Quality of Alcohol Based Hand Sanitizers Marketed in the Nairobi Metropolitan Area

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The emergence of the COVID-19 pandemic has propelled the use of alcohol-based hand sanitizers to the fore as a SARS-CoV-2 control measure. To be effective these products must comply with relevant quality parameters such as alcohol concentration, methanol limits and purity. The current study was designed to determine the quality of alcohol-based hand sanitizer products in the Nairobi metropolitan area. For this purpose, 74 commercially marketed samples were collected and subjected to analysis by gas chromatography. Only three samples (4.1%) complied with the regulatory specifications for alcohol content, methanol limits and pH. Five samples (6.8%) complied with the specification for alcohol content but did not meet methanol or pH limits. A total of 44 (59.5%) samples had methanol levels that exceeded threshold limits. Eleven samples (14.9%) were found with methanol substitution (i.e., methanol, instead of ethanol or isopropanol, was the main alcohol component). The results show that users of alcohol-based hand sanitizers are being exposed to substandard and falsified products which in addition to being non-efficacious pose harm due to unacceptable levels of toxic impurities. Regular, routine post-market surveillance is needed to prevent such products from reaching the market.

Key words: Hand sanitizer, COVID-19, alcohol, methanol substitution, gas chromatography, substandard products, falsified products, post-market surveillance.

INTRODUCTION

The coronavirus disease 2019 (COVID-19) pandemic caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) has led to the extensive use of alcohol-based hand sanitizers (ABHS), hand washing, masking and social distancing and as preventative measures to curb the spread of the infection. Independently, several COVID-19 vaccines have been developed and promoted for adaptive immunity towards the virus [1]. SARS-CoV-2 is an enveloped virus that is susceptible to inactivation by soap and alcohol [2]. Thus, hand washing and use of ABHS are the recommended means of hand hygiene essential for controlling the spread of COVID-19 [3]. The World Health Organisation (WHO) procedures for hand washing and ABHS application are instrumental for infection control when applied properly [4]. For effectiveness, ABHS products must have an alcohol concentration range of 60 - 95% (v/v). Marketed ABHS formulations include low viscosity liquids, gels, foams, dispensers and wipes [5]. The efficacy of ABHS is a multi-faceted phenomenon dependent on an interplay of several factors including alcohol type and level, formulation, other ingredients, manufacturing process as well as proper usage technique [6,7].

The World Health Organisation (WHO) has developed two formulations which contain either ethanol (80% v/v) or isopropanol (75% v/v) in admixture with glycerol (1.45% v/v), hydrogen peroxide (0.125% v/v) and water. These formulations can be employed in local production and industrial manufacture of ABHS [8].

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Recent studies [9,10], however, revealed that numerous, diverse formulations are commercially available in the Kenyan market with none of the sampled products being based on the WHO formulas. ABHS manufacturers in Kenya are required to secure market authorization from the domestic regulatory agency, Kenya Bureau of Standards (KEBS), after demonstration that their products comply with the specification for instant hand sanitizers, KS EAS 789:2013 [11]. This specification includes tests for alcohol content (ethanol, isopropyl alcohol or n-propanol), pH and antimicrobial efficacy. Products registered by KEBS must possess a registration number, an S-mark of quality and be listed on the KEBS website for verification purposes.

The accurate determination of the alcohol (active ingredient) content of an ABHS product is a key quality evaluation test and may also act as surrogate for efficacy. The KEBS specification for hand sanitizers does not itself provide a test for alcohol content, but instead refers to another KEBS standard, KS EAS 104 ("Alcoholic beverages – Methods of sampling") [11,12]. Technically, the KS EAS 104 test applies only to ethyl alcohol as it is the only alcohol used to manufacture alcoholic beverages. Additionally, KS EAS 104 uses specific gravity, a non-specific analytical method, to estimate alcohol concentration based on the density ranges of alcohol-water mixtures [8,11]. Non-specific methods do not distinguish permitted alcohols (ethanol, isopropyl alcohol) from toxic alcohols such as methanol which may occur in adulterated products. Ideally, methanol content is determined by spectrophotometry or gas chromatography techniques [13]. Low quality raw materials may contribute to unacceptable impurity profiles in the final product with respect to contaminants which in addition to methanol may include benzene, acetaldehyde, acetal and ethyl acetate [14-17]. Thus, the use of specific methods is necessary in ABHS analysis to accurately determine alcohol content, purity and exclude substitution or contamination with non-permitted alcohols.

The COVID-19 pandemic induced a massive demand for ABHS in the year 2020 against an unprepared manufacturing landscape. This development presented manufacturing opportunities which were incidentally taken up by many inexperienced players, without the requisite capability to produce products under good manufacturing practices (GMP) environments. It may also have attracted unscrupulous individuals who sold substandard and falsified products to the unsuspecting public [9].

Since the year 2020, several reports of substandard and falsified ABHS products have been published both locally and internationally [9,18,19]. Several substandard hand sanitizers in the Kenyan market were found and recalled soon after the first COVID-19 case was reported [20,21]. Elsewhere, the United States Food and Drug Administration (FDA) impounded ABHS imports from Mexico with methanol substitution or contamination [22]. ABHS products not meeting regulatory requirements for various reasons including the presence of impurities were recalled in Canada [23,24]. Products containing methanol pose a grave danger through accidental or deliberate exposure. A report published by the Centers for Disease Control and Prevention (CDC) revealed that out of 15 cases of methanol contaminated ABHS ingestion reported in May to June 2020, four fatalities and three cases of severe sequelae (visual impairment) occurred [25].

A market survey carried out in the Nairobi Metropolis in 2020 revealed existence of substandard, unlicensed and counterfeit products in circulation [9]. This paper is a sequel of that report and presents analytical results obtained through gas chromatography (GC) on the collected samples. This is the first report on alcohol profile of ABHS products obtained through market surveillance in Kenya.

MATERIALS AND METHODS

Samples

Study samples were purchased from the Nairobi metropolis incorporating the Central

Business District (CBD), Kibera, Karen, Kilimani, Ngong and Thika town as described previously [9]. The samples were stored in their original primary packaging under ambient conditions until analysis. All samples were analysed before the expiry dates indicated on their labels.

Materials, reagents and solvents

Analytical grade isopropyl alcohol (Loba Chemie, Mumbai, India), methanol (Finar Limited, Ahmedabad, India) and ethanol (Hayman Group Ltd, Witham, UK) were used as standard solvents for GC analysis. HPLC grade acetonitrile (Scharlab S.L., Sentmenat, Spain) was applied as an internal standard. Freshly distilled water was prepared in the laboratory and used for dilution of analytical solutions. Analytical solutions were filtered through PTFE 0.22 µm microfilters (Nantong Filter-Bio Membrane Co., Jiangsu, China) before injection.

pH determination

The pH of the samples was measured using a TitroLine® 6000 titrator (SI Analytics GmbH, Mainz, Germany), equipped with VGA TFT display operating in the pH module. This test was performed on the neat products.

Gas chromatography

Ethanol, isopropyl alcohol and methanol content were determined using gas chromatography (GC). For this purpose, a Shimadzu GC-2010 plus gas chromatograph (Shimadzu Corporation, Tokyo, Japan) equipped with a flame ionization detector supported by GC solution software version 2.42 (Shimadzu Corporation, Tokyo, Japan) was utilized. Separation was achieved using a ZB-WAX plus column (60 m × 0.25 mm i.d., film thickness 0.25 µm) (Phenomenex, Torrance, CA, USA) operated under a temperature program of: 45 °C held for 7 min, 30 °C/min to 240 °C, held for 7 min. The temperature of the injection port and detector were set at 270 °C. Helium at a flow rate of 1.36 ml/min was employed as carrier gas. This method was adapted from that described by Zhang [26] with some modifications with regard to column length, flow rate and temperature program.

Calibration solutions

The internal standard stock solution (ISSS) was prepared by dilution of one ml of acetonitrile to 10 ml using distilled water.

Alcoholic standard solutions for calibration were prepared by diluting one ml of solvent to 10 ml in distilled water. The resulting solution (300 µl) was mixed with 500 µl ISSS and diluted to 1000 µl with water to form the standard stock solution (SSS) equivalent to 100% solution. Dilutions of the SSS were performed to obtain linear calibration curves within the 33 – 133% range.

Sample preparation

One ml of the neat sample was diluted to 10 ml with distilled water. An aliquot of this solution equivalent to 300 µl was mixed with 500 µl ISSS and diluted to 1000 µl prior to injection.

Alcohol content

The alcohol concentration of analytical solutions was calculated by solving the regression equations of the calibration curves. The sample alcohol concentration was determined by correcting the result for dilution factor and solvent potency.

RESULTS AND DISCUSSION

Calibration curves

Calibration for ethanol, isopropyl alcohol and methanol was fitted into six-point linear curves of peak area ratio vs concentration within the range 1.0 - 4.0% v/v of the final solution injected. To permit predictive ability at low concentration, the y-intercept was set at zero. The linear regression equations and the coefficients of determination (R^2) thereof are recorded in Table 1.

Table 1: Calibration equations for ethanol, isopropyl alcohol and methanol

	Regression equation	R^2
Ethanol	y = 0.1976x	0.9998
Isopropyl alcohol	y = 0.1979x	0.9988
Methanol	y = 0.1456x	1.0000

y – peak area ratio, x – alcohol concentration of the injected solution in % v/v.

Quality parameters

A total of 74 samples representing 62 unique brands were analysed for ethanol, isopropyl alcohol (IPA), methanol concentration as well as pH. The results obtained for these parameters are listed in Table 2. Samples are coded using Arabic numerals according to the brand distribution while different batches (of a single brand) were designated A, B, C as appropriate. The methanol concentration was expressed in three decimals to permit direct comparison with the US-FDA interim limits of 630 ppm (0.063% v/v) [27]. The tests listed in the KEBS specification for hand sanitizers are alcohol content (no less than 60%); pH (range 6 - 8); and bactericidal efficacy. The specification does not address the content or limits of methanol and other impurities [11].

Sixty-two samples contained the permitted alcohols, ethanol (n = 24, 32.4%), IPA (n = 6, 8.1%) and ethanol/IPA mixture (n = 32, 43.2%) with varying methanol levels. Eleven samples (14.9%) showed methanol substitution (methanol was the main alcohol present) with nine having ethanol/IPA as minor components and two as major co-constituents. In one sample (S56), neither ethanol nor IPA was detected while the methanol concentration therein was below limits.

In the assay test, samples were evaluated on the sum total of the two permitted alcohols viz ethanol and IPA. Eight samples (10.8%) complied with assay limits (alcohol concentration ≥ 60 % v/v). On the other hand, 30 samples (40.5%) complied with methanol limits while the remainder showed either methanol substitution (n = 11, 14.9%) or were above the 630 ppm threshold (n = 33, 44.6%). Three samples with methanol substitution (MS) were found on the KEBS website as authorized brands at the time of sampling [28]

Aside from methanol substitution, 18 samples (24.3%) were found to contain different alcohol(s) (ethanol or IPA) from those stated on the label as the main active ingredient(s). With regard to pH, 44 samples (59.5%) complied with the KEBS standard for ABHS.

Overall, only three (4.1%) of the ABHS samples analysed complied with all the tests under consideration. The remaining samples failed in at least one of the tests outlined in Table 2. There was lack of batch consistency of test results among brands with multiple samples except S20 which had quality problems nevertheless. No regional patterns were discernible with regard with non-compliant samples from the various metropolitan sampling locations, thus demonstrating the vulnerability of consumers to poor quality ABHS products across the socio-economic strata.

ABHS products with alcohol concentrations of < 60% offer ineffective antisepsis hence predisposing users to infection. This is aggravated by the false sense of protection and confidence that unsuspecting users will commonly have in the products they apply. On the other hand, methanol in ABHS products is toxic to the users when absorbed transdermally, by inhalation or ingestion. The latter may occur among paediatrics (accidental ingestion) and alcoholics (intentional ingestion) who may partake ABHS as surrogate alcohols [6]. Several press reports about Kenyan youths drinking alcoholic hand sanitizers have been published since the advent of the COVID-19 pandemic [29]. In some cases, the victims have either died or suffered blindness which indicates the presence of methanol in the products ingested [30].

Table 2: Results of alcohol-based hand sanitizer samples analyzed

Sample number	pH	Alcohol concentration (% v/v)			Tests failed
		Ethanol	IPA	Methanol	
S1	4.8	6.8	2.1	0.850	A, M, P
S2	6.1	7.7	6.7	5.859	A, M*
S3A	6.2	54.2	ND	0.098	A, M
S3B	6.6	52.0	ND	0.153	A, M
S4A	7.0	63.2	ND	1.811	M
S4B	6.5	40.2	ND	1.354	A, M
S5	6.2	78.5	ND	0.241	M
S6	5.6	21.7	18.4	ND	A, P
S7	8.4	56.2	ND	0.079	A, M, P
S8	6.3	38.2	7.9	0.220	A, M
S9A	8.2	38.2	8.4	0.144	A, M, P
S9B	8.2	46.8	ND	ND	A, P
S10	6.9	1.6	0.4	41.585	A, M*
S11	6.5	74.2	ND	0.114	M
S12	3.8	52.7	0.1	ND	A, P
S13	4.5	65.7	ND	ND	P
S14	4.1	65.2	ND	ND	P
S15	7.0	26.7	ND	ND	A
S16	5.5	7.1	43.2	ND	A, P
S17	7.2	19.9	17.5	0.462	A, M
S18	7.0	40.5	1.9	0.483	A, M
S19	6.5	ND	41.1	ND	A
S20A	7.5	0.2	ND	0.175	A, M
S20B	7.5	0.8	ND	0.165	A, M
S21	5.3	33.9	ND	ND	A, P
S22	6.7	62.0	0.8	ND	NONE
S23	8.3	5.5	0.2	0.704	A, M, P
S24	7.5	30.2	0.1	0.475	A, M
S25	6.4	1.3	ND	13.833	A, M*
S26A	6.7	36.7	ND	ND	A
S26B	5.9	58.6	ND	0.052	A, P
S27	4.3	0.7	1.2	0.509	A, M, P
S28	7.4	24.7	14.8	ND	A
S29	3.9	8.7	2.8	ND	A, P
S30	6.5	35.7	1.1	ND	A
S31	5.6	49.8	10.0	0.304	A, P
S32A	6.4	ND	38.3	ND	A
S32B	6.4	34.6	5.4	ND	A
S33A	6.5	65.8	ND	ND	NONE
S33B	6.1	65.3	ND	ND	NONE
S33C	6.6	ND	39.1	0.055	A
S34	6.1	3.7	ND	ND	A

Sample number	pH	Alcohol concentration (% v/v)			Tests failed
		Ethanol	IPA	Methanol	
S35	6.1	38.4	ND	0.030	A
S36	6.8	48.5	ND	0.048	A
S37	5.2	24.9	5.7	0.529	A, M, P
S38	8.1	5.2	6.8	1.418	A, M, P
S39	6.0	42.3	0.1	1.455	A, M
S40	6.8	7.8	1.4	1.011	A, M
S41	5.4	0.2	0.2	18.019	A, M*, P
S42	7.1	1.1	1.7	0.531	A, M
S43	7.2	16.7	1.7	1.254	A, M
S44	7.1	ND	0.1	17.941	A, M*
S45	5.5	11.9	0.2	0.615	A, M, P
S46A	7.8	50.3	ND	1.593	A, M
S46B	7.4	31.4	0.3	1.032	A, M
S47	4.7	17.2	3.8	0.115	A, M, P
S48	5.7	36.5	0.6	1.408	A, M, P
S49A	5.6	ND	1.4	77.031	A, M*, P
S49B	5.5	ND	1.8	37.842	A, M*, P
S50	6.0	0.1	0.1	16.408	A, M*
S51	7.6	0.8	ND	ND	A
S52A	6.0	ND	55.9	0.076	A, M
S52B	5.8	ND	69.4	0.071	M, P
S52C	5.7	ND	58.7	0.064	A, M, P
S53	5.8	7.5	0.9	0.098	A, M, P
S54	6.7	8.6	8.7	0.279	A, M
S55	7.3	6.0	34.1	ND	A
S56	5.7	ND	ND	0.056	A, P
S57	6.3	38.8	0.6	19.633	A, M*
S58	5.1	1.1	4.1	42.815	A, M*, P
S59	5.4	24.3	16.2	ND	A, P
S60	7.2	1.5	1.6	0.032	A
S61	5.7	8.5	0.5	ND	A, P
S62	6.0	1.7	1.5	33.301	A, M*

* – methanol substitution, A – Alcohol assay, IPA – isopropyl alcohol,
M – methanol limit, ND – not detected, P – pH (limits 6 – 8 in the KEBS standard [11])

The results obtained demonstrate high incidences of substandard and falsified ABHS products (SFP) in the study area. WHO recommendations and campaigns for hand hygiene as a prevention strategy against COVID-19 from early 2020 led to an unprecedented demand for ABHS leading to supply chain disruptions, shortages and stockpiling. The Kenyan government responded to shortages by sanctioning manufacture of ABHS for free distribution to the population. This approach was not adequately responsive, hence leading to the contribution of various industrial players

towards meeting demand. Consequently, many manufacturers who had no previous experience, diversified into ABHS production.

Due to shortages of pharmaceutical/food grade alcohol as a raw material during the COVID-19 pandemic, manufacturers may have used technical grade ethanol (TGE) in ABHS production. TGE is known to contain higher levels of impurities including methanol which have adverse toxicological effects [15]. This may account for the high non-compliance among the samples analysed for methanol levels (44.6%). Good manufacturing practice entails manufacturers carrying out regular audits of alcohol suppliers and testing of all raw materials before usage. Ethanol distillers in Kenya utilize molasses sourced from sugarcane millers for alcohol production [31]. Cohen et al. found that non-traditional high purity ethanol manufacturing plants may require infrastructural and process upgrades in order to produce alcohol that meets FDA impurity limits [17]. Nevertheless, ABHS producers bear the responsibility of ensuring that their products released into the market are consistently quality assured. Additionally, it is imperative that regulatory authorities regularly audit manufacturers for compliance with manufacturing and quality standards.

Non-compliance with KEBS pH specifications could result from excipients used in the formulation such as acrylic acid based polymers, aminomethyl propanol and triethanolamine [6]. It is not clear why the specification's pH limit is set at the 6 - 8 range since skin pH while exhibiting inter-individual variation tends to be somewhat acidic and in region of 5.0 - 5.5 [32,33].

The findings of this study portend a worse scenario compared to similar research in other jurisdictions. A South African study carried out in Johannesburg in March - June 2020 revealed that 41% of samples contained less than 60% v/v ethanol or IPA. While 11 % of the samples contained methanol above limits, none had methanol substitution. Other contaminants encountered were ethyl acetate, isobutanol, 1-propanol and 3-methyl-butanol [19]. In contradistinction, a Canadian study, found that all samples analyzed except one complied with alcohol content and methanol limits while 26 % did not comply with acetaldehyde levels [14].

Regular post-market surveillance (PMS) is necessary to prevent SFP in circulation. The existence of SFP undermines government policies and campaigns that promote use of ABHS as COVID-19 prevention strategy as well as exposing the population to infection risk. It should however, be acknowledged that effective control of the ABHS market is an intricate affair requiring close collaboration between the regulatory authorities, manufacturers, vendors, law enforcement agencies and the public [9,34]. The findings of this study underscore the need for stringent market control of ABHS products in order to protect unsuspecting consumers and safeguard public health.

During GC analysis of the samples, several products were found to contain numerous unidentified volatiles that require further investigation. For this purpose, more advanced techniques such as gas chromatography tandem mass spectrometry (GC-MS) may be employed to fully characterize ABHS products. Other important aspects of ABHS use such as formulation, labelling, use instructions and their relationship/impact on efficacy have been reported elsewhere in the literature [6,7].

Based on the delineations of the present study, it is recommended that the KEBS specification for hand sanitizers be urgently revised to use current test methods more appropriate for alcohol-based hand sanitizers. The specification should also incorporate more stringent requirements including: definition of permissible grades of ethanol or isopropanol and their quality control criteria; use of specific test methods (e.g. GC) for determination of constituent alcohols and other volatiles; setting of limits for impurities; mandatory testing of raw materials using specific test methods by manufacturers prior to use in ABHS production.

CONCLUSION

This study was carried at the onset of the COVID-19 pandemic in Kenya whence ABHS were promoted as a plausible public health approach towards preventing spread of the infection. It reflects the initial response to the ABHS demand spike. The market dynamics may have shifted since then, hence the need for follow up post-marketing surveillance studies to elucidate the current situation. Moreover, regular data acquisition is necessary to inform policy and regulatory interventions so as to improve the quality of products in circulation. Additional studies are required to fully understand the composition of ABHS products in the market and the attendant safety implications. It would also be of interest to conduct country-wide ABHS post market surveillance to evaluate the quality of these products in other regions.

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