMN 014
15	C Cotrim - 480	Co-trimoxazole*	CITICARE LAB. LTD.	Nigeria	B	04-2872	not found	018	HPLC	falsified	extreme deviation	falsified	QMN 015
16	Emtrim	Co-trimoxazole*	emzor Pharmaceutical Industries Ltd.	Nigeria	B	04-0267	verified	R0371SA	HPLC	in specification	in specification	in specification	QMN 016
17	Emgyl	Metronidazole	emzor Pharmaceutical Industries Ltd.	Nigeria	B	04-0412	not found	2557A	HPLC	in specification	in specification	in specification	QMN 017
18	Nemegyl	Metronidazole	NEMEL PHARMACEUTICALS LIMITED	Nigeria	B	04-5326	not found	11B	HPLC	in specification	in specification	in specification	QMN 018
19	Albegyl	Metronidazole	ALBEN HEALTHCARE IND. LTD.	Nigeria	B	A4-7707	verified	043	HPLC	in specification	in specification	in specification	QMN 019
20	Emgyl	Metronidazole	emzor Pharmaceutical Industries Ltd.	Nigeria	B	04-0412	not found	S0156SA	HPLC	in specification	in specification	in specification	QMN 020
21	New Divine Frusemide	Furosemide	New Divine Favour Pharmaceutical Industries Ltd.	Nigeria	B	A4-8776	not found	0029	UV/Vis	in specification	in specification	in specification	QMN 021
22	Lasimac	Furosemide	Mancare PHARMACEUTICALS PVT. LTD.	India	B	B4-6708	verified	TUK07	UV/Vis	in specification	in specification	in specification	QMN 022
23	Aphantix	Furosemide	Mancare PHARMACEUTICALS PVT. LTD.	India	B	04-9146	product of different API and brand registered under this Reg. No.	TVK32	UV/Vis	in specification	in specification	in specification	QMN 023
24	Nkoyosix	Furosemide	Mancare PHARMACEUTICALS PVT. LTD.	India	B	A4-9179	verified	TUL35	UV/Vis	in specification	in specification	in specification	QMN 024
25	Chloroquine	Chloroquine	emzor Pharmaceutical Industries Ltd.	Nigeria	B	04-1218	not found	1817Z	HPLC; UV/Vis	in specification	in specification	in specification	QMN 025
26	Quimal	Chloroquine	DANA PHARMACEUTICALS LIMITED	Nigeria	B	04-1785	verified	QT145	HPLC; UV/Vis	in specification	in specification	in specification	QMN 026
27	Sa'a Quine	Chloroquine	SA'A Pharmaceutical Products Limited	Nigeria	B	04-2855	not found	SQ19043	HPLC; UV/Vis	probably falsified	extreme deviation	probably falsified	QMN 027
28	Dexacure	Dexamethasone	Unicure Pharmaceutical Ltd.	Nigeria	B	A4-7117	verified	201101	HPLC	moderate deviation	moderate deviation	moderate deviation	QMN 028
29	Rich Dexa	Dexamethasone	Brussels Laboratories Pvt Ltd.	India	B	B4-5389	not found	Z19003	HPLC	extreme deviation	extreme deviation	extreme deviation	QMN 029
30	Dexamethasone 0.5	Dexamethasone	Surmount Laboratories Private Limited	India	B	B4-9983	not found	TD9003	HPLC	extreme deviation	moderate deviation	extreme deviation	QMN 030
31	Zanelb	Dexamethasone	VAKS Pharma Pvt. Ltd.	India	B	B4-8496	verified	V20169	HPLC	extreme deviation	moderate deviation	extreme deviation	QMN 031
32	Glanil	Glibenclamide	Nigerian-German Chemicals Plc	Nigeria	B	04-2450	not found	FPA070221	HPLC	in specification	extreme deviation	extreme deviation	QMN 032
33	Gliben-J	Glibenclamide	JUHEL NIGERIA LIMITED	Nigeria	B	04-5735	not found	0041	HPLC	in specification	in specification	in specification	QMN 033
34	Tionil	Glibenclamide	Merit Organics Ltd.	India	B	B4-7811	not found	T32002	HPLC	extreme deviation	extreme deviation	extreme deviation	QMN 034

35	Redrex 25	Hydrochlorothiazide	WEST-COAST Pharmaceutical Works Ltd.	India	B	unknown	-	WG19285	HPLC	in specification	in specification	in specification	QMN 035
36	Hydrex	Hydrochlorothiazide	JUHEL NIGERIA LIMITED	Nigeria	B	A4-1209	verified	0139	HPLC	in specification	in specification	in specification	QMN 036
37	Eden Atenolol	Atenolol	IMPULSE PHARMA PVT LTD.	India	B	B4-6760	not found	200164	HPLC	in specification	in specification	in specification	QMN 037
38	Atenolol	Atenolol	ALPA LABORATORIES LTD.	India	B	B4-8238	verified	TE0184	HPLC	in specification	in specification	in specification	QMN 038
39	Chupet Ceftriaxone Sodiun	Ceftriaxone	Hunan Zhongnan Kelun Pharmaceutical Co., Ltd.	China	B	A4-9142	verified	200303	-	in specification	-	in specification	QMN 039
40	Pocco Ceftriaxone Injectio	Ceftriaxone	Scott-Edil Advance Research Laboratories & Education Ltd.	India	B	B4-9368	verified	1340Z157	-	in specification	-	in specification	QMN 040
41	Rebok Ceftriaxone Sodium	Ceftriaxone	China National Medicines Guorui Pharmaceutical Co., Ltd.	China	B	A4-5327	not found	200946	-	in specification	-	in specification	QMN 041
42	Macephin	Ceftriaxone	Shandong Xier Kangtai Pharm Co. Ltd	China	B	B4-5559	not found	201221	-	in specification	-	in specification	QMN 042
43	Chloro	Chloroquine	LEOBEN HEALTHCARE	Nigeria	B	04-4166	not found	0432	HPLC; UV/Vis	falsified	extreme deviation	falsified	QMN 043
44	Poletrim	Co-trimoxazole*	MAOBISON INTER-LINK & ASSOCIATES LTD.	Nigeria	B	A4-8482	not found	777.51	HPLC	probably falsified	extreme deviation	probably falsified	QMN 044
45	Rotrim	Co-trimoxazole*	ROTAC MEDICAL LAB.	Nigeria	B	04-5745	product of different API and brand registered under this Reg. No.	RML478	HPLC	falsified	extreme deviation	falsified	QMN 045
46	Weltrim	Co-trimoxazole*	WELTEC HEALTHCARE LTD	Nigeria	B	04-5245	not found	NHL-1001	HPLC	falsified	extreme deviation	falsified	QMN 046
47	Hydrochlorothiazide	Hydrochlorothiazide	missing	missing	B	missing	-	AE-19118	HPLC	in specification	in specification	in specification	QMN 047
48	Redrex 25	Hydrochlorothiazide	WEST-COAST Pharmaceutical Works Ltd.	India	B	B4-9818	verified	WG20005	HPLC	in specification	in specification	in specification	QMN 048
49	Esidrex	Hydrochlorothiazide	DELPHARM L'AIGLE	France	B	missing	-	2OFA301	HPLC	in specification	in specification	in specification	QMN 049 (1/2)
50	Johnbee Fluconazole Table	Fluconazole	Scott-Edil Pharmacia Ltd.	India	B	B4-6796	not found	XT9L037	HPLC	in specification	in specification	in specification	QMN 050
51	Fungiban	Fluconazole	Mancare PHARMACEUTICALS PVT. LTD.	India	B	A4-8168	verified	TUE113	HPLC	extreme deviation	moderate deviation	extreme deviation	QMN 051
52	Eden Atenolol	Atenolol	IMPULSE PHARMA PVT LTD.	India	B	B4-6760	not found	200164	HPLC	in specification	in specification	in specification	QMN 052
53	Emgyl	Metronidazole	emzor Pharmaceutical Industries Ltd.	Nigeria	B	04-0412	not found	S0156SA	HPLC	in specification	in specification	in specification	QMN 053
54	Cisepro-500	Ciprofloxacin	Fredun Pharmaceuticals Ltd.	India	B	B4-6330	not found	AA0036	HPLC	in specification	in specification	in specification	QMN 054
55	G.Ossy Ceftriaxone	Ceftriaxone	Shandong Xier Kangtai Pharm Co. Ltd	China	B	B4-4640	not found	201216	-	in specification	-	in specification	QMN 055
56	Dexacure	Dexamethasone	Unicure Pharmaceutical Ltd.	Nigeria	B	A4-7117	verified	210401	HPLC	in specification	in specification	in specification	QMN 056
57	Diatab	Glibenclamide	MAY&BAKER NIGERIA PLC	Nigeria	B	04-7837	verified	A202435	HPLC	in specification	in specification	in specification	QMN 057
58	Glanil	Glibenclamide	Nigerian-German Chemicals Plc	Nigeria	B	04-2450	not found	FPD070421	HPLC	in specification	extreme deviation	extreme deviation	QMN 058
59	Sivophage	Metformin	Globela Pharma Pvt. Ltd.	India	B	B4-0684	not found	GT20258	HPLC	in specification	in specification	in specification	QMN 059
60	Gluformin	Metformin	Nigerian-German Chemicals Plc	Nigeria	B	04-6426	verified	FPD080121	HPLC	moderate deviation	in specification	moderate deviation	QMN 060
61	Atenolol	Atenolol	missing	missing	B	missing	-	BPQ170002	HPLC	in specification	in specification	in specification	QMN 061
62	Latrim 480	Co-trimoxazole*	Me Cure Industries Ltd.	Nigeria	B	04-4483	verified	CT.1146	HPLC	in specification	in specification	in specification	QMN 062
63	Metrozol	Metronidazole	VITABIOTICS (NIG.) LTD.	Nigeria	B	A4-6028	not found	T21521	HPLC	in specification	in specification	in specification	QMN 063
64	Esodrex 25 mg	Hydrochlorothiazide	Anhui Medipharm Co. Ltd	China	B	missing	-	190329	HPLC	in specification	in specification	in specification	QMN 064
65	Johnbee Fluconazole Table	Fluconazole	Scott-Edil Pharmacia Ltd.	India	B	B4-6796	not found	XT9L037	HPLC	in specification	in specification	in specification	QMN 065
66	Xymatyl 500	Cefuroxime axetil	Adora Products Pvt. Ltd.	India	B	B4-5993	not found	HG303L20	UV/Vis	in specification	in specification	in specification	QMN 066
67	Cefurite	Cefuroxime axetil	ASIAN PHARMA	India	B	missing	-	AT11721	UV/Vis	moderate deviation	in specification	moderate deviation	QMN 067
68	Lasimac	Furosemide	Mancare PHARMACEUTICALS PVT. LTD.	India	B	B4-6708	verified	TUK03	UV/Vis	in specification	in specification	in specification	QMN 068
69	Glulife-500 mg	Metformin	Jiangsu Ruinian Qianjin Pharmaceutical Co. Ltd.	China	B	A4-6354	not found	200310	HPLC	in specification	in specification	in specification	QMN 069
70	Me cure Dexamethasone	Dexamethasone	Me Cure Industries Ltd.	Nigeria	B	A4-0201	verified	DC.319	HPLC	moderate deviation	moderate deviation	moderate deviation	QMN 070
71	Dexacure	Dexamethasone	Unicure Pharmaceutical Ltd.	Nigeria	B	A4-7117	verified	210201	HPLC	moderate deviation	moderate deviation	moderate deviation	QMN 071
72	Dexacortin	Dexamethasone	Maxwell Life Science Pvt. Ltd.	India	B	04-2446	not found	ET9514	HPLC	extreme deviation	moderate deviation	extreme deviation	QMN 072
73	Xasten	Dexamethasone	Jiangsu Pengyao Pharmaceutical Co. Ltd. (INC.)	China	B	04-6822	verified	200925	HPLC	moderate deviation	moderate deviation	moderate deviation	QMN 073
74	Frusemide tablets shree ax	Furosemide	Mancare PHARMACEUTICALS PVT. LTD.	India	B	A4-0604	not found	TUK16	UV/Vis	in specification	in specification	in specification	QMN 074
75	Aphantix	Furosemide	Mancare PHARMACEUTICALS PVT. LTD.	India	B	04-9146	product of different API and brand registered under this Reg. No.	TVK28	UV/Vis	in specification	in specification	in specification	QMN 075
76	Lasimac	Furosemide	Mancare PHARMACEUTICALS PVT. LTD.	India	B	B4-6708	verified	TUK02	UV/Vis	in specification	in specification	in specification	QMN 076
77	Flucoxiom-150	Fluconazole	Lesanto Laboratories	India	B	C4-1024	not found	L718002	HPLC	in specification	not tested (capsule)	in specification	QMN 077
78	Fluconazole 150 mg	Fluconazole	Globela Pharma Pvt. Ltd.	India	B	B4-7568	not found	GT20110	HPLC	in specification	in specification	in specification	QMN 078
79	Nkoyo Fluconazole	Fluconazole	Mancare PHARMACEUTICALS PVT. LTD.	India	B	A4-0421	not found	TUL43	HPLC	in specification	in specification	in specification	QMN 079
80	Roxirite	Cefuroxime axetil	HEALTH CARE FORMULATIONS PVT. LTD.	India	B	C4-1189	verified	T-220	UV/Vis	in specification	in specification	in specification	QMN 080

81	Oxispa 500	Cefuroxime axetil	MEDICO REMEDIES LTD.	India	B	B4-6770	not found	OXS001	UV/Vis	in specification	in specification	in specification	QMN 081
82	Harvad Cefuroxime tablets	Cefuroxime axetil	ALPA LABORATORIES LTD.	India	B	B4-7976	verified	TC0011	UV/Vis	in specification	in specification	in specification	QMN 082
83	Ibu Ciprofloxacin - 500	Ciprofloxacin	Kesar Pharma (P) Ltd.	India	B	C4-0487	not found	T21001	HPLC	moderate deviation	in specification	moderate deviation	QMN 083
84	Osworth Metformin	Metformin	MAY&BAKER NIGERIA PLC	Nigeria	B	A4-4310	verified	AC20039	HPLC	in specification	in specification	in specification	QMN 084
85	Ciprofloxacin	Ciprofloxacin	Fredun Pharmaceuticals Ltd.	India	A	B4-1176	verified	FC0020	HPLC	in specification	in specification	in specification	QMN 085
86	Metformin	Metformin	Fredun Pharmaceuticals Ltd.	India	A	B4-0944	not found	FK0003	HPLC	in specification	in specification	in specification	QMN 086
87	Quimal	Chloroquine	DANA PHARMACEUTICALS LIMITED	Nigeria	B	04-1785	verified	QT145	HPLC; UV/Vis	moderate deviation	in specification	moderate deviation	QMN 087
88	Albequine	Chloroquine	ALBEN HEALTHCARE IND. LTD.	Nigeria	B	B4-0086	not found	017	HPLC; UV/Vis	in specification	moderate deviation	moderate deviation	QMN 088
89	Softhealth Ciprofloxcin tab	Ciprofloxacin	Halewood Laboratories Pvt. Ltd.	India	B	B4-6819	not found	HV1003	HPLC	in specification	in specification	in specification	QMN 089
90	Cipro-500	Ciprofloxacin	NUEL PHARM. LTD.	Nigeria	B	A4-9505	not found	0621NCPO2	HPLC	in specification	in specification	in specification	QMN 090
91	Ceftriaxone injection	Ceftriaxone	Anhui Chengshi Pharmaceutical Co. Ltd.	China	B	B4-7640	not found	303201201	-	in specification	-	in specification	QMN 091
92	Atenolol	Atenolol	missing	missing	B	missing	-	K4548002	HPLC	in specification	in specification	in specification	QMN 092
93	Atenolol	Atenolol	ALPA LABORATORIES LTD.	India	B	B4-8238	verified	TE0184	HPLC	in specification	in specification	in specification	QMN 093
94	New Divine Frusemide	Furosemide	New Divine Favour Pharmaceutical Industries Ltd.	Nigeria	B	A4-8776	not found	0029	UV/Vis	in specification	in specification	in specification	QMN 094
95	Furosemide	Furosemide	Bristol Laboratories Ltd	UK	B	missing	-	AUC240012	UV/Vis	in specification	in specification	in specification	QMN 095
96	Eden Atenolol	Atenolol	IMPULSE PHARMA PVT LTD.	India	B	B4-6760	not found	200165	HPLC	in specification	in specification	in specification	QMN 096
97	Zuntrim	Co-trimoxazole*	ZUNAMEDIKS PHARM. LTD.	Nigeria	B	A11-0988	verified	RT0003C	HPLC	extreme deviation	moderate deviation	extreme deviation	QMN 097
98	Zunagyl	Metronidazole	ZUNAMEDIKS PHARM. LTD.	Nigeria	B	A11-0295	verified	GT0063D	HPLC	probably falsified	extreme deviation	probably falsified	QMN 098
99	Elcexone	Ceftriaxone	Inject Care Parenterals Pvt Ltd.	India	B	B4-7427	not found	IC21263004	-	in specification	-	in specification	QMN 099
100	Derm Ceftriaxone 1G Injec	Ceftriaxone	Shandong Xier Kangtai Pharm Co. Ltd	China	B	B4-5844	not found	201172	-	in specification	-	in specification	QMN 100
101	Rebok Ceftriaxone Sodium	Ceftriaxone	China National Medicines Guorui Pharmaceutical Co., Ltd.	China	B	A4-5327	not found	200235	-	in specification	-	in specification	QMN 101
102	Macephin	Ceftriaxone	Shandong Xier Kangtai Pharm Co. Ltd	China	B	B4-5559	not found	201221	-	in specification	-	in specification	QMN 102
103	Betafil	Atenolol	Fourrts (India) Laboratories Pvt. Limited	India	B	04-8111	verified	H0410	HPLC	in specification	in specification	in specification	QMN 103
104	Atenolol	Atenolol	missing	missing	B	missing	-	BPQ179021	HPLC	in specification	in specification	in specification	QMN 104
105	Emgyl	Metronidazole	emzor Pharmaceutical Industries Ltd.	Nigeria	B	04-0412	not found	338A	HPLC	in specification	in specification	in specification	QMN 105
106	Loxagyl 200	Metronidazole	MAY&BAKER NIGERIA PLC	Nigeria	B	04-0283	not found	A182113	HPLC	in specification	in specification	in specification	QMN 106
107	Diamet	Metformin	MAY&BAKER NIGERIA PLC	Nigeria	B	04-7945	not found	A210792	HPLC	in specification	in specification	in specification	QMN 107
108	Tricophage - 500	Metformin	BAROQUE PHARMACEUTICALS PVT. LTD.	India	B	B4-2429	not found	G039008	HPLC	in specification	in specification	in specification	QMN 108
109	Roxirite	Cefuroxime axetil	HEALTH CARE FORMULATIONS PVT. LTD.	India	B	C4-1189	verified	T-218	UV/Vis	in specification	in specification	in specification	QMN 109
110	Cefurite	Cefuroxime axetil	ASIAN PHARMA	India	B	missing	-	AT11721	UV/Vis	moderate deviation	in specification	moderate deviation	QMN 110
111	Harvad Cefuroxime tablets	Cefuroxime axetil	ALPA LABORATORIES LTD.	India	B	B4-7976	verified	TC0011	UV/Vis	in specification	in specification	in specification	QMN 111
112	Cefuroxime Deno	Cefuroxime axetil	Scott-Edil Advance Research Laboratories & Education Ltd.	India	B	C4-0958	not found	1130Z007	UV/Vis	in specification	in specification	in specification	QMN 112
113	Emtrim	Co-trimoxazole*	emzor Pharmaceutical Industries Ltd.	Nigeria	B	04-0267	verified	S0412SA	HPLC	in specification	in specification	in specification	QMN 113
114	Tionil	Glibenclamide	Merit Organics Ltd.	India	B	B4-7811	not found	T32002	HPLC	in specification	moderate deviation	moderate deviation	QMN 114
115	Glibenclamide	Glibenclamide	ZLF PHARMA UK LIMITED	UK	B	missing	-	190201	HPLC	in specification	moderate deviation	moderate deviation	QMN 115
116	Glibenclamide	Glibenclamide	MEDICO REMEDIES LTD.	India	B	B4-8197	verified	GIB903	HPLC	moderate deviation	extreme deviation	extreme deviation	QMN 116
117	Transglobe	Glibenclamide	OSAKA Pharmaceuticals Pvt. Ltd.	India	B	unknown	-	OS20032	HPLC	in specification	in specification	in specification	QMN 117
118	Redrex 25	Hydrochlorothiazide	WEST-COAST Pharmaceutical Works Ltd.	India	B	B4-9818	verified	WG20004	HPLC	in specification	in specification	in specification	QMN 118
119	Hydrochlorothiazide	Hydrochlorothiazide	missing	missing	B	missing	-	AE-19118	HPLC	in specification	in specification	in specification	QMN 119
120	Hydrochlorothiazide	Hydrochlorothiazide	missing	missing	B	missing	-	D200272	HPLC	in specification	in specification	in specification	QMN 120
121	HCTZ 25	Hydrochlorothiazide	T.O Chemical	Thailand	B	missing	-	S102021	HPLC	in specification	in specification	in specification	QMN 121
122	Chloroquine	Chloroquine	emzor Pharmaceutical Industries Ltd.	Nigeria	B	04-1218	not found	1840Z	HPLC; UV/Vis	in specification	in specification	in specification	QMN 122
123	Dr. Meyer's Maxiquine	Chloroquine	VITABIOTICS (NIG.) LTD.	Nigeria	B	A11-0393	not found	T61220	HPLC; UV/Vis	in specification	in specification	in specification	QMN 123
124	Quimal	Chloroquine	DANA PHARMACEUTICALS LIMITED	Nigeria	B	04-1785	verified	QT145	HPLC; UV/Vis	in specification	in specification	in specification	QMN 124
125	Albequine	Chloroquine	ALBEN HEALTHCARE IND. LTD.	Nigeria	B	B4-0086	not found	017	HPLC; UV/Vis	moderate deviation	moderate deviation	moderate deviation	QMN 125
126	Gluformin	Metformin	Nigerian-German Chemicals Plc	Nigeria	B	04-6426	verified	FPD080521	HPLC	in specification	in specification	in specification	QMN 126
127	Diabetmin	Metformin	HOVID Bhd.	Malaysia	B	04-0810	verified	CB01603	HPLC	in specification	in specification	in specification	QMN 127
128	Biocipro	Ciprofloxacin	McCoy Pharma Pvt. Ltd.	India	B	B4-2452	not found	MP9420	HPLC	moderate deviation	moderate deviation	moderate deviation	QMN 128
129	Cenox	Ciprofloxacin	Mediios Laboratories Ltd.	India	B	04-3002	verified	M0063	HPLC	in specification	in specification	in specification	QMN 129

130	Nemel Cipro	Ciprofloxacin	NEMEL PHARMACEUTICALS LIMITED	Nigeria	B	B4-1405	verified	02E	HPLC	in specification	in specification	in specification	QMN 130
131	Cisepro-500	Ciprofloxacin	Fredun Pharmaceuticals Ltd.	India	B	B4-6330	not found	AA0037	HPLC	in specification	in specification	in specification	QMN 131
132	Flucozar	Fluconazole	J.DUNCAN HEALTHCARE PVT. LTD.	India	B	B4-2169	not found	J005B915	HPLC	in specification	not tested (capsule)	in specification	QMN 132
133	Johnbee Fluconazole Table	Fluconazole	Scott-Edil Pharmacia Ltd.	India	B	B4-6796	not found	XT9L037	HPLC	in specification	in specification	in specification	QMN 133
134	Berlin Fluconazole	Fluconazole	Kesar Pharma (P) Ltd.	India	B	C4-0748	not found	T20462	HPLC	in specification	in specification	in specification	QMN 134
135	AD-Fluconazole	Fluconazole	Globela Pharma Pvt. Ltd.	India	B	B4-1543	not found	20GT047	HPLC	in specification	in specification	in specification	QMN 135
136	Dexalab	Dexamethasone	Laborate Pharmaceuticals India Ltd.	India	B	04-5413	not found	KDSTE-003	HPLC	moderate deviation	moderate deviation	moderate deviation	QMN 136
137	Me cure Dexamethasone	Dexamethasone	Me Cure Industries Ltd.	Nigeria	B	A4-0201	verified	DC.227	HPLC	in specification	moderate deviation	moderate deviation	QMN 137
138	Nkoyo Dexamethasone	Dexamethasone	AR Lifesciences	India	B	04-8665	not found	L263	HPLC	extreme deviation	moderate deviation	extreme deviation	QMN 138
139	Pauco Dexamethasone tab	Dexamethasone	PAUCO Pharmaceutical Ind. Ltd.	Nigeria	B	A4-1036	not found	016	HPLC	moderate deviation	moderate deviation	moderate deviation	QMN 139
140	Loxaprim	Co-trimoxazole*	MAY&BAKER NIGERIA PLC	Nigeria	B	04-5567	verified	A170506	HPLC	in specification	in specification	in specification	QMN 140
141	Frusemide tablets shree ax	Furosemide	Mancare PHARMACEUTICALS PVT. LTD.	India	B	A4-0604	not found	TUK17	UV/Vis	in specification	in specification	in specification	QMN 141
142	Frusatex	Furosemide	Surelife Pharmaceutical Industries Ltd.	Nigeria	B	A11-0107	not found	028	UV/Vis	in specification	moderate deviation	moderate deviation	QMN 142
143	Nemegyl	Metronidazole	NEMEL PHARMACEUTICALS LIMITED	Nigeria	B	04-5326	not found	O1G	HPLC	in specification	in specification	in specification	QMN 143
144	Co-Trox	Co-trimoxazole*	VITABIOTICS (NIG.) LTD.	Nigeria	B	04-0061	not found	T59421	HPLC	in specification	in specification	in specification	QMN 144
145	Atenolol	Atenolol	ALPA LABORATORIES LTD.	India	B	B4-8238	verified	TE0183	HPLC	in specification	in specification	in specification	QMN 145
146	Metrozol	Metronidazole	VITABIOTICS (NIG.) LTD.	Nigeria	B	A4-6028	not found	T461119	HPLC	in specification	in specification	in specification	QMN 146
147	Cipxin-500	Ciprofloxacin	EUROLIFE HEALTHCARE PVT. LTD.	India	B	04-6293	not found	CPN046	HPLC	in specification	in specification	in specification	QMN 147 (1/2)
148	Camtaxone	Ceftriaxone	Shandong Xier Kangtai Pharm Co. Ltd	China	B	A4-7940	not found	20538	-	in specification	-	in specification	QMN 148
149	Pulmocef 500	Cefuroxime axetil	Micro Labs Ltd.	India	A	A4-1971	verified	PEFB0063	UV/Vis	in specification	in specification	in specification	QMN 149
150	Gecip	Ciprofloxacin	Jiangsu Ruinian Qianjin Pharmaceutical Co. Ltd.	China	A	B4-5856	not found	200417	HPLC	in specification	in specification	in specification	QMN 150
151	GG Dexamethasone Tablet	Dexamethasone	Jiangsu Pengyao Pharmaceutical Co. Ltd. (INC.)	China	A	A4-1598	not found	200821	HPLC	extreme deviation	moderate deviation	extreme deviation	QMN 151
152	Triaxin	Ceftriaxone	CSPC Zhongnuo Pharmaceuticals Co. Ltd.	China	A	04-8886	verified	659200615	-	in specification	-	in specification	QMN 152 (1/2)
153	Oxispa 500	Cefuroxime axetil	MEDICO REMEDIES LTD.	India	A	B4-6770	not found	OXS001	UV/Vis	in specification	in specification	in specification	QMN 153
154	Doncinat - 500	Cefuroxime axetil	BAROQUE PHARMACEUTICALS PVT. LTD.	India	A	A4-6907	verified	C010058	UV/Vis	in specification	in specification	in specification	QMN 154
155	Cipronol 500	Ciprofloxacin	Maxheal Laboratories Pvt. Ltd.	India	A	04-6340	not found	PL21007	HPLC	in specification	in specification	in specification	QMN 155
156	Ceftriaxone for injection	Ceftriaxone	Aqua Vitoe Laboratories	India	A	B4-3696	not found	B042020	-	in specification	-	in specification	QMN 156
157	Ciprofloxacin 500	Ciprofloxacin	Fidson Healthcare Plc.	Nigeria	A	A11-0403	not found	T2521001	HPLC	in specification	moderate deviation	moderate deviation	QMN 157
158	Xymatyl 500	Cefuroxime axetil	Adora Products Pvt. Ltd.	India	A	B4-5993	not found	HG303L20	UV/Vis	in specification	in specification	in specification	QMN 158
159	Nkoyo Fluconazole	Fluconazole	Mancare PHARMACEUTICALS PVT. LTD.	India	A	A4-0421	not found	TVB62	HPLC	in specification	in specification	in specification	QMN 159
160	Nkoyo Dexamethasone	Dexamethasone	McCoy Pharma Pvt. Ltd.	India	A	04-8665	not found	L20072	HPLC	moderate deviation	moderate deviation	moderate deviation	QMN 160
161	Ceftriaxone Injection	Ceftriaxone	Shanxi Zhongbao Shuguang Pharmaceutical Co., Ltd.	China	A	A4-9551	not found	210120	-	in specification	-	in specification	QMN 161
162	IVIM Ceftriaxone for Inject	Ceftriaxone	Scott-Edil Advance Research Laboratories & Education Ltd.	India	A	B4-4837	not found	1340Z081	-	in specification	-	in specification	QMN 162
163	Ciprobiotic-Forte	Ciprofloxacin	Emcure PHARMACEUTICALS LTD.	India	A	04-2307	not found	E16QP20046	HPLC	in specification	in specification	in specification	QMN 163
164	Diaformin	Metformin	BAL PHARMA LIMITED	India	A	B4-7950	not found	MTE42	HPLC	in specification	in specification	in specification	QMN 164
165	Glanil	Glibenclamide	Nigerian-German Chemicals Plc	Nigeria	A	04-2450	not found	FPD070321	HPLC	in specification	moderate deviation	moderate deviation	QMN 165
166	Gluformin	Metformin	Nigerian-German Chemicals Plc	Nigeria	A	04-6426	verified	FPC080121	HPLC	in specification	in specification	in specification	QMN 166
167	Clezide	Glibenclamide	Jiangsu Ruinian Qianjin Pharmaceutical Co. Ltd.	China	A	A4-2100	verified	190524	HPLC	moderate deviation	in specification	moderate deviation	QMN 167
168	Xasten	Dexamethasone	Jiangsu Pengyao Pharmaceutical Co. Ltd. (INC.)	China	A	04-6822	verified	200925	HPLC	moderate deviation	moderate deviation	moderate deviation	QMN 168
169	Cevmid	Ceftriaxone	Shandong Xier Kangtai Pharm Co. Ltd	China	A	A4-3304	not found	200954	-	in specification	-	in specification	QMN 169
170	Sopro Caplet	Ciprofloxacin	Jiangsu Pengyao Pharmaceutical Co. Ltd. (INC.)	China	A	B4-0053	not found	190819	HPLC	in specification	in specification	in specification	QMN 170
171	Vixa-Metformin	Metformin	Jiangsu Ruinian Qianjin Pharmaceutical Co. Ltd.	China	A	A4-2031	not found	191237	HPLC	in specification	in specification	in specification	QMN 171
172	Cefsafe-500	Cefuroxime axetil	missing	India	A	C4-0252	verified	HH108B21	UV/Vis	in specification	in specification	in specification	QMN 172
173	Eden Fluconazole	Fluconazole	IMPULSE PHARMA PVT LTD.	India	A	C4-0072	not found	200149	HPLC	in specification	not tested (capsule)	in specification	QMN 173

174	Famagyl	Metronidazole	PHAMATEX INDUSTRIES LIMITED	Nigeria	A	B4-2269	verified	T0157	HPLC	in specification	in specification	in specification	QMN 174
175	Pilotab	Ciprofloxacin	PHAMATEX INDUSTRIES LIMITED	Nigeria	A	B4-2270	verified	T1037	HPLC	in specification	in specification	in specification	QMN 175
176	Diapil	Metformin	PHAMATEX INDUSTRIES LIMITED	Nigeria	A	A11-0211	not found	T0082	HPLC	in specification	in specification	in specification	QMN 176
177	Flucox	Fluconazole	PHAMATEX INDUSTRIES LIMITED	Nigeria	A	B4-2972	verified	C1002	HPLC	in specification	not tested (capsule)	in specification	QMN 177
178	Licafur 500 Tablets	Cefuroxime axetil	BAROQUE PHARMACEUTICALS PVT. LTD.	India	A	B4-0098	verified	C010009	UV/Vis	in specification	in specification	in specification	QMN 178
179	Biophin Injection	Ceftriaxone	Intracin Pharmaceutical Pvt. Ltd.	India	A	04-6529	not found	20P10	-	in specification	-	in specification	QMN 179
180	Gluconorm SR 500	Metformin	LINCOLN PHARMACEUTICALS LTD.	India	A	A4-6949	verified	HB9003	HPLC	in specification	in specification	in specification	QMN 180
181	Galcipro 500	Ciprofloxacin	SKG-Pharma Limited	Nigeria	A	A4-0327	not found	2101	HPLC	moderate deviation	moderate deviation	moderate deviation	QMN 181
182	Primpex	Co-trimoxazole*	SKG-Pharma Limited	Nigeria	A	04-1959	not found	2136	HPLC	in specification	in specification	in specification	QMN 182
183	Metrotab 400	Metronidazole	SKG-Pharma Limited	Nigeria	A	04-9101	verified	0721	HPLC	in specification	in specification	in specification	QMN 183
184	Biophage 500	Metformin	SKG-Pharma Limited	Nigeria	A	A4-6597	verified	2120	HPLC	in specification	in specification	in specification	QMN 184
185	Avrotrim	Co-trimoxazole*	SKG-Pharma Limited	Nigeria	A	A4-4549	verified	2148	HPLC	in specification	in specification	in specification	QMN 185
186	Avrogyl	Metronidazole	SKG-Pharma Limited	Nigeria	A	A4-4725	verified	2107	HPLC	in specification	in specification	in specification	QMN 186
187	Avrocipro	Ciprofloxacin	SKG-Pharma Limited	Nigeria	A	A11-0786	verified	0221	HPLC	moderate deviation	moderate deviation	moderate deviation	QMN 187
188	Gauze Chloroquin	Chloroquine	Gauze Pharm. & Labs. Ltd.	Nigeria	A	A11-0076	not found	GCT031	HPLC; UV/Vis	in specification	in specification	in specification	QMN 188
189	Cyplox	Ciprofloxacin	MEDREICH LIMITED	India	A	04-3202	verified	B00045	HPLC	in specification	moderate deviation	moderate deviation	QMN 189
190	Glucophage 500 mg	Metformin	Merck S.L. Poligono Merck	Spain	A	04-6233	verified	E206246	HPLC	in specification	in specification	in specification	QMN 190
191	Zimatrim	Co-trimoxazole*	Gauze Pharm. & Labs. Ltd.	Nigeria	A	A11-0064	not found	ZGT037	HPLC	probably falsified	extreme deviation	probably falsified	QMN 191
192	Co-Trox	Co-trimoxazole*	VITABIOTICS (NIG.) LTD.	Nigeria	A	04-0061	not found	T17919	HPLC	in specification	in specification	in specification	QMN 192
193	Unigyl 200	Metronidazole	Unique Pharmaceuticals Ltd.	Nigeria	A	04-8426	verified	UGT9011	HPLC	in specification	in specification	in specification	QMN 193
194	Zimagil	Metronidazole	Gauze Pharm. & Labs. Ltd.	Nigeria	A	A11-0059	not found	ZGT091	HPLC	in specification	in specification	in specification	QMN 194
195	Zimagil	Metronidazole	Gauze Pharm. & Labs. Ltd.	Nigeria	A	A11-0059	not found	ZGT082	HPLC	in specification	in specification	in specification	QMN 195
196	Zimagil	Metronidazole	Gauze Pharm. & Labs. Ltd.	Nigeria	A	A11-0059	not found	ZGT089	HPLC	in specification	in specification	in specification	QMN 197
197	Metformin	Metformin	SWISS PHARMA PVT LTD.	India	A	C4-0429	not found	0211	HPLC	in specification	in specification	in specification	QMN 198
198	Tricophage - 500	Metformin	BAROQUE PHARMACEUTICALS PVT. LTD.	India	A	B4-2429	not found	G039009	HPLC	in specification	in specification	in specification	QMN 199
199	Axacef	Cefuroxime axetil	MEDREICH LIMITED	India	A	04-6027	not found	C00127	UV/Vis	in specification	in specification	in specification	QMN 200
200	Tribinat-500	Cefuroxime axetil	BAROQUE PHARMACEUTICALS PVT. LTD.	India	A	B4-2436	not found	C039009	UV/Vis	in specification	in specification	in specification	QMN 201
201	Zoxon	Ceftriaxone	MEDREICH LIMITED	India	A	04-9534	verified	C00073	-	in specification	-	in specification	QMN 202
202	Pocco Ceftriaxone Injectio	Ceftriaxone	Scott-Edil Advance Research Laboratories & Education Ltd.	India	A	B4-9368	verified	1340Z136	-	in specification	-	in specification	QMN 203
203	Zidek	Ceftriaxone	CSPC Zhongnuo Pharmaceuticals Co. Ltd.	China	A	B4-8006	not found	2005801	-	in specification	-	in specification	QMN 204
204	Nkoyo Dexamethasone	Dexamethasone	Mancare PHARMACEUTICALS PVT. LTD.	India	A	04-8665	not found	TVL55	HPLC	moderate deviation	moderate deviation	moderate deviation	QMN 205
205	Atenolol 50 mg Tablets	Atenolol	Scott-Edil Pharmacia Ltd.	India	A	B4-1651	verified	XT9L027	HPLC	in specification	in specification	in specification	QMN 206
206	Hydrex	Hydrochlorothiazide	JUHEL NIGERIA LIMITED	Nigeria	A	A4-1209	verified	0131	HPLC	in specification	in specification	in specification	QMN 207
207	New Divine Frusemide	Furosemide	New Divine Favour Pharmaceutical Industries Ltd.	Nigeria	A	A4-8776	not found	0029	UV/Vis	in specification	moderate deviation	moderate deviation	QMN 208
208	Fluconazole 150 mg	Fluconazole	Globela Pharma Pvt. Ltd.	India	A	B4-7568	not found	GT20110	HPLC	in specification	in specification	in specification	QMN 209
209	Trust Time Dexamethason	Dexamethasone	DUPEN LABORATORIES PVT. LTD.	India	B	B4-5651	verified	A009	HPLC	moderate deviation	moderate deviation	moderate deviation	QMN 210
210	Tamaflex 500	Ciprofloxacin	Maxtar Bio-Genics	India	A	A4-9436	not found	M3TGU1902	HPLC	in specification	in specification	in specification	QMN 211
211	Destrax	Dexamethasone	Jiangsu Pengyao Pharmaceutical Co. Ltd. (INC.)	China	A	B4-3876	not found	181201	HPLC	probably falsified	extreme deviation	probably falsified	QMN 212
212	Novalor caplets	Chloroquine	SKG-Pharma Limited	Nigeria	A	04-1442	not found	2001	HPLC; UV/Vis	in specification	extreme deviation	extreme deviation	QMN 213
213	Zoxon	Ceftriaxone	MEDREICH LIMITED	India	A	04-9534	verified	C00150	-	in specification	-	in specification	QMN 214
214	Zoxon	Ceftriaxone	MEDREICH LIMITED	India	A	04-9534	verified	C00069	-	in specification	-	in specification	QMN 215
215	Esidrex	Hydrochlorothiazide	DELPHARM L'AIGLE	France	B	missing	-	2OFA379	HPLC	in specification	in specification	in specification	QMN 216 (2/2)
216	Triaxin	Ceftriaxone	CSPC Zhongnuo Pharmaceuticals Co. Ltd.	China	A	04-8886	verified	659200616	-	in specification	-	in specification	QMN 217 (2/2)
217	Famagyl	Metronidazole	PHAMATEX INDUSTRIES LIMITED	Nigeria	A	B4-2269	verified	T1137	HPLC	in specification	in specification	in specification	QMN 218
218	Afrab Chloroquine	Chloroquine	Afrab-Chem Ltd.	Nigeria	A	A11-100076	verified	21252	HPLC; UV/Vis	in specification	in specification	in specification	QMN 219
219	Flucox	Fluconazole	PHAMATEX INDUSTRIES LIMITED	Nigeria	A	B4-2972	verified	C1005	HPLC	in specification	not tested (capsule)	in specification	QMN 220
220	Ciproheal Tablets	Ciprofloxacin	Maxheal Laboratories Pvt. Ltd.	India	A	04-7436	not found	CF21036	HPLC	in specification	in specification	in specification	QMN 221
221	Tionil	Glibenclamide	Merit Organics Ltd.	India	A	B4-7811	not found	T32004	HPLC	moderate deviation	in specification	moderate deviation	QMN 222

222	Nkoyosix	Furosemide	Mancare PHARMACEUTICALS PVT. LTD.	India	A	A4-9179	verified	TUL36	UV/Vis	in specification	in specification	in specification	QMN 223
223	Chloroquine	Chloroquine	JUHEL NIGERIA LIMITED	Nigeria	A	04-0171	not found	0006	HPLC; UV/Vis	in specification	in specification	in specification	QMN 224
224	Hydrex	Hydrochlorothiazide	JUHEL NIGERIA LIMITED	Nigeria	A	A4-1209	verified	0157	HPLC	in specification	in specification	in specification	QMN 225
225	Avrotrim	Co-trimoxazole*	SKG-Pharma Limited	Nigeria	A	A4-4549	verified	2205	HPLC	in specification	in specification	in specification	QMN 226
226	Adnil	Glibenclamide	Globela Pharma Pvt. Ltd.	India	A	B4-9967	not found	GT21094	HPLC	in specification	in specification	in specification	QMN 227
227	Gliben-J	Glibenclamide	JUHEL NIGERIA LIMITED	Nigeria	A	04-5735	not found	0041	HPLC	in specification	in specification	in specification	QMN 228
228	Tribinat-500	Cefuroxime axetil	BAROQUE PHARMACEUTICALS PVT. LTD.	India	A	B4-2436	not found	C031010	UV/Vis	in specification	in specification	in specification	QMN 229
229	Eden Fluconazole	Fluconazole	IMPULSE PHARMA PVT LTD.	India	A	C4-0072	not found	200149	HPLC	in specification	not tested (capsule)	in specification	QMN 230
230	AD-Fluconazole	Fluconazole	Globela Pharma Pvt. Ltd.	India	A	B4-1543	not found	20GT183	HPLC	in specification	in specification	in specification	QMN 231
231	AD-Fluconazole	Fluconazole	Globela Pharma Pvt. Ltd.	India	A	B4-1543	not found	20GT048	HPLC	in specification	in specification	in specification	QMN 232
232	Cefsafe-500	Cefuroxime axetil	missing	India	A	C4-0252	verified	HH1015B21	UV/Vis	in specification	in specification	in specification	QMN 233
233	Avrogyl	Metronidazole	SKG-Pharma Limited	Nigeria	A	A4-4725	verified	2201	HPLC	in specification	in specification	in specification	QMN 234
234	Ricogyl	Metronidazole	RICO PHARMACEUTICAL IND. LTD.	Nigeria	A	04-4590	not found	RGT002	HPLC	moderate deviation	in specification	moderate deviation	QMN 235
235	Ricotrin	Co-trimoxazole*	RICO PHARMACEUTICAL IND. LTD.	Nigeria	A	04-4589	not found	RTN001	HPLC	extreme deviation	extreme deviation	extreme deviation	QMN 236
236	Primpex	Co-trimoxazole*	SKG-Pharma Limited	Nigeria	A	04-1959	not found	2210	HPLC	in specification	in specification	in specification	QMN 237
237	Clezide	Glibenclamide	Jiangsu Ruinian Qianjin Pharmaceutical Co. Ltd.	China	A	A4-2100	verified	210331	HPLC	in specification	in specification	in specification	QMN 238
238	Metrotab 200	Metronidazole	SKG-Pharma Limited	Nigeria	A	04-9936	verified	2202	HPLC	in specification	in specification	in specification	QMN 239
239	Glanil	Glibenclamide	Nigerian-German Chemicals Plc	Nigeria	A	04-2450	not found	FPJ070121	HPLC	in specification	extreme deviation	extreme deviation	QMN 240
240	Clamide	Glibenclamide	HOVID Bhd.	Malaysia	A	04-4015	verified	CA06595	HPLC	in specification	in specification	in specification	QMN 241
241	Glanil	Glibenclamide	Nigerian-German Chemicals Plc	Nigeria	A	04-2450	not found	FPD070421	HPLC	in specification	moderate deviation	moderate deviation	QMN 242
242	Hydrex	Hydrochlorothiazide	JUHEL NIGERIA LIMITED	Nigeria	A	A4-1209	verified	0158	HPLC	in specification	in specification	in specification	QMN 243
243	Unigyl 200	Metronidazole	Unique Pharmaceuticals Ltd.	Nigeria	A	04-8426	verified	UGT1067	HPLC	in specification	in specification	in specification	QMN 244
244	Gliben-J	Glibenclamide	JUHEL NIGERIA LIMITED	Nigeria	A	04-5735	not found	0043	HPLC	in specification	in specification	in specification	QMN 245
245	Sivonat	Cefuroxime axetil	Saga Lifesciences Limited	India	A	C4-0482	not found	SAKUO22101	UV/Vis	in specification	moderate deviation	moderate deviation	QMN 246
246	Eden Atenolol	Atenolol	IMPULSE PHARMA PVT LTD.	India	A	B4-6760	not found	210917	HPLC	in specification	extreme deviation	extreme deviation	QMN 247
247	Triflucon	Fluconazole	BAROQUE PHARMACEUTICALS PVT. LTD.	India	A	A4-6953	verified	G031002	HPLC	in specification	not tested (capsule)	in specification	QMN 248
248	Ratenol	Atenolol	OSAKA Pharmaceuticals Pvt. Ltd.	India	A	A4-3899	not found	OS033	HPLC	extreme deviation	moderate deviation	extreme deviation	QMN 249
249	Eden Atenolol	Atenolol	IMPULSE PHARMA PVT LTD.	India	A	B4-6760	not found	210916	HPLC	in specification	extreme deviation	extreme deviation	QMN 250
250	M&B Chloroquine	Chloroquine	MAY&BAKER NIGERIA PLC	Nigeria	A	04-0705	not found	A200600	HPLC; UV/Vis	in specification	in specification	in specification	QMN 251
251	Hydrex	Hydrochlorothiazide	JUHEL NIGERIA LIMITED	Nigeria	A	A4-1209	verified	0127	HPLC	moderate deviation	in specification	moderate deviation	QMN 252
252	Unigyl 200	Metronidazole	Unique Pharmaceuticals Ltd.	Nigeria	A	04-8426	verified	UGT1103	HPLC	in specification	in specification	in specification	QMN 253
253	GG Dexamethasone Tablet	Dexamethasone	Jiangsu Pengyao Pharmaceutical Co. Ltd. (INC.)	China	A	A4-1598	not found	200821	HPLC	extreme deviation	moderate deviation	extreme deviation	QMN 254
254	Hydrex	Hydrochlorothiazide	JUHEL NIGERIA LIMITED	Nigeria	A	A4-1209	verified	0157	HPLC	in specification	in specification	in specification	QMN 255
255	Chloroquine Tablets	Chloroquine	emzor Pharmaceutical Industries Ltd.	Nigeria	A	04-1218	not found	1819Z	HPLC; UV/Vis	in specification	in specification	in specification	QMN 256
256	Loxagyl 200	Metronidazole	MAY&BAKER NIGERIA PLC	Nigeria	A	04-0283	not found	A201841	HPLC	in specification	in specification	in specification	QMN 257
257	Nkoyo Dexamethasone	Dexamethasone	Astamed Healthcare (I) Pvt. Ltd.	India	A	04-8665	not found	1008	HPLC	moderate deviation	extreme deviation	extreme deviation	QMN 258
258	Nkoyo Dexamethasone	Dexamethasone	Maxwell Life Science Pvt. Ltd.	India	A	04-8665	not found	LT110	HPLC	moderate deviation	moderate deviation	moderate deviation	QMN 259
259	Nkoyo Fluconazole	Fluconazole	Maxheal Laboratories Pvt. Ltd.	India	A	A4-0421	not found	KF21001	HPLC	in specification	moderate deviation	moderate deviation	QMN 260
260	Cipxin-500	Ciprofloxacin	EUROLIFE HEALTHCARE PVT. LTD.	India	B	04-6293	not found	CPN048	HPLC	in specification	not tested (not enough tabl	in specification	QMN 261 (2/2)

Supplementary Table S3. Results of the examined PIN codes for the Mobile Authentication Service Scheme.

Product name	NAFDAC Reg. No	Tested MAS PIN code*	Short phone number or website for MAS provider#	SMS response text received	Response complete$	Response correct	Comments
Biophage 500	A4-6597	3037252567259	Sproxil (www.sproxil.com/verify)	(no response)			
Oxispa 500	A4-4096	2003971268069	Sproxil (www.sproxil.com/verify)	(no response)			
Tribinat-500 (cefuroxime axetil tablets)	B4-2436	441101032981	www.1393.co (M-Pedigree)	**GENUINE Triclav Syrup, 70ml bottle, Amoxicillin 200mg & Clavulanate 28.5mg BATCH: Po39008, EXP: Dec/2021 Quality guaranteed**	No	**No**	**Incorrect product identified**
Tricophage - 500 (metformin tablets)	B4-2429	101152044312	www.1393.co (M-Pedigree)	**GENUINE Triclav Syrup, 70ml bottle, Amoxicillin 200mg & Clavulanate 28.5mg BATCH: Po39008, EXP: Dec/2021 Quality guaranteed**	No	**No**	**Incorrect product identified** Expired 12/2022, but no warning
Triflucon (fluconazole tablets)	A4-6953	133551738573	www.1393.co (M-Pedigree)	**GENUINE Triclav Syrup, 70ml bottle, Amoxicillin 200mg & Clavulanate 28.5mg BATCH: Po39008, EXP: Dec/2021 Quality guaranteed**	No	**No**	**Incorrect product identified**
Glulife-500 mg	A4-6354	304924177735	www.1393.co (M-Pedigree)	This is an Original Product Marketed by Company: **Maydon Pharmaceuticals LTD**. For additional info, call 08039012030 or email nig@mpedigree.net.	No	**No**	**Incorrect MAH stated** Expired 03/2023, but no warning
Cenox	04-3002	2003585274982	Sproxil (38353)	Genuine PRODUCT Your PIN:2003585274982 Problem? Call 08039012929	No	+/-	Expired 05/2023, but no warning

Product name	NAFDAC Reg. No	Tested MAS PIN code*	Short phone number or website for MAS provider#	SMS response text received	Response complete$	Response correct	Comments
Ciprobiotic-Forte	04-2307	2003540121858	Sproxil (38353)	Genuine PRODUCT Your PIN:2003540121858 Problem? Call 08039012929	No	+/-	Expired 02/2023, but no warning
Ciproheal Tablets	04-7436	2003 38784 7342	Sproxil (38353)	Genuine PRODUCT Your PIN:2003387847342 Problem? Call 08039012929	No	+/-	
Doncinat - 500	A4-6907	2003557512765	Sproxil (38353)	Genuine PRODUCT Your PIN:2003557512765 Problem? Call 08039012929	No	+/-	
Elcexone	B4-7427	2003956193498	Sproxil (38353)	Genuine PRODUCT Your PIN:2003956193498 Problem? Call 08039012929	No	+/-	
Oxispa 500	B4-6770	2003658753644	Sproxil (38353)	Genuine PRODUCT Your PIN:2003658753644 Problem? Call 08039012929	No	+/-	
Oxispa 500	B4-6770	2003730651937	Sproxil (38353)	Genuine PRODUCT Your PIN:2003730651937 Problem? Call 08039012929	No	+/-	
Pocco Ceftriaxone Injection	B4-9368	2003 01148 8354	Sproxil (38353)	Genuine PRODUCT Your PIN:2003011488354 Problem? Call 08039012929	No	+/-	
Pocco Ceftriaxone Injection	B4-9368	2003 57420 1148	Sproxil (38353)	Genuine PRODUCT Your PIN:2003574201148 Problem? Call 08039012929	No	+/-	
Biophage 500	A4-6597	3037 22711 7565	Sproxil (38353)	Genuine Biophage product Your PIN:3037227117565 Problem? Call 08039012929	No	+/-	
Pilotab	B4-2270	3037 29691 4132	Sproxil (38353)	Genuine Pharmatex Product Your PIN: 3037296914132 Problem? Call 08039012929	No	+/-	
Sopro Caplet	B4-0053	3036 8990 66358	Sproxil (38353)	Genuine Sopro Tablet 500mg PIN:3036899066358 NRN:B4-0053 Problem? Call 08039012929	No	Yes	Expired 08/2022, but no warning

Product name	NAFDAC Reg. No	Tested MAS PIN code*	Short phone number or website for MAS provider#	SMS response text received	Response complete$	Response correct	Comments
Tamaflex 500	A4-9436	2003 17177 3226	Sproxil (38353)	Genuine Tamar & Pharez Products Your PIN:2003171773226 Problem? Call 08039012929	No	Yes	Expired 06/2022, but no warning
Ceftriaxone for injection	B4-3696	118784041873	www.1393.co (M-Pedigree)	GENUINE Product, 1 Pack, Approved batch	No	+/-	Expired 05/2022, but no warning
Harvad Cefuroxime tablets	B4-7976	297807456353	www.1393.co (M-Pedigree)	GENUINE Product, 1 Pack, Genuine Batch	No	+/-	
Harvad Cefuroxime tablets	B4-7976	838903420108	www.1393.co (M-Pedigree)	GENUINE Product, 1 Pack, Genuine Batch	No	+/-	
Harvad Cefuroxime tablets	B4-7976	157942465615	www.1393.co (M-Pedigree)	GENUINE Product, 1 Pack, Genuine Batch	No	+/-	
Roxirite	C4-1189	339243381288	www.1393.co (M-Pedigree)	GENUINE Product, 1 Pack, Genuine Batch	No	+/-	
Roxirite	C4-1189	808405138219	www.1393.co (M-Pedigree)	GENUINE Product, 1 Pack, Genuine Batch	No	+/-	
Xymatyl 500	B4-5993	258811498601	www.1393.co (M-Pedigree)	GENUINE Product, 1 Pack, Genuine Batch	No	+/-	
Xymatyl 500	B4-5993	170309522090	www.1393.co (M-Pedigree)	GENUINE Product, 1 Pack, Genuine Batch	No	+/-	
Flucoxiom-150	C4-1024	302477155688	www.1393.co (M-Pedigree)	GENUINE Product, Single pack, Genuine Batch	No	+/-	
Pulmocef 500	A4-1971	111878197880	www.1393.co (M-Pedigree)	GENUINE Product, Genuine batch, NAFDAC approved	No	+/-	Expired 05/2023, but no warning

Product name	NAFDAC Reg. No	Tested MAS PIN code*	Short phone number or website for MAS provider#	SMS response text received	Response complete$	Response correct	Comments
Ugolife Ciprofloxacin-500	B4-7467	891830284925	www.1393.co (M-Pedigree)	This is an Original Product Marketed by Company: Kesar Pharma Pvt Ltd. For additional info, call 08039012030 or email nig@mpedigree.net.	No	+/-	
Sivonat	C4-0482	293978918492	www.1393.co (M-Pedigree)	This is an Original Product Marketed by Company: Saga. For additional info, call 08039012030 or email nig@mpedigree.net.	No	+/-	Expired 01/2023, but no warning
Axacef	04-6027	118955608358	www.1393.co (M-Pedigree)	This is an Original Product Marketed by Company: Sanofi Aventis. For additional info, call 08039012030 or email nig@mpedigree.net.	No	+/-	Expired 05/2023, but no warning
Cyplox	04-3202	202727241800	www.1393.co (M-Pedigree)	This is an Original Product Marketed by Company: Sanofi Aventis. For additional info, call 08039012030 or email nig@mpedigree.net.	No	+/-	Expired 12/2022, but no warning
Zoxon	04-9534	537656158458	www.1393.co (M-Pedigree)	This is an Original Product Marketed by Company: Sanofi Aventis. For additional info, call 08039012030 or email nig@mpedigree.net.	No	+/-	Expired 04/2023, but no warning
Zoxon	04-9534	798019221133	www.1393.co (M-Pedigree)	This is an Original Product Marketed by Company: Sanofi Aventis. For additional info, call 08039012030 or email nig@mpedigree.net.	No	+/-	
Zoxon	04-9534	307043651856	www.1393.co (M-Pedigree)	This is an Original Product Marketed by Company: Sanofi Aventis. For additional info, call 08039012030 or email nig@mpedigree.net.	No	+/-	Expired 04/2023, but no warning
Tricophage - 500	B4-2429	605171935945	www.1393.co (M-Pedigree)	This is an Original Product Marketed by Company: Tricare Pharmaceutical Nig, Ltd. For additional info, call 08039012030 or email nig@mpedigree.net.	No	+/-	Expired 12/2022, but no warning
Licafur 500 Tablets	B4-0098	130265549005	www.1393.co (M-Pedigree)	This is an Original Product Marketed by Company: Zolon Healthcare Limited. For additional info, call 08039012030 or email nig@mpedigree.net.	No	+/-	Expired 05/2022, but no warning

Product name	NAFDAC Reg. No	Tested MAS PIN code*	Short phone number or website for MAS provider#	SMS response text received	Response complete$	Response correct	Comments
Tribinat-500	B4-2436	444025028540	www.1393.co (M-Pedigree)	GENUINE NAFDAC Approved Pharmaceutical Product, Marketed and Distributed by, Tricare Pharmaceutical Nigeria Ltd	No	+/-	Expired 01/2023, but no warning
Cisepro-500	B4-6330	246882900773	www.1393.co (M-Pedigree)	GENUINE Cisepro 500 , 1X10, Ciprofloxacin Tablets USP 500 mg BATCH: AA0036 - AA0038, EXP: Dec/2023	No	Yes	
Cisepro-500	B4-6330	278007167152	www.1393.co (M-Pedigree)	GENUINE Cisepro 500 , 1X10, Ciprofloxacin Tablets USP 500 mg BATCH: AA0036 - AA0038, EXP: Dec/2023	No	Yes	
Ibu Ciprofloxacin - 500	C4-0487	189229109167	www.1393.co (M-Pedigree)	GENUINE IBU CIPROFLOXACIN 500 TABLETS, 1x10, CIPROFLOXACIN HYDROCHLORIDE USP 500 mg BATCH: T21001 - T21008, EXP: Dec/2023	No	Yes	
Nemel Cipro	B4-1405	289128501270	www.1393.co (M-Pedigree)	GENUINE Nemel Cipro, 1x10 caplets, Ciprofloxacin 500mg BATCH: 02E, EXP: Apr/2026	No	Yes	
Gecip	B4-5856	5262 8948 118465	20966 (UBQ-t/Kezzler)	Original Gecip from Geneith Pharm Problem? Call 09095966343	No	Yes	Expired 04/2023, but no warning
Ciprofloxacin	B4-1176	ZYA994KE	38351 (Pharmasecure)	Warning! this product CIPROFLOXACIN TABLETS USP 500 MG expired on Feb-2023. Please return product to Chemist.	No	Yes	

Abbreviations: NAFDAC, National Agency for Food and Drug Administration and Control. MAS, Mobile Authentication Service.

* For 15 samples, several packages were available, each carrying a different MAS PIN code. A maximum of three MAS PINs were tested for one sample; in this table, only the first of the three tested MAS PINs is listed. For all these 15 samples, the responses received for the second and the third sample were identical to that received for the first sample.

In addition to the 46 listed samples, one sample carried a PIN code by www.chekkit.app. This Service Provider is not listed by NAFDAC and was not tested.

$ According to the NAFDAC Guidelines for the Mobile Authentication Service (MAS) Scheme of 2018, the following minimum information must be contained in the SMS response:

- classification as "genuine product" or "Product not verifiable"
- product name
- NAFDAC registration number
- expiry date
- batch number
- helpline for further information)