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Article · January 2023

DOI: 10.35248/2329-6836.23.11.1.1-5

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Assessing the Quality and Effectiveness of Alcohol Based Hand Sanitizers Commercially Available in Mbarara City

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Received: Sep 29, 2022, Manuscript No. NPCR-22-19389; **Editor assigned:** Oct 03, 2022, PreQC No. NPCR-22-19389 (PQ); **Reviewed:** Oct 17, 2022, QC No. NPCR-22-19389; **Revised:** Jan 20, 2023, Manuscript No. NPCR-22-19389 (R); **Published:** Jan 27, 2023, DOI: 10.35248/2329-6836.23.11.1.1-5

Abstract

Alcohol based hand sanitizers are currently recommended for routine use in curbing the spread of the serious infectious diseases like COVID-19. This survey examined hand sanitizers marketed in Mbarara city with regards to product physical characteristics, certification, labelling and declared composition which all constitute the overall quality of the hand sanitizers. Thirty six samples of 9 brands were randomly collected from six pharmacies and six supermarkets. These samples were assessed for certification status by verification with Uganda National Bureau of Standards (UNBS) logo and presence on the list of registered manufacturers. Parameters analyzed included physical parameters like clarity using visual inspection and pH using a pH meter; alcohol content was quantified using an alcolyzer which uses a principle of IR spectroscopy. Results revealed alcohol content ranging between 65.1% to 81.24% which were in range of UNBS; US 1693: 2017 standards. However despite falling in the required ranges, 55.6% of brands (5) had the alcohol content within the expected 95%-105% error range, two brands had the alcohol content higher while two had them lower deviation from the label claim. Also all the 9 brands (100%) were correctly labelled and passed clarity tests. Three brands (33.3%) of the samples failed the pH test of 6-8 in the standards. There was further elucidation on the effects of these deviations and of lack of consistency.

This study concluded that there is good adherence to regulatory standards by manufacturers of hand sanitizers which is important to ensure that only compliant products are available on the market.

Keywords: COVID-19 • Hand sanitizers • Ethanol • IR spectroscopy • pH meter

Introduction

In healthcare settings and within communities, proper hand hygiene is a highly recommended practice for the prevention and control of communicable infections, especially washing one's hands with water and soap. In the context of Coronavirus Disease 2019 (COVID-19) pandemic, routine use of hand sanitizers is a favorable alternative to hand washing in stopping the spread of the virus. Hand sanitizers are products applied and rubbed on hands to inactivate pathogenic microorganisms. These products are designed to dry rapidly after application, thereby eliminating the need for soap, water and drying aids such as towels. Theconvenience and portability of hand sanitizers has led to their widespread usage since 2020 due to the pandemic. Depending on the active ingredient used, hand sanitizers can be classified as either alcohol based or alcohol free. Alcohol Based Hand Sanitizers (ABHS) are preferred to alcohol free sanitizers because they are safer, less irritating to the skin and can be applied on the skin more quickly than the alcohol free sanitizers. Alcohol based hand sanitizers can be made of n-propyl alcohol, isopropyl alcohol, ethanol, or a combination of alcohol types. These sanitizers can be formulated as gels, foams, liquids or even sprays in volumes of 60 mL, 100 mL, 200 mL, 500 mL, 1 L or even 20 L packs. Because of the high demand of these sanitizers during the COVID-19 pandemic, there has been an increase in the prevalence of falsified alcohol based hand sanitizers. These falsifications include, methanol contamination, additives not listed as ingredients and sanitizers with an alcohol content less than 60%. This has been observed in both the locally made and also the exported alcohol based hand sanitizers. Methanol should not be used in hand sanitizers because of its toxicity to the skin, lungs and mouth. Also, a hand sanitizer that contains less than 60%alcohol is ineffective against the viruses, which may leave the public vulnerable to contracting infections among which is COVID-19.

Materials and Methods

Study area

The study was carried out in Mbarara city pharmacies and supermarkets that sell alcohol hand sanitizers.

Study design

The first part of the study was a descriptive cross sectional survey to determine the different brands available and where they are sold, their certification status and the location of the site of manufacture. The second part was a laboratory based experimental study using both pharmacopeia and non-pharmacopeia tests on selected samples of hand sanitizers.

Inclusion criteria

Only hand sanitizers that were manufactured between April 2020 to date and packaged in at most one litre bottles. Both ethanol and isopropyl based hand sanitizers. Both registered and none registered alcohol based hand sanitizers.

Exclusion criteria

Any sanitizer without labels. Products with damaged packaging. All hand sanitizers that were expired.

Results

This chapter presents data findings of the study according to specific objectives and analysis of the data collected. Results of the study are presented both in text and graphic formats while findings from qualitative study are presented in text format only.

Physical assessment

The physical characteristics of the selected brands of sanitizers on market (Table 1).

Table 1. Physical parameters.

Physical assessment parameters	Brands of ABHS								
	A	B	C	D	E	F	K	J	M
Name of the product as alcohol based hand sanitizer	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Manufacturer's name and physical address	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Batch or code number	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Net content	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
List of ingredients used	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
General instructions for use	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Date of manufacture and expiry date	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Country of origin/ manufacture	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Precautionary warnings	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes

All the assessed brands and their respective samples had the listed parameter for physical assessment considered by the study, and they were deemed to have passed this part of the quality check.

The strength of alcohol content and other ingredients in the different brands of sanitizers on Mbarara market (Table 2).

Table 2. Showing label claims.

Sample	Sample component (% v/v)	Alcohol content % (label claim)
A	Ethanol, glycerin, Isopropyl, myristate, allantoin phosphoric acid and water	80
B	Ethanol, hydrogen peroxide, PEG-60, glycerides, treated H_2O and triisopropanolamine	80
C	Glycerin, triethylamine, carbomer, hydrogen peroxide, distilled water and fragnance	80
D	Ethyl alcohol, glycerin and water	75
E	Ethanol, distilled water, hydrogen peroxide, vitamin E and glycerin	80
F	Ethanol, water, glycerin and fragrances	80
K	Ethanol, glycerin and purified water	70
J	Ethanol, Isopropyl alcohol 3.3% and permitted colors	70
M	Ethanol, triethanolamine and carbomer	70

The study found out that three brands out of the nine brands had a label claim of 70%, five brands had a label claim of 80% alcohol and one brand had a label claim of 75% which was within the recommended 60%-80%WHO range.

pH analysis for ABHS brands

The Relative Standard Deviation (RSD) greater than 1% show poor inter brand consistence in pH values (Tables 3 and 4).

Table 3. pH value RSD analysis.

Samples	A	E	D	J	K	M	F	C	B
3.035	6.269	6.656	5.969	8.209	8.194	6.641	7.412	6.668	
3.06	6.138	7.192	5.92	6.179	8.244	6.491	5.948	6.664	
2.989	6.303	6.522	5.903	8.021	8.065	6.385	7.168	6.971	
3.012	3.104	6.309	-	-	-	-	-	-	
5.938	5.91	6.988	-	-	-	-	-	-	
3.063	6.323	7.329	-	-	-	-	-	-	
Average	3.516	5.675	6.833	5.931	7.47	8.168	6.506	6.843	6.768
SD	1.187	1.269	0.4	0.034	1.122	0.092	0.129	0.784	0.176
RSD%	33.752	22.356	5.86	0.578	15.017	1.131	1.977	11.463	2.602

Table 4. A table showing the pH averages.

Brands	Mean of the sample pH	Acceptable range 6-8
A	3.516	Failed
B	6.768	Passed
C	6.843	Passed
D	6.833	Passed
E	5.674	Failed
F	6.699	Passed
K	7.47	Passed
J	5.931	Failed
M	8.168	Passed

The above analysis implied that 66.7% of the brands (6 brands) had a pH within the acceptable pH range values while 33.3% (3 brands) had their pH values outside the acceptable ranges. There was no correlation between pH values and mean percent of the stated alcohol content.

The product range and certification status

One brand had both the NBS and NDA logo, all the nine brands had the UNBS logo and seven brands were from a list of registered companies as per 7th July 2020.

Alcohol content

Of the 9 brands analyzed, 55.6% (5 brands) had their alcohol concentration within the pharmacopeia accepted error range of 95%-105%. Contrary, 2 brands had their percentage of the stated alcohol below 95% and the other two were above 105% (Table 5).

Table 5. Calculated alcohol concentration.

Brands obtained value	Alcohol content % label claim value	Percentage of measured alcohol content	Acceptable range (95%-105%)	Comment (pass or failed)
A	79.03	80	98.8	Pass
B	70.8	80	88.5	Failed
C	77.73	80	97.2	Pass
D	75.04	75	100.1	Pass
E	81.24	80	101.6	Pass

F	79.15	80	98.9	Pass
K	75.33	70	107.6	Failed
J	76.65	70	109.5	Failed
M	65.1	70	93	Failed

Brands A, E and D were purchased from both the pharmacies and supermarkets and they had their mean percent of the stated alcohol content within the acceptance range. Brands F, B and C were purchased from pharmacies alone with brand B failing on the basis of the mean of the stated alcohol content.

Brands J, K and M were purchased from supermarkets alone and all failed on the basis of the mean percent of the stated alcohol content. Brands B and M had their percentage of stated alcohol content below the acceptance of 95%-105% whereas brand J and K had their percentage of stated alcohol content above the acceptance range. All the other brands were within the acceptance range.

Differences between brands and sources

Homogeneous test: There was homogeneity in the brands A with F and brands F with D. However, brand A was not homogeneous with brand D. Having received a significant p-value for the homogeneous test, we decided to do an Analysis of Variance (ANOVA) which also gave a significant p-value (<0.05). A welch test was also done which agreed with the ANOVA result. The lack of homogeneity accompanied by the agreement of ANOVA with the Welch test prompted us to do a post hoc test identifying the Inter brand differences.

Post Hoc test: A post hoc test using a Dunnett T3 test where unequal variance was assumed showed an insignificant p-value (p-value>0.05) for the comparison of A with C, A with F, C with F and D hat the mean percentage of the stated alcohol content of brand A was not statistically different from that of brand C and brand F. The mean percentage of the stated alcohol content of brand F was not statistically different from that of brand C and brand.

However, the mean percentage of the stated alcohol content of brand D was statistically different from that of brand D.

The analysis of the supermarket only samples against the samples got from both the pharmacy and the supermarket showed a statistically insignificant p-value (0.236). Therefore, there was no significant difference between the means of the brand samples from these two groups. However, there was a statistical difference between the pharmacy only samples with Supermarket only samples and pharmacy only samples with both pharmacy and supermarket samples.

There was a great consistence in the percentage of the stated alcohol content for the samples got from both pharmacy and supermarket compared to the supermarket alone samples. However, there was a greater skew to the lower values in the Pharmacy only brands compared to the supermarket only brands. The Supermarket samples had great variability and the values were skewed towards high concentrations. Standard addition of three sanitizer brands E, M and D using pure ethanol (99.99%) as a standard. Comparison of standard addition, expected and measured value (Table 6).

Table 6. Standard addition.

Brand	Equation	X Intercept	R^2	Calculated ethanol concentration (%v/v)	Label value	Alcolyzer value
E	y+8.082= 0.9846x	-8.208	0.9999	82	80	80.7
M	y+6.542= 0.9874x	-6.625	1	66	70	65.4
D	y+7.444= 0.9977x	-7.461	0.9999	74	75	74.25

The R^2 of 0.9999 and 1 explain that the machine readings were 99.99%and 100% ethanol which means that the likely hood of interference from other molecules was not significant (less than 0.0001%). The p value (0.963) is greater than 0.05, there is no statistically significant difference between the means in alcohol concentration because of standard addition and measured values against the label values [1-5].

Discussion

Labelling

All the samples (9 brands) tested passed the 'proper labelling' criteria which is important. This strengthens the fact that the current manufacturers follow the guidelines and standards in place on proper product labelling. Proper labelling is integral to quality requirements since the label confers product identity and elicits consumer confidence in the product. Manufacturers of ABHSs' indication of the specific alcohol content of the sanitizer on the label helps for customers to easily identify products that meet the recommended 60 percent alcohol minimum.

Label contents enable customers to better understand the product and make informed choices. Some samples had figures printed on the products; 99.99% microbe kill. Use of any of these specific figures however, if not supported by actual experimental data is questionable and may give consumers a false sense of security.

Range and certification status

The samples purchased from both pharmacies and supermarkets all had the UNBS logo and brand K had both the UNBS and NDA logo. Despite passing all the quality tests, brands K and C manufacturers were not listed in the UNBS list of registered companies availed to the public as of 7th July 2021 which may be because the list was not updated. Products of manufacturers not present on the list of registered companies may be considered as counterfeits.

Determination of ethanol content

The result on this analysis revealed that all the ABHS tested had ethanolic content within the range recommended by regulatory agencies for disinfection (60% v/v to 80% v/v) as in the Uganda standards 2017. The lowest being 65.1% in brands M and the highest being 81.24% in brands E [6-8].

Samples obtained from the supermarkets of brands K and J had a relatively higher alcohol content of 75.33% and 76.65% respectively compared to than the label claims of 70% while sample brands B and

M showed a significantly lower content of 70.8 and 65.1 compared to 80% and 70% respectively. These deviations was initially thought to be because the determination of ethanol content in the samples may suffer interference of other additives and/or the change in the 29 content of substances such as glycerol, hydrogen peroxide and carbomer, fragrances, colors and triethanomine already present in formulations.

About twelve additives were reported in the labels of the commercial products used in this study. The most common are glycerol and hydrogen peroxide. Though the manufacturers mention the composition, they do not mention the quantities of the additives. Berardi A, et al. refers to these substances that are present in small quantities in the sanitizer formulation do not significantly affect the determination of the ethanol content using the methods. However, positive interference may be caused by the glycerol which can be anticipated, as its structure has three O–H groups and its readings may overlap that of ethanol almost along the entire NIR spectral region in the alcolyzer used for the experiment.

In addition, these deviating values could mean the manufactures do not put the alcohol content they claim, which means cGMPs are not followed stringently and overall pricing of products may be affected [9-14].

Physical chemical parameters

The physical parameters tested was clarity. All the samples (9 brands) were clear and colorless showing no specs on visual inspection. pH tests showed that 3 brands A, E and J had the pH values lower than that range stipulated in the standards. A study by Geun Woo Park, et al. found that ethanol and low pH can act synergistically to improve efficacy against viruses, with efficacy of 70% alcohol increasing from 2.6 log PFU/ml to > 4.4 log PFU/ml when the pH was adjusted from 7.4 to 3.0. These findings challenge the standards which suggest a higher pH range of 6-8, with these regards a fail in pH may not be considered entirely substandard and hence of poor quality.

Conclusion

The present study was designed to assess the level of alcohol content in nine hand sanitizers common in the Mbarara city market. The results and findings of the study indicate that all of the hand sanitizers on market meet the Uganda standards recommended limits with respect to alcohol content. Despite this, it is conclusive that some sanitizers on market in Mbarara town have lower or higher contents of alcohol than the amounts indicated on their labels. Therefore, the need for proper monitoring of the production and marketing of hand sanitizers and adherence to cGMPs is strongly recommended.

Limitations

- The study did not check for the efficacy of the sanitizers.
- The method of alcohol quantification was not specific hence exact values. couldn't be computed. Therefore, the study could not encompass gel ABHS due to possible positive interference.
- Toxic impurities of alcohol which have been reported to be toxic could not be analyzed and quantified.
- ABHS with more advanced packaging like sprays could not be studied.

Recommendations

- Using the alcolyzer is mostly favorable for liquid ABHS using standards additions analysis to remove matric effects.
- The efficacy using microbial analysis is a crucial aspect of the overall quality of ABHS hence, further research is recommended to evaluate this property especially during this COVID-19 era.
- Several reports have reported the availability of adulterants in ABHS and FDA has withdrawn several products with these claims, benzene, methanol, acetaldehydes.

Acknowledgement

We highly acknowledge the whole team for sparing time to engage in developing

Funding

This review manuscript is not funded.

Conflicts of Interest

No conflicts of interest

Author's Contribution

Conceived and designed the manuscript synopsis: Nathan Mugenyi

Edited manuscript: Prize Ninsiima, Racheal Nalunkuma

Wrote the first draft of the manuscript: Nathan Mugenyi

Wrote the paper: Nathan Mugenyi, Prize Ninsiima

Agreed with manuscript review and conclusions: Nathan Mugenyi, Prize Ninsiima, Racheal Nalunkuma

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Cite this article: Mugenyi N, et al. Assessing the Quality and Effectiveness of Alcohol Based Hand Sanitizers Commercially Available in Mbarara City. Nat Prod Chem Res. 2023, 11 (1): 1-5