

Quality Assessment of Some Alcohol-Based Hand Sanitizers Circulating in the Federal Capital Territory, Abuja. Nigeria

Obi Adigwe

National Institute for Pharmaceutical Research and Development (NIPRD)

Judith John

National Institute for Pharmaceutical Research and Development (NIPRD)

Christianah Isimi

National Institute for Pharmaceutical Research and Development (NIPRD)

Simisola Oloye

National Institute for Pharmaceutical Research and Development (NIPRD)

Godspower Onavbavba

National Institute for Pharmaceutical Research and Development (NIPRD)

Martins Emeje (✉ martinsemeje@yahoo.com)

National Institute for Pharmaceutical Research and Development (NIPRD)

Research Article

Keywords: Covid-19, hand sanitizer, quality assessment, substandard products

Posted Date: December 29th, 2021

DOI: <https://doi.org/10.21203/rs.3.rs-1208457/v1>

License: © ⓘ This work is licensed under a Creative Commons Attribution 4.0 International License.

[Read Full License](#)

Abstract

Background

The emergence of corona virus disease caused by SARS-COV-2 (Covid-19) and the subsequent recommendation by the World Health Organization (WHO) on the use of non-pharmaceutical measures led to an upsurge in the production and sale of hand sanitizers across the globe including Nigeria. It is important that product regulation schemes are designed in such a way as to ensure the continual quality of the products to potential clients. Hence, this paper provides an understanding of the quality of alcohol based hand sanitizers in Abuja, Nigeria.

Methods

A total of fifty (50) different brands of alcohol-based hand sanitizers were purchased from different pharmacies, supermarkets, and stores, within Abuja. In the laboratory, samples were checked for their label claims, NAFDAC registration number, batch number, manufacturing and expiration dates. The information was recorded in the laboratory notebook in accordance with ISO 17025 requirement, then samples were coded as SAN1 to SAN50 and assessed for pH values and Alcohol Content.

Results

About 40% of the circulating hand sanitizers in the market did not go through regulatory vetting, 34% of the products did not have information on the country of manufacture, 32% of the sanitizers had pH values within acceptable range, while 78% of the products contained less than 60% alcohol.

Conclusion

This study gives an insight into the quality of alcohol-based hand sanitizers and we suggest an urgent need for the regulatory authorities of developing countries to enhance their surveillance and control of these substandard products in the society.

Introduction

Coronavirus disease 2019 (COVID-19) represents a significant challenge to global public health. Currently, no licensed therapies except emergency use vaccines exist to treat or prevent COVID-19, which has been reported to cause up to 3.0% mortality in human cases in some countries including Nigeria. The outbreak also poses a serious threat to global and local economies, and obviously, the world is still struggling to survive both health and economic collapse arising from COVID-19. "Globally, as of 11:46 am CEST, 21 June 2021, there have been 178,118,597 confirmed cases of COVID-19, including 3,864,180 deaths. The need for use of non-pharmaceutical intervention such as the washing of hands with soap and water or

alcohol based hand sanitizers have been re-iterated by the World Health Organization (WHO). [1, 2]. Studies have shown that good hand hygiene reduces the incidence of nosocomial infections [3]. Presently, washing of hands with soap and water and the use of hand sanitizers are the two most important hand hygiene methods in clinical practice, and they have been reported not only to reduce hand bacterial contaminations but also enhance hygiene compliance among health care workers [4]

It has also been reported that, about 80% of individuals retain some pathogens on their hands after washing, and this exercise removes the body's own fatty acids from the skin, sometimes resulting in cracked skin that provides an entry portal for pathogens [5]. To overcome these limitations, hand sanitizers discovered to be effective against those pathogens while improving the skin condition due to the added emollients were introduced [6, 7]. The correct use of hand sanitizers takes less time than hand washing, and at the same time, does not require drying of hands with potentially contaminated surfaces.

Alcohol is the main antimicrobial component of most HS and WHO particularly recommends either ethanol or isopropyl alcohol for the production of HS [8]. Some alcohol-based hand sanitizers have been reported to kill up to 99.9% of pathogens within 15 seconds of application [9]. Ethanol has the record of being the oldest skin disinfectant, it acts as a permeation enhancer when applied topically to human skin [10].

The availability of quality health commodities is important in promoting good health and to assure this, there is the need for routine quality assessment tests of pharmaceutical products and other health commodities. Poor quality health commodities pose a significant threat to consumers especially with covid-19 and heavy reliance on hand sanitizers as a veritable means of preventing infection and transmission. Getu and Awot [11] opined that, the quality control of pharmaceuticals is an integral part of ensuring that pharmaceutical products are fit for their intended use, comply with the requirements of marketing authorization, and at the same time do not expose consumers to risks, and that for this to be achieved, there must be a system of quality assurance which incorporates aspects of product development, manufacturing, distribution, and storage.

The recommended amount of alcohol in an alcohol-based HS should be between 60 to 80%, [8], no study has yet been carried out to determine the content of alcohol in HS circulating in the Nigerian market, however, some studies have been carried out on the antibacterial efficacy of HS marketed in Nigeria [12]. This study which is therefore the first, seeks not only to quantify the alcohol content of the sanitizers, but, assess their overall quality.

Materials And Methods

MATERIALS

Alcohol-meter (Mettler Toledo S400), pH meter (Mettler Toledo) and other laboratory Glass wares

Sample Collection

A total of fifty (50) different brands of alcohol-based HS were purchased from different pharmacies, supermarkets, and stores, within Abuja. In the laboratory, samples were checked for their label claims, NAFDAC registration number, batch number, manufacturing and expiration dates. The information were recorded in the laboratory notebook in accordance with ISO 17025 requirement, then samples were coded as SAN1 to SAN50.

Determination of pH

A 20 mL quantity of alcohol-based HS was transferred into a beaker and the pH reading was taken using the pH meter (Mettler Toledo). This procedure was repeated in triplicate and for all the samples.

Determination of Alcohol Content

This was undertaken by simply placing a calibrated alcohol-meter inside the alcohol-based HS in 250 mL measuring cylinder, the solution was allowed to settle completely and the percent content of alcohol was recorded. Triplicate determination was recorded for each sample. This process was carried out for all the 50 samples.

Results And Discussion

Information on the label, batch numbers, expiry dates and place of manufacture are presented in figure 1. It shows that 46% of the hand sanitizers were not registered with the regulatory body in Nigeria (NAFDAC), 66% have manufacturing dates, while 74% had expiring dates. Only 54% of the sanitizers are registered, while 44% did not even have batch number

Figure 2 shows that most (70%) of the hand sanitizers analyzed were locally produced in Nigeria 24% had no country of manufacture on their labels, while 6% were from other countries. It is important for HS to meet the requirements for proper labelling with full information on their packages in order to avoid misuse and accidental use of such products, the possible effects of lack of or improper labeling or package information has been expounded by previous researchers [13, 14].

Figures 3 and 4 show the alcohol content and status of the samples respectively; It can be observed that majority of the samples have alcohol content between 60 to 69%, a few (4%) of the samples had alcohol content of 80%, however, on a general note, most (78%) of the samples failed the alcohol content test, and are therefore unfit for human use.

The World health organization (WHO) report on local production of HS, [8] only 22% of the samples passed as seen in figure 4. It has been reported [14] that low concentrations of alcohols in hand sanitizers is a major challenge, and this has been implicated in their low efficacy and quality. In their report [14], the United states Pharmacopoeia claimed that, out of 200 samples of sanitizers investigated for quality in Africa, 20 (10%) were of low quality; their report is sharply different from our present study, in that, we observed that 78% of the samples we interrogated were substandard, of not however is the fact that, the USP study did not take samples from Nigeria. Our present report is however similar to that reported from

another African country, Ethiopia [15], where 70% of hand sanitizers marketed in that country did not comply with the WHO requirement for alcohol content. A similar study conducted in yet another African country of Kenya returned the worst outcome with none of the samples meeting regulatory requirements [13]. The report from Uganda [16] was however excellent, with all the samples analyzed complying with the regulatory requirements for quality. Researchers and quality control experts agree that the efficacy of hand sanitizers is dependent on the concentration of alcohols used, the type of alcohol, presence of inactive excipients, type of formulation, contact time and volume of alcohol used [15 – 17], and the recommended concentration of alcohols in hand sanitizers range between 60 – 95%, this is because, at this concentration, the alcohols interact with the proteins in the organisms to exert its activity. Concentrations between 60 – 75% have been found to denature the proteins in the organisms, while concentrations greater than 95% causes coagulation of the membrane proteins to prevent penetration of the alcohol into the cells of the organisms [16]. It has also been opined that, at 80% or more, alcohol evaporate quickly from the surface of application leading to less contact time with the organisms, therefore, excessive amount of alcohol in sanitizers may be counterproductive. It should be noted though that, sanitizers with alcohol levels close to 60% may face the danger of losing its recommended concentration during transportation, handling and shelf-life [8]. Hence, WHO came to the conclusion that, the most appropriate concentration of alcohols to be contained in hand sanitizers for maximum efficacy should range between 70 – 80% [8]. On the basis WHO recommendation alone, 78% of the hand sanitizers marketed in Abuja, Nigeria at this time is substandard and unfit for use in preventing the spread or transmission of covid-19.

“Healthy human skin lies in the pH range of 4 to 6.1. An increase in stratum corneum (SC) pH can disrupt the activity of enzymes involved in keratinization, barrier restoration, and anti-microbial function. This phenomenon is seen in atopic dermatitis and other xerotic skin diseases and correlates with disease severity of dryness, pruritus, and total skin involvement. Chemicals applied to the skin are an important exogenous factor that may stabilize the skin’s acid mantle. Therefore, topical products with near-physiologic pH are considered best in prevention and treatment of these same skin abnormalities” [18]. According to Sayaka et al [19], the skin is usually kept slightly acidic by acidic keratin sebum and eccrine secretions to form a film on the surface of the stratum corneum, but if the pH is increased from normal baseline, the number of bacteria on the skin surface is increased, the types of bacteria change, and transepidermal water loss increases. Therefore, abnormal pH of the skin surface causes the destruction of the skin barrier function; this underscores the need to have sanitizers properly formulated not just with the recommended concentration of alcohol, but pH also. In our study as shown in Figures 5 and 6,

68% of the sanitizers failed. At pH of 7.5, it is reported that, there will be overgrowth of staphylococcus aureus, [20]. It has also been reported that some hand sanitizers cause irritations and allergic contact dermatitis, while others have been reported to cause itching, cracking and peeling of the skin [21]. Overall, sanitizers with unfriendly pH have been implicated in these findings, and 68% of the sanitizers interrogated in this study have questionable pH values. We opine strongly that, besides the inadequate alcohol content displayed by these hand sanitizers, their pH values reveal that they may support the

emergence of skin infections. In fact, some of the pH values may equally contribute to instability in the sanitizer formulation [21].

In sub-Saharan Africa where the literacy level is still low, compounded by weak health system and regulatory regime as well as corruption, our study shows that some manufacturers of hand sanitizers took advantage of these lapses to manufacture products of substandard quality with the intention of making profits while endangering the lives of the populace. That substandard hand sanitizers and the use of unwholesome medicines can have a devastating effect on the health of a nation and on the healthcare systems in countries is no longer in doubt [21; 22] For example, it has been reported that, at least, 10% of medicines in sub-Saharan Africa are substandard, accounting for over 30 million Dollars in expenditure. To reverse this trend is a task that must be taken with all the seriousness it deserves; either by way of institutional strengthening, capacity building, increased resource allocation, public enlightenment or deterrent sanctions against offenders [23, 24].

Conclusion

This study gives an insight into the quality of alcohol-based hand sanitizers circulating in the Nigerian market, and the findings revealed that there are many substandard alcohol-based hand sanitizers in circulation, suggesting an urgent need for the regulatory agencies responsible for assuring quality as well as the consumers themselves to be more circumspect when procuring these products This is a call to action on the part of both the citizens and the responsible authorities.

References

1. R. Pandit, "Basic protective measures against the new coronavirus pandemic– COVID-19," *J. Manag. Res. Anal.* 7(1), 2020, 1–2.
2. R. Agbana, S. Ogundeji, and J. Owoseni, "A survey of hand hygiene knowledge, attitude and practices among health care workers in a tertiary hospital, Southwestern Nigeria," *Arch. Community Med. Public Heal.* 6, 2020, 146–151.
3. V. Erasmus, M. N. Kuperus, J. H. Richardus, M. C. Vos, A. Oenema, and E. F. Van Beeck, "Improving hand hygiene behaviour of nurses using action planning: a pilot study in the intensive care unit and surgical ward," *J. Hosp. Infect.* 76(2), 2010, 161–164.
4. E. J. Fendler, Y. Ali, B. S. Hammond, M. K. Lyons, M. B. Kelley, and N. A. Vowell, "The impact of alcohol hand sanitizer use on infection rates in an extended care facility," *AJIC.* 2000, 9–13.
5. J. Lee *et al.*, "Hand Sanitizers: A Review on Formulation Aspects, Adverse Effects ,and Regulations."
6. F. Fallica, C. Leonardi, V. Toscano, D. Santonocito, P. Leonardi, and C. Puglia, "Assessment of Alcohol-Based Hand Sanitizers for Long-Term Use, Formulated with Addition of Natural Ingredients in Comparison to WHO Formulation 1," *Pharmaceutics.* 13(571), 2021, 1–16.
7. D. Assefa, T. Melaku, B. Bayisa, and S. Alemu, "Knowledge, Attitude and Self-Reported Performance and Challenges of Hand Hygiene Using Alcohol-Based Hand Sanitizers Among Healthcare Workers

- During COVID-19 Pandemic at a Tertiary Hospital : A Cross-Sectional Study,” *Infect. Drug Resist.* 14, 2021, 303–313.
8. World Health Organization, “Guide to Local Production: WHO-recommended Handrub Formulations.” 2010, 1–9.
 9. D. Dastider, D. Jyoti Sen, S. Kumar Mandal, S. Bose, S. Ray, and B. Mahanti, “Hand Sanitizers Bid Farewell To Germs on Surface Area of Hands,” *Eur. J. Pharm. Med. Res.* 7(4), 2020, 648–656.
 10. D. W. Lachenmeier, “Safety evaluation of topical applications of ethanol on the skin and inside the oral cavity,” *J. Occup. Med. Toxicol.* 3(1), 2008, 1–16.
 11. K. Getu and G. Awot, “Quality Assessment of the Commonly Prescribed Antimicrobial Drug, Ciprofloxacin Tablets, Marketed in Tigray, Ethiopia,” *Momona Ethiop. J. Sci.* 2(1), 2010, 1–15.
 12. M. B. Odebisi-Omokanye, E. A. Ahmed, S. O. Arshad, and M. A. Oke, “Comparative Assessment of Antibacterial Efficacy of four popular hand sanitizers sold in Nigeria,” *Fountain J. Nat. Appl. Sci.* 4(1), 2015, 1–9.
 13. N. N. Nyamweya and K. O. Abuga, “A Survey of Alcohol-Based Hand Sanitizers in Nairobi: Packaging, Labelling and Regulatory Compliance,” *East Cent. African J. Pharm. Sci.* 23, 2020, 72–76.
 14. USP, “Supporting Quality Hand Sanitizer Production Section 1: USP Resources for Manufacturers,” 2021, 1–7.
 15. M. N. Selam, “Hand Sanitizers Marketed in the Streets of Addis Ababa, Ethiopia, in the Era of COVID-19 : A Quality Concern,” *Risk Manag. Healthc. Policy.* 13, 2020, 2483–2487.
 16. T. Fred, K. Sophia, S. Alex, B. Emmanuel, L. Tom, and A. Lucas, “Comparison of Antibacterial Efficacy of Locally Produced Alcohol Based Hand Sanitizer and Commonly Available Commercial Hand Sanitizer Used in Healthcare Facilities in Uganda,” *OALib.* 7(4), 2020, 1–13.
 17. N. N. Nyamweya and K. O. Abuga, “Alcohol-Based Hand Sanitizers – A Multidimensional Perspective.” 2020, 1–25.
 18. Olubunmi Olayemi, Christianah Isimi, Kokonne Ekere, Mahmood Abdullahi Gbate and Martins Emeje. (2017). Determination of sunscreen protection factor number: an emerging *in-vitro* tool for predicting UV protection capabilities. *International Journal of Herbal Medicine*, 5(1): 06–09.
 19. Sayaka Ono, Ryutro Imai, Yukiko Ida, Dai Shibata, Takako Komiya, Hajime Matsumura. Increased wound pH as an indicator of local wound infection in second degree burns. *burns* 41 (2015) 820 – 824
 20. J. M. Boyce and D. Pittet, “Guideline for Hand Hygiene in Health-Care Settings: Recommendations of the Healthcare Infection Control Practices Advisory Committee and the HICPAC/SHEA/APIC/IDSA Hand Hygiene Task Force,” *Infect. Control Hosp. Epidemiol.* 23(12), 2002, 3–40.
 21. M. Shoge, A. Abdullateef, E. N. Ozioko, A. Muhammad, and H. A. Lawal, “Evaluation of Heavy Metals and Antimicrobial Efficacy of Four Hand Sanitizers Used during COVID-19 in AFIT, Kaduna .,” *Int. J. Eng. Sci.* 1(1), 2021, 24–27.

22. R. D. Dicken, T. Gallagher, and S. Perks, "Overcoming the Regulatory Hurdles for the Production of Hand Sanitizer for Public Health Protection: The UK and US Academic Perspective," *ACS Chem. Heal. Saf.* 27, 2020, 209–213.
23. A. Petersen, N. Held, and L. Heide, "Surveillance for falsified and substandard medicines in Africa and Asia by local organizations using the low-cost GPHF Minilab," *PLoS One.* 2017, 1–22.
24. H. J. Zar, J. Dawa, G. Bueno, and J. A. Castro-rodriguez, "Challenges of COVID-19 in children in low- and middle-income countries," *Paediatr. Respir. Rev.* 35, 2020, 70–74.

Figures

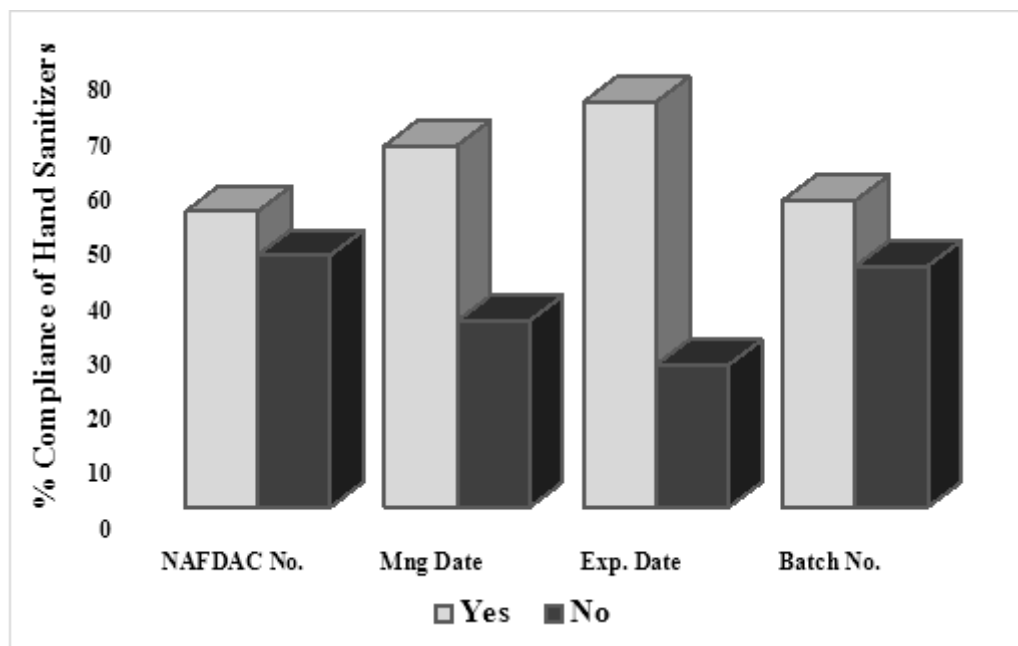


Figure 1

Chart showing percentage compliance of hand sanitizers and labels

Figure 2

Chart showing the Country of manufacture of hand sanitizers

Figure 3

Frequency distribution of Alcohol Content of Hand Sanitizers

Figure 4

Chart showing the compliance of HS to alcohol content based on WHO Guideline

Figure 5

Frequency distribution of pH of Hand Sanitizers

Figure 6

Showing the compliance rate of pH of hand sanitizers