Alcohol Content of Hand Sanitizers Marketed in Selected Towns in Eastern Ethiopia

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Abstract

Background: Many generic brand hand sanitizers have been flooding the market because of the high surge in the demand for hand sanitizers around the globe due to rising prevalence of the COVID-19 and increase in consumer awareness pertaining to personal hygiene worldwide. However, the quality of most sanitizers available on the market is questionable.

Objective: The purpose of this study was to determine ethanol concentration of commercially available ethanol-based hand sanitizers that are marketed in selected cities in eastern Ethiopia (Haramaya, Dire Dawa, and Harar) and validate whether they meet the standard concentration recommended by World Health Organization (WHO) and recommend Food and Drug Authority of Ethiopia to check the quality of hand sanitizers marketed in all corners of the country very seriously and take necessary measures for the poor quality of marketed hand sanitizers.

Materials and Methods: Attenuated Total Reflectance-Fourier Transform Infrared Spectroscopy (ATR-FTIR) was used to determine the concentration of ethanol in five brand hand sanitizers purchased from Haramaya, Dire Dawa, and Harar.

Results: The results of the study showed that the concentration of ethanol in Brand 1, Brand 2, Brand 3, Brand 4 and Brand 5 was 58.20, 56.51, 55.02, 51.33 and 93.03%, respectively, and was not in good agreement with the label claim marked as ethanol concentration. The hand sanitizer formulated by the Department of Chemistry, Haramaya University was found to contain 77.2% ethanol, which was in acceptable concentration range recommended by the World Health Organization (WHO).

Conclusion: Of the six samples of hand sanitizer tested, four of them fail below the WHO recommended concentration (80%), while one brand had ethanol concentration exceeding the WHO standard. The determined ethanol concentration of the analyzed hand sanitizers showed a poor correlation with the claimed label except that of hand sanitizer formulated in the Haramaya Chemistry Department Laboratory with a significant deviation from the expected values ranging from 16.25% to 35.87%. The poor quality of these hand sanitizers can contribute to the spread of the virus rather than preventing it. Therefore, the continued vigilance is required from all stakeholders and authorities to ensure that the product is formulated in accordance with the guidelines recommended by WHO.

Keywords: Alcohol-based handrubs; Attenuated Total Reflectance-Fourier Transform Infrared Spectroscopy; COVID-19; Ethanol Concentration

1. Introduction

Hand sanitizers are one of the key disinfectants being utilized to control the spread of Coronavirus disease 2019 (COVD-19) (Golin *et al*., 2020). Hand sanitizers, also called hand antiseptic or handrub are agents applied to the hands to remove common pathogens (Todd *et al*., 2010). The best way to prevent the spread of infections and decrease the risk of getting sick is by washing our hands with plain soap and water. However, if soap and water are not available for hand washing, Center for Disease Control and Prevention (CDC) recommends consumers

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to use an alcohol-based hand sanitizer that contains at least 60% alcohol (CDC, 2020).

Hand sanitizers or the alcohol-based handrubs are consumer products in the form of liquid, spray or gel and are thought to generally be effective in killing microorganisms and decreasing infectious agents on hands. The alcohol-based sanitizers are typically the most popular and effective and claims to kill 99.99% of bacteria within seconds including the most resistant form (Mithun *et al*., 2015; Tamimi *et al*., 2015). The principal component and active ingredient of hand sanitizers that are recommended for coronavirus is alcohol at a concentration of at least 60% (*v*/*v*). The two formulations recommended by WHO should comprise either ethanol or isopropyl alcohol. Since COVID-19 has become a global pandemic, several guidelines have been published by international organizations, such as CDC and WHO on personal hygiene including, hand washing and hand sanitization (WHO, 2009; CDC, 2020). This in turn has increased the demand for alcohol-based sanitizers.

The demand of hand sanitizers has been steadily increasing in the past 15 months since the outbreak of the COVID-19 virus in the globe (Berardi *et al*., 2020), but a sudden spike in demand has been observed in recent months as the rate of infection has surged across the globe. As the virus has begun to spread widely across the world, people have started to "panic-buy" hand sanitizers as a preventive measure. Although hand washing with soap and water is strongly recommended for prevention of COVID-19, the CDC and WHO "lists alcohol-based hand sanitizer (with an alcohol content above 60 %) as an alternate for reducing the spread of the virus (CDC, 2020). From the two formulations recommended by WHO, the COVID-19 pandemic has created a considerable demand for alcohol-based hand sanitizers for personal disinfection as well as for disinfection of hard surfaces that the virus can inhabit. This increased demand has pushed many new manufacturers to produce ethanol and isopropyl alcohol based hand-sanitizing products.

In Ethiopia, in response to the ongoing effort of the country to control the potential outbreak of COVID-19, the Federal Food and Drug Authority drafted a new temporary directive that gives an exclusive license to manufacturers, enabling them to make hand sanitizer, disinfectant and face masks (EFDA, 2020). With the COVID-19 infection rate surging in Ethiopia and the entire world, the sales of hand sanitizers are becoming popular. As a result, numerous generic brands of hand sanitizers have been flooding the market. However, most of the generic brand hand-sanitizers available in Ethiopian and the entire world market were not formulated following the WHO recommended hand rub formulations, and hence, their quality is questionable (Berardi *et al*., 2020; Fonseca *et al*., 2020). Therefore, the objective of the study was to investigate the alcoholic content and quality of five different brands of hand sanitizers available in Dire-Dawa, Harar and Haramaya markets in eastern Ethiopia against the WHO recommended formulations.

2. Materials and Methods

2.1. Apparatus and Instruments

A Fourier Transform Infrared (FT-IR) Spectrometer (Spectrum 65, PerkinElmer, Waltham, USA) equipped with attenuated total reflectance (ATR) accessory was used for acquisition of FTIR spectra of the samples.

2.2. Chemicals and Reagents

H_2O_2 (30%) and glycerol (99%) were purchased from Mulu pharmaceuticals (Addis Ababa, Ethiopia). Standard ethanol (99.99%) was purchased from Carlo-Elba (Val-de-Reuil, France). Homemade distilled and sterilized water was used throughout the experimental work.

2.3. Sample Collection and Preparation

Five different brands of commercially available hand sanitizers, each 100 ml (Brand 1, Brand 2, Brand 3, Brand 4 and Brand 5) were purchased from supermarkets and local pharmacies at Haramaya, and Harar, and Dire Dawa towns in July 2020. An ethanol-based hand sanitizer (approximately 78% ethanol) was formulated as per the WHO recommendation at the Department of Chemistry, Haramaya University for comparison.

2.4. Experimental Procedure

2.4.1. Formulation of ethanol-based hand sanitizer

The Ethanol-based hand sanitizer (500 mL) containing ethanol 78% (*v*/v) was formulated as per the WHO recommended guideline (WHO, 2009). In detail, 425.5 mL of ethanol (94%), 7.32 mL of glycerol (99%) and 2.08 mL of hydrogen peroxide (30%) were added to polypropylene plastic tank and mixed gently. Then, sterilized distilled water (65 mL) was added to bring to final volume (500 mL). The mixture was mixed well and

the final solution was transferred into suitable containers and quarantined for 72 hours.

2.4.2. Physical identification of ethanol in samples

The ethanol-based hand sanitizer formulated as per the WHO Guidelines was labeled as HrU Chem hand sanitizer. The commercial hand sanitizers purchased from supermarkets and local pharmacies were labeled as Brand 1, Brand 2, Brand 3, Brand 4, and Brand 5. To confirm that the samples contained ethanol, flammability of the purchased samples were compared to that of homemade ethanol-based hand sanitizer (Almengor & Monaghan, 2015). For the flammability test, equal amounts of each brand of alcohol-based hand sanitizers purchased from the market and the one formulated in HrU Chem lab were simply dripped on six different crown corks. Then, the sanitizers were lit with lighter to test the presence of alcohol in the samples (qualitative test).

2.4.3. Determination of ethanol concentration

The ethanol concentrations in the samples were determined using the PerkinElmer Spectrum 65 FT-IR spectrometer equipped with attenuated total reflectance (ATR) accessory. The spectral acquisition was made in the range of 4000–600 cm^{-1} with 4 scans and resolution of 4 cm^{-1}. An external calibration curve drawn from ten standard solutions (0–80%) of ethanol comprising the same quantity of glycerol and hydrogen peroxide (1.45 and 0.125% w/w, respectively) were used to estimate ethanol concentration from the instrument response.

3. Results and Discussion

3.1. Determination of Ethanol Concentration

The ethanol-based hand sanitizer model was created based on the standard calibration curve derived from the area of a peak at 1043 cm^{-1}, which corresponds to the C-O stretching frequency in a primary alcohol. The FT-IR spectrum containing 80% ethanol in the region 1150-950 cm^{-1} is shown in Figure 1.

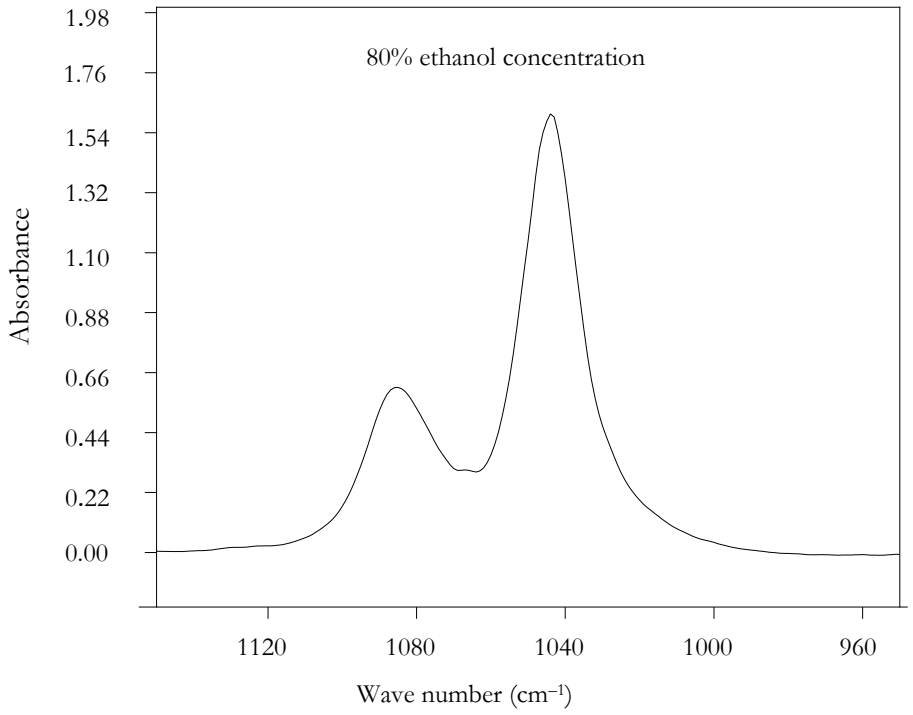

Figure 1. FT-IR Spectrum of 80% ethanol.

The FTIR spectra of a series of standard ethanol solutions with ethanol levels ranging from 0–80% (Blank, 10, 20, 30, 40, 50, 60, 70, and 80%) in the region 1150-950 cm^{-1} were acquired and given in Figure 2.

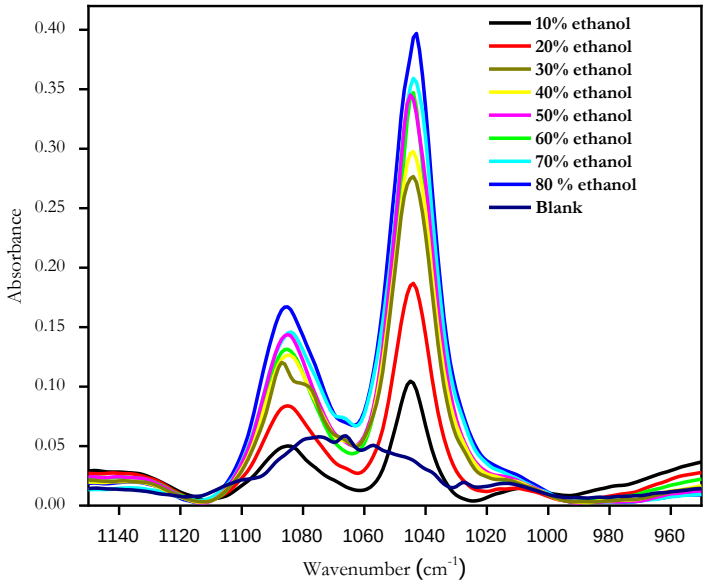

Figure 2. FT-IR Spectra of different concentration of ethanol ranging from 0–80% in the region 1150-950 cm^{-1}.

The area of the peak at 1043 cm^{-1} was then used to construct a calibration curve using simple Beer's Law. The calibration curve exhibits an excellent linearity with a correlation coefficient of 0.9907. The calibration curve was produced using the peak area at 1043 cm^{-1} and shown in Figure 3.

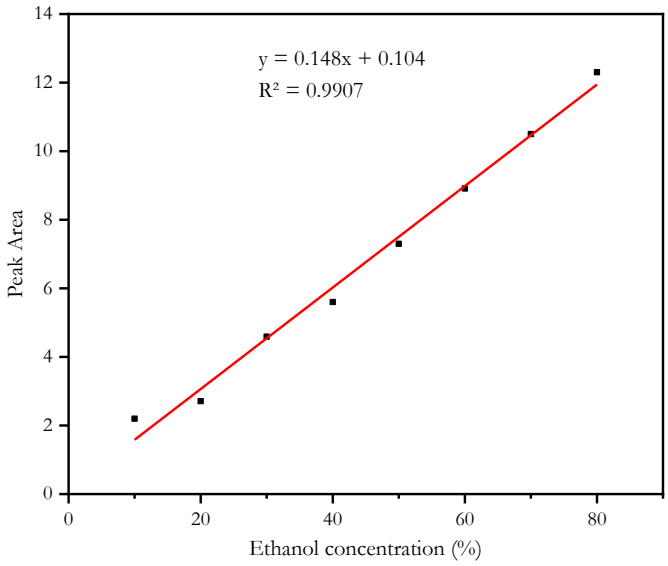

Figure 3. Calibration curve of ethanol % produced using peak area of 1043 cm^{-1}.

The calibration curve was then used to determine the concentration of ethanol in five commercial hand sanitizers and hand sanitizer formulated at Chemistry Department Laboratory of Haramaya University. The FTIR Spectra of the samples were acquired and presented in Figure 4. The peak area of 1043 cm^{-1} was obtained and the percentage of ethanol in each samples were determined against the calibration curve. The corresponding ethanol concentration versus label claim of the hand sanitizer products is given in Table 1. The percent error between the label claim and the determined concentration of ethanol in each sample was calculated using the following equation (Fonseca *et al.*, 2020):

$$\text{Percent error} = \frac{\text{Determined concentration of ethanol} - \text{label claim concentration of etahnol}}{\text{Label claim concentration of ethanol}} \text{ X } 100$$

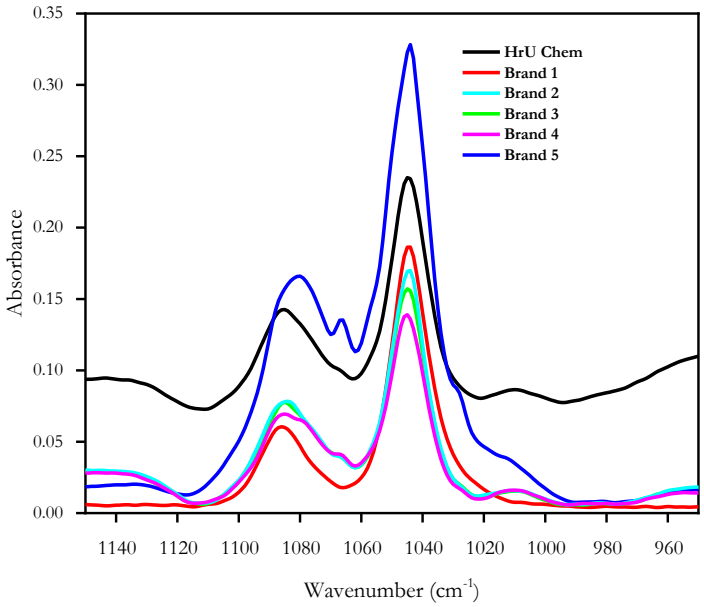

Figure 4. ATR-FTIR spectra of the six samples of Hand sanitizer.

Table 1. Concentration of ethanol in five brands of commercial ethanol-based hand sanitizers and hand sanitizer HrU Chem.

Sample	Mean ± standard deviation	Label claim ethanol concentration (%)	Error (%)
Brand 1	58.20±0.199	80	27.5
Brand 2	56.51±0.090	80	29.37
Brand 3	55.02±0.192	80	31.25
Brand 4	51.33±0.061	80	35.87
Brand 5	93.03±0.071	80	16.25
HrU Chem	77.17±0.061	80	3.62

The determined ethanol concentration of the sample hand sanitizers showed a poor correlation with the claimed label except that of HrU Chem hand sanitizer with a significant deviation from the expected values ranging from 16.25% to 35.87%. Among the commercial samples of hand sanitizers, the highest and the lowest percent deviations from the claimed label of ethanol concentration were observed for Brand 4 and Brand 5 hand sanitizers, respectively. Among the six samples, Brand 5 contained a higher percentage of ethanol than the label claim concentration of ethanol (80%) and HrU Chem hand sanitizer, which is in a good agreement with the expected value.

The antimicrobial activity of alcohols is linked to their ability to denature proteins. The best antimicrobial efficacy can be achieved with solution of ethanol (60 to

80%) (Kampf and Kramer, 2004). The higher percentage of ethanol (>80%) is not a guarantee for better antimicrobial efficacy. Higher concentrations are less potent/effective because proteins are not denatured easily in the absence of water, which means proteins requires the presence of water to be easily denatured, whereas solutions with a lower than 60% alcohol concentration may only reduce/slow the growth of germs but not kill them.

3.2. Physical Properties of Commercial Hand Sanitizers

The results obtained showed that the five hand sanitizers, Brand 1, Brand 2, Brand 3, Brand 4 and Brand 5, purchased from the local market were not formulated as per the WHO recommended hand rub formulations and hence not effective against coronaviruses. This may have negatively affected the nation's efforts to prevent the spread of the virus, and predisposes communities to unnecessary costs. While Brand 5 hand sanitizer seemed to have been distributed in the market simply by bottling the ethanol pure as purchased from the sugar factory without any formulation.

3.2.1. Flammability test

All the five samples and HrU Chem hand sanitizer were ignited at a rapid rate. This test indicated that all samples contained ethanol.

3.2.2. Evaporation rate test

Each of the six hand sanitizers was spritzed on palms separately and rubbed over the hand surface. The four generic Brand sanitizers named Brand 1, Brand 2, Brand 3 and Brand 4 evaporate/dried slowly within 32 seconds while Brand 5 dried very quickly within 8 seconds and the HrU Chem hand sanitizer dried within 13 seconds. This indicate that Brand 1, Brand 2, Brand 3 and Brand 4 generic hand sanitizers purchased from the local market contained low levels of the active ingredient (ethanol) compared to Brand 5 and HrU Chem hand sanitizers.

4. Conclusion and Recommendation

In this study, ethanol concentrations of five generic Brand hand sanitizers available in eastern Ethiopian markets were analyzed using ATR-FTIR. The results showed that the commercially available hand sanitizers were not formulated as per the WHO recommended hand rub formulations and their quality is low (in terms of ethanol concentration). This would negatively affect Ethiopia's efforts to prevent the spread of the Coronavirus in the country. Based on the experimental results, the researchers recommend that the Food and Drug authority of Ethiopia needs to inspect and check the quality of hand sanitizers marketed in all corner of the country very frequently and take the necessary measures to maintain the required quality and effectiveness of marketed hand sanitizers in controlling COVID-19 and other contagious respiratory diseases

5. Acknowledgments

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