DOES PRODUCT FORMAT IMPACT EFFICACY OF ALCOHOL-BASED HAND HYGIENE PRODUCTS?

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Abstract

Background / Objectives: Hand hygiene is one of the most important interventions for reducing the incidence of healthcare-associated infections. Alcohol-based hand hygiene products have been recommended by the WHO for use in Healthcare settings. Traditionally these products have been gels, and only recently have foams and wipes been introduced into hospitals. The aim of this study is to determine whether there are differences in the antimicrobial efficacy of alcohol-based hand hygiene products with different formats: gel, foam, and wipe.

Methods: Test products chosen were representative of alcohol-based hand hygiene products currently found in hospital settings including a 70% ethanol gel hand sanitizing wipe, a 70% ethanol foam hand sanitizing wipe, and a 62% ethanol hand sanitizing wipe. These products were tested against various standard test methodologies in vitro: EN 1275 versus Candida albicans, EN 1500 versus Staphylococcus aureus, EN 1500 versus Staphylococcus epidermidis, and EN 1275 vs. Staphylococcus haemolyticus, Serratia marcescens, Pseudomonas aeruginosa, Proteus mirabilis, Klebsiella pneumoniae, and Escherichia coli for 15 seconds exposure. An aliquot was removed and neutralized and serially diluted in BBP++, and plated in duplicate using TSA+. Plates were incubated at 35°C for 24-48 hours, and colony forming units were counted. Log10 reductions were calculated using the following equation:

\[ \text{Log}_{10} \text{Reduction} = \text{Log}_{10} \text{Initial Concentration} - \text{Log}_{10} \text{Final Concentration} \]

Results: All products achieved >6 log10 reduction against all organisms tested, which was consistent with the EN 1500 test method. EN 1500 was the most efficacious test format, followed by EN 1275 and Time-Kill. All products tested met the EN 1500 and Time-Kill method requirements.

Conclusions: This data supports US CDC3, WHO4, and CHICA-Canada5 recommendations for use of >60% alcohol-based hand hygiene products, since all products tested ranging from 62-70% alcohol, with various product formats were efficacious.

• This study, in vitro data were a good predictor of the efficacy observed in vivo using EN 1500.

Based upon the Time-Kill and EN 1500 results, all products tested would meet the bactericidal test requirements outlined in Health Canada’s Guidance for Human-Use Antiseptic Drugs used in HealthCare settings, as all products achieved >5 log10 reduction in vitro and >3 log10 reduction in vivo.

References


Materials and Methods

Test Products: Products representative of those found in healthcare settings in Canada were chosen for this evaluation. These included a 62% ethanol EtOH wipe (PURELL Hand Sanitizing Wipes), a 70% EtOH gel (PURELL 70 Instant Hand Sanitizer), and a 70% EtOH foam (PURELL 70 Instant Hand Sanitizer Moisturizing Foam). All products were manufactured by GOJO Industries, Inc., Akron, Ohio.

EN 1275: Products were tested according to EN norm 12757, where an 80% concentration of test product was exposed to Candida albicans (ATCC 10231) for 30 seconds. Results were calculated using the Spearman-Kärber calculation. Log10 of infectivity was calculated, and Log10 reductions were calculated by comparison to the virus control. Evaluations included a virus control, cytotoxicity control, neutralization control, and negative control.

EN 1500: Products were tested according to ASTM E 1052-06, “Standard Test Method for Efficacy of Antimicrobial Agents Against Viruses in Suspension”. The challenge virus was Swine-like H1N1 Influenza A virus strain A/California/04/2009 (CDC 12006/2010). Test products were mixed with virus suspension to give a 10% volume of test product. After 15 seconds exposure, the virus was neutralized by dilution in 1x Minimum Essential Medium. Selected dilutions of the mixture were plated to allow growth of viable virus. The endpoint was 50% tissue culture infectious dose (TCID50) was calculated using the Spearman-Kärber calculation. Log10 of infectivity was calculated, and Log10 reductions were calculated by comparison to the virus control. Evaluations included a virus control, cytotoxicity control, neutralization control, and negative control.

Time-Kill (E 2315): Products were tested according to ASTM E 2315, “Standard Guide for Assessment of Antimicrobial Activity Using a Time-Kill Procedure”8. The test organisms were prepared to reach a challenge suspension of 10^5 CFU/mL. The initial population was determined by ten-fold dilutions in Butterfield's Phosphate Buffer with antibiotics (10 μg/mL gentamicin, 10 μg/mL amphotericin B). A 0.1mL aliquot of a challenge suspension containing 10^9 CFU/mL was transferred to sterile test tube containing 9.9mL of test product and mixed immediately. An aliquot was removed and neutralized and serially diluted in BBP++, and plated in duplicate using TSA+. Plates were incubated at 35°C for 24-48 hours, and colony forming units were counted. Log10 reductions were calculated using the following equation:

\[ \text{Log}_{10} \text{Reduction} = \text{Log}_{10} \text{Initial Concentration} - \text{Log}_{10} \text{Final Concentration} \]

Results

• All products achieved >99.99% reduction against all organisms tested using in vitro Time-Kill, EN 1275, and Viral Suspension Tests.
• All products met the requirements of EN 1500 as all were statistically equivalent to the reference product, 60% isopropanol.
• All test products achieved >5 log10 reduction in vivo using EN 1500, which was consistent with the in vitro results where all products achieved >6 log10 reduction against E. coli.

Method Organism ATCC # 70% ETOH Gel 70% ETOH Foam 62% ETOH Wipe Log10 Reduction

EN 1275
Candida albicans 10231 ≥6.64 ≥6.54 ≥6.54
Staphylococcus aureus 12228 ≥6.41 ≥6.54 ≥6.41
Staphylococcus epidermidis 12578 ≥6.67 ≥6.54 ≥6.67
Staphylococcus haemolyticus 43253 ≥6.17 ≥6.77 ≥6.15
Staphylococcus hominis 6651 ≥5.97 ≥6.54 ≥6.33
Staphylococcus epidermidis 5638 ≥5.97 ≥6.33 ≥6.33
Serratia marcescens 6538 ≥5.97 ≥6.81 ≥6.33
Pseudomonas aeruginosa 15442 ≥6.34 ≥6.22 ≥6.01
Proteus mirabilis 13883 ≥6.49 ≥6.11 ≥6.08
Klebsiella pneumoniae 856 ≥6.28 ≥5.94 ≥6.12
Escherichia coli 196155 ≥5.53 ≥4.77 ≥4.15
E. coli 33400 ≥5.86 ≥6.82 ≥6.54
Acinetobacter baumannii 4085 ≥6.41 ≥6.74 ≥6.81
Acinetobacter baumannii ESBL BAA-194 62% ≥6.27 ≥7.02 ≥6.51
Acinetobacter baumannii Escherichia coli K12 NCTC 10538 according to EN 1500, where 3 ml of product was applied to the hands for a 30 seconds contact time. A total of 12-15 subjects were evaluated for each test product.

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