Investigation of a Surgical Hand Antiseptic Containing 70% Ethanol and a Polyquaternium Polymer Synergist: Antimicrobial Efficacy, Skin Tolerance and End User Acceptance.

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ABSTRACT

Background/Objectives: There has been a recent trend toward the use of alcohol-based products for hand hospital antiseptics due to rapid bactericidal activity, ease of use, and better skin tolerance compared to traditional surfactant-based products. Although alcohol is generally better tolerated than antiseptic hand washes, the presence of secondary antimicrobials such as chlorhexidine gluconate (CHG) or preservatives can cause skin irritation or sensitization. A surgical hand antiseptic based on 70% ethanol formulated with a synergistic level of polyquaternium polymer has been developed. In this study the antimicrobial efficacy, skin performance and end-user acceptability has been evaluated.

Methods: In vivo efficacy studies were carried out using criteria for Effectiveness Testing of Surgical Hand Scrubs as described in the Tentative Final Monograph for Healthcare Antiseptic Drug Products (TFM). Evaluation of skin irritation potential in humans was performed by applying fresh product over a 21 day period. Product acceptability was evaluated by a hospital field trial carried out in 4 Q.R. locations in Northeast Ohio. Eighty-eight (n=88) surgical staff members over a four week period evaluated the prototype product. Comparator products were 91% ethanol, 1% CHG surgical hand antiseptic gel and a 62% ethanol based aerosol foam surgical hand antiseptic.

Results: The 70% ethanol test formulation exhibited enhanced antimicrobial efficacy over 70% ethanol control formulations lacking the polyquaternium synergist. The test product met all immediate microbial kill and persistence requirements dictated by the TFM when 2 applications of 2 ml were applied. When 3 applications of 2 ml were applied, the product met the day 5 requirement (a 3 log reduction) on the first wash of day 1. In vitro time-kill experiments demonstrated that the test formulation exhibited broad spectrum bactericidal activity in a 15 second exposure time. The test product was found to be mild to the skin (average irritancy score = 6.38 on a 6 point scale) by a 21-day cumulative irritancy study, and was statistically superior to 3 commercial alcohol-based surgical hand antiseptics (average irritancy scores were 0.25, 0.18, and 0.56, respectively). The hospital field test revealed statistically superior overall product acceptability (97% vs. 79% for comparator products) and statistically improved aesthetic attributes of mildness, skin dryness, irritation and feel, ease of ploving, and drying time.

Conclusions: A new surgical hand antiseptic based on 70% ethanol has been formulated to meet the antimicrobial and persistence requirements of the TFM without the use of CHG or secondary antimicrobials. The product is mild to the skin and was preferred over current surgical hand antiseptics. Because application volumes are lower than currently marketed surgical hand antiseptics, pre-surgical hand hygiene prep time can be reduced.

INTRODUCTION

Hand hygiene is one of the most important infection control measures in healthcare today. Until recently, the surgical scrub product category has been dominated by soap or surfactant-based products requiring 5-10 minute wash and the use of a scrub brush. These products contain antimicrobial compounds such as povidone iodine, chlorhexidine gluconate (CHG) or paracrichromatexylenol (PMDM). Although the antimicrobial agents provide persistence to the product, they can be irritating or sensitizing. Additionally, brush scrubbing is known to damage the skin and contribute to increased shedding of bacteria from the hands and lower compliance.

In October 2002, the Centers for Disease Control and Prevention issued a Guideline for Hand Hygiene which defines and supports the use of alcohol-based products as an alternative to traditional products. Properly formulated alcohol-based products are excellent substitutes and are desirable due to their high efficacy, dermal compatibility, and ease of use. Unfortunately, development of alcohol-based surgical antiseptic products that meet the requirements of the FDA’s Tentative Final Monograph for Healthcare Antiseptic Drug Products can be quite challenging. Effective systems have been formulated by combining alcohol with other actives such as CHG. This type of “dual-active” system requires a New Drug Application (NDA) to ensure the product’s safety and effectiveness. The NDA process is complicated, time consuming and very costly.

A new surgical hand antiseptic containing 70% ethanol has been developed. The product is formulated with a synergistic amount of polyquaternium polymer and a special blend of emollients, which effectively eliminates irritation and sensitization problems associated with other alcohol-based surgical scrub products. In this study the antimicrobial efficacy, skin performance and end-user acceptability has been evaluated.
Figure 3: Product Usage

Figure 3 shows the in vitro immediate log reductions of PURELL Surgical Scrub. Two usage levels are shown: 3 applications of 2 mls compared to 2 applications of 2 mls. When 3 applications of 2 mls are used, the Day 5 log reduction requirement is achieved on Day 1.

Table 1: In vitro Bactericidal / Fungicidal Efficacy

Table 2: End User Acceptance

Table 2 summarizes the clinical field testing results. End-users have rated those attributes as statistically better than a benchmark alcohol based surgical scrub (Avagard). Values represent the percentage of respondents reporting a high score on a 7 point scale. ‘Values’ represent percentage of respondents reporting “Excellent” or “Good”.

SUMMARY AND CONCLUSIONS

- A new surgical hand antiseptic based on 70% ethanol (PURELL Surgical Scrub) has been demonstrated to be broad spectrum, fast-acting, and to meet FDA requirements for immediate bactericidal activity and persistence.
- The product has been formulated without the addition of CHG or secondary antimicrobials to decrease the risk of dermatitis, skin irritation or sensitization.
- The product was found to be equal to or more mild to the skin when compared to a commercial alcohol-based surgical scrub product.
- In hospital field testing, PURELL Surgical Scrub was preferred over the benchmark surgical hand antiseptic.
- Because the product is effective at a lower application volume than currently marketed surgical hand antiseptics, use of PURELL Surgical Scrub can reduce pre-surgical hand hygiene prep time.
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