Topical Film Forming Polymers Formulated in Non-Women Fabric Substrates as an Approach to Microbial Reduction and Wound Protection

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Introduction

The skin is the body's first line of defense against bacterial infections; however, when the skin becomes compromised through skin disorders, wounds or surgical procedures, the barrier properties are negated, which may result in infection of the skin, the surrounding tissue or the infection may spread systemically. Current approaches to microbial reduction and wound protection address only components of the complete solution to reducing skin infections by delivering antisepsic active ingredients and maintaining a protective barrier to allow for skin and wound healing.

Dermatologic Clinical Challenge

Proper cleansing and topically applied products, although effective in reducing bacterial count have a short period of effectiveness before the product is rubbed off or wounds are exposed to other bacterial sources (particularly in pediatric applications). Wound dressings improve the retention of anti-infection drugs on the skin, but are susceptible to the rigors of daily wear, while topical brush-on bandages are most suitable for small surface wounds. The current solutions address only aspects of the on-going need for an effective, convenient approach for the prolonged maintenance of conditions that promote the safe and rapid healing of compromised or wounded skin.

Targeted Properties:
- Fast Drying on the Skin
- Simple Formulations
- Controlled Dosage of Active Ingredient
- Good Bioadhesion to the Skin Surface
- Mild Chemistries for Compromised Skin
- API Compatible

Technical Solution

The development of a non-woven fabric product that incorporates both an antisепtic component and film forming polymer, provides a vehicle for the reduction of bacterial count on the skin surface or at the wound site while depositing a thin polymeric film that quickly dries to form a cohesive barrier against environmental exposure, rub-off or sweat.

Formulations containing (1) ~5 wt% of Kollicoat® SR 30D, Kollidon® SR, Kollidon® VA 64 or Kollidon® 90F, (2) solvent (3) viscosity enhancer, (4) lipidic fluid and (5) an emulsifier (when indicated) yield smooth, fast drying cohesive films on the skin. These films demonstrate excellent water resistance, but can be washed off with warm water and some rubbing. Microscopy analysis reveals excellent model API (gold pigment) retention on the skin, and formulations have demonstrated stability for 3+ months in accelerated conditions (40°C/75% RH).

Optical Microscopy of neat Vitro-Skin® (left), gold pigment (faux API) containing topical film on Vitro-Skin® (middle) and interface between neat skin and faux API containing topical film (right).

Development Plan

This solution is currently in the concept stage. The present evaluation has been completed on standard dosage forms through the incorporation of film-forming polymers into sprays, gels, and foams. The next milestone would be to increase an understanding of the requirements to incorporate the formulation into the substrate and package accordingly. Evaluation of the reduction in bacterial count, deposition and retention of an antiseptic active ingredient on the skin, and barrier properties of the topically applied film must be evaluated. Furthermore, determining the most effective approach to bring the solution to end-product developers and manufacturers is an initial, critical component of the development plan.

Next Steps:
- Technical evaluation of non-woven fabric manufacture
- Extending formulation analysis
- Communicating functionality

Value of the Solution

The market for skin infection drugs is estimated to reach $7.02bn in 2020 with anticipated continued growth.1 Concentrating solely on pediatric use in the United States, it can be approximated that 15 million households have children between the ages of 3-10, and would likely be targeted consumers.

Current estimates of topical bandage, first-aid tape and gauze annual sales exceed $500M,2 and a topically applied, film forming non-woven fabric wipe would likely capture a significant segment of this business as it offers dual functionality and the flexibility of formulating with a range of active ingredient chemistries.

The convenience of these wipes will ultimately improve user compliance and use in a broad population. The utility of these particular polymeric components is their broad functionality in topical dosage forms and their ability to be used with a range of active ingredient chemistries.

1Visiongain. Dermatological Drugs Market Forecast 2016-2026