**RESULTS**

A series of polymeric systems were explored in sprays, gels and creams for the potential to apply a thin polymeric film to the skin surface. It was determined that the efficacy and properties of the resulting film were highly dependent on other formulation components; and thus, dictated by the dosage form.

Key Properties:
- Fast Drying
- Simple Formulations
- Controlled Dosage
- Good Bioadhesion
- Compatible with Film Formers

These films demonstrate some moisture resistance, but can washed off with warm water and soap. Microscopy reveals excellent API retention on the skin (based on a visible gold pigment), and these gels are stable for up to 3+ months in accelerated conditions (40°C/75% RH). Sprays were found to be the most versatile dosage form to deliver these polymers, with quality films applied using Kollidon® 90F (polyvinylpyrrolidone), Kollidur® SR30D (poly(vinyl acetate) dispersion), Kollidur® SR (PVAc, povidone, SLSilica) and Kollidon® 30 (povidone).

**CONCLUSIONS**

Topical films using polymeric chemistries have demonstrated good bioadhesion and flexibility on the skin, painless removal of the film with a level of moisture resistance, improved retention of a model active pharmaceutical ingredient on the surface of the skin and barrier properties against environment exposures. By combining formulation expertise of topical dosage forms with established pharmaceutical polymers, the feasibility and efficient development of film forming formulations can rapidly be realized through the extension of the presented data.

**METHODS**

**Formulation**

Formulations were prepared as follows: Sprays - ethanol, DI water, and ethyl acetate (for more mild smelling formulations do not use ethyl acetate) were weighed into appropriately sized beaker and blended under a propeller stirring apparatus. Film forming polymer was added and system was stirred until polymer was dissolved. Additional plasticizers or preservatives were added, and formulation charged into a metered dosage spray applicator. Gels - DI water and glycerin were weighed into an appropriately sized beaker and blended using propeller stirrer. In a separate beaker Carbomer and Kollisolv® PG were stirred by hand to make a Carbomer slurry. The Carbomer/PG blend was added to water/glycerin blend under constant stirring, and ethanol slowly added. Once the Carbomer was fully dispersed, the system was neutralized using trisopropanolamine (TPA). Kollidon® 90F was slowly added and stirred until polymer was dissolved. Any additional plasticizers or preservatives were added and system reneutralized to pH=7 if necessary using TPA. Foams were prepared by formulating an o/w emulsion (oil and water phase at 80%) homogenized at 3000 rpm, polymer was added while cooling, and charged into an aerosol container with appropriate dosing of propellant.

**Evaluation**

Dry time was measured by applying a glass slide on the skin and evaluating residue upon removal. Film coverage and API retention was visualized by using a HiScope (in-vivo measurements) or transmission microscope (Nikon Labophot). Moisture resistance and washability were analyzed by applying light moisture to dried film and observing, and evaluating the film after washing gently with soap and water. In-vitro drug release was studied using a Franz Diffusion Cell apparatus, Strat-M® membrane (n=6); PBS pH=7.4, 32°C.

**RESULTS**

Additional considerations, including the interaction of the polymer with other formulation components have been considered and evaluated, and successfully incorporated into more complex systems, such as cream and foams. The presented data on the use of film forming polymers supports their use in topical dosage forms for a range of targeted chemistries and applications.

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**PURPOSE**

The advantages of topical drug delivery are resulting in a growing emphasis on pharmaceutical development of technologies and active ingredients that may be delivered through the skin. The advantages are quite broad, but can be summarized in three primary areas (1) the ability to deliver a range of active ingredient chemistries with sometimes complex formulations (2) ease of application, and the ability to administer a prescribed or OTC treatment at home, and (3) the ability to deliver localized treatment or avoid first pass metabolism for systemically delivered active ingredients. One opportunity in topical development is to extend the delivery of active ingredients and prolong the maintenance of skin conditions that promotes safe drug delivery through film forming technology. Of key importance, is the understanding of the interaction and synergies of film forming polymers with formulation components, the skin, and active ingredient(s).