Efficacy of Alcohol-Based Hand Rubs at an "In Use" Volume

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ABSTRACT

Background / Objectives

Alcohol-based hand rubs (ABHRs) are the primary form of hand hygiene in healthcare settings. Most Canadian hospitals utilize wall-mounted dispensers throughout the facility. However, there is little data on the efficacy of ABHRs at dispensed volumes. The objective of this study was to evaluate the efficacy of ABHR formulations when tested at the quantity dispensed.

Methods

Three commercially available ABHR, Gel A (70% ethanol gel), Foam B (70% ethanol foam), and Foam C (70% ethanol foam) were evaluated according to ASTM E1174 as described by the US FDA at a 1.3 ml volume, which represents the normal output from a wall-mounted dispenser. A total of 10 hand contamination and product application cycles were executed and \log_{10} reductions from baseline were calculated for applications 1 and 10.

Results

 Log_{10} reductions for Gel A, Foam B, and Foam C after a single application were 3.10, 3.06, and 3.10, respectively, and after ten applications were 3.11, 3.26, and 3.28, respectively. All test products met Health Canada requirements for a \geq 3 log_{10} reduction after 1 and 10 applications.

Conclusions

This is the first report of ABHR formulations meeting Health Canada requirements with a single actuation from a wall-mounted dispenser. These data indicate well-formulated products can meet regulatory efficacy requirements at dispensed quantities.

METHODS

Health Care Personnel Hand Wash (HCPHW) studies were conducted according to the ASTM E 1174-94 "Standard Test Method for Evaluation of the Effectiveness of Health Care Personnel Handwash Formulations". A total of 3 test products were evaluated: PURELL® Advanced Hand Rub, PURELL Advanced Foam Hand Rub and PURELL Advanced Moisturizing Foam Hand Rub, all manufactured by GOJO Industries, Inc. A neutralization study per ASTM E1054-08 was successfully performed to ensure the neutralizer employed in this study was effective. Subjects hands were contaminated with *S. marcescens* (ATCC #14756). The test product was applied to the hands with a volume of 1.3 ml, and rubbed in until dry. A minimum of 24 subjects were evaluated for each test product for a series of 10 applications, with samples completed after applications 1 and 10. \log_{10} reductions from baseline were calculated and statistical comparisons were made using a 1 way ANOVA (α =0.05). For demonstration of *in vivo* bactericidal efficacy, Health Canada requires a minimum 3 \log_{10} reduction after the first and tenth application¹.

The objective of this study was to determine if efficacy of products when tested at the amount dispensed from a wall-mounted dispenser (1.3 ml) is sufficient to meet the efficacy requirements for Health Canada.

Figure 1. Steps for E 1174



1. Contaminate Hands.



2. Sample for Baseline.



3. Contaminate Hands.



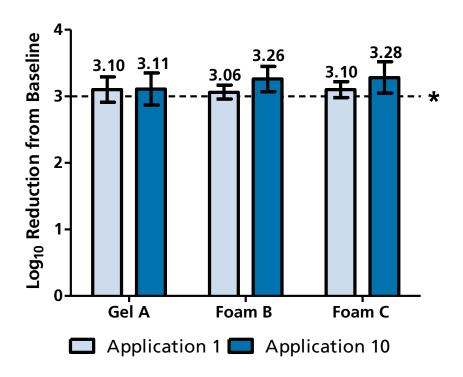
4. Apply Test Product.



5. Sample. Repeat Steps 3-4 9x. Sample after App 10.

RESULTS

Figure 2: E 1174 Results at 1.3 ml



All products met Health Canada efficacy requirements, and were statistically equivalent.

Error Bars Represent 95% Confidence Intervals

* Health Canada Log₁₀ Reduction Requirement

SUMMARY & CONCLUSIONS

- This is the first report of an ABHR meeting Health Canada efficacy requirements with a single actuation from a wall-mounted dispenser.
- ABHR efficacy is strongly influenced by application volume.
 - Most ABHR don't meet Health Canada requirements at 2 ml, and would require multiple dispenser actuations to meet efficacy requirements^{2,3}.
 - There is a practical limit to how much product HCWs will apply.
- It is important to consider both formulation and application volume when assessing ABHR efficacy.
- Further work is warranted to understand dispenser output, HCW practices, and the impact of ABHR use volume on clinical efficacy (i.e. infection rates).

- 2. Edmonds et al. 2012. Comparative Efficacy of Commercially Available Alcohol-Based Hand Rubs and World Health Organization-Recommended Hand Rubs: Formulation matters. *American Journal of Infection Control*. 40:521-525.
- 3. Macinga et al. 2013. Efficacy of Novel Alcohol-Based Hand Rub Products at Typical In-Use Volumes. Infection Control & Hospital Epidemiology. 34:299-301.

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