

Evaluating Oral Drugs For Topical Application

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Dermatology provides an unmet need for drug development. There are two reasons to develop drugs for topical use. The first is to treat skin diseases and disorders such as psoriasis, acne, actinic keratosis, cancer, eczema, etc. These conditions represent some of the most common and chronic disease states in man. The second reason is to deliver systemically active drugs through the skin to enhance drug activity by, 1. avoiding first pass metabolism, 2. reducing toxicity and 3. improving compliance. There are many drugs that have failed in development as oral formulations for which there are extensive pharmacology, pharmacokinetics, toxicology, and even clinical data which could support topical use. Companies could reassess the use of "old" drugs for topical application and open up new therapeutic approaches. In order to reassess a company's portfolio, a company needs to search their libraries to identify potential topical therapeutics. Once this is done, an assessment can be made of the usefulness of already accumulated toxicology and/or clinical data. Pharmacokinetic approaches should be considered in order to accelerate the drug approval process. Most important to this process, is the utilization the FDA as a partner to assess the steps needed to satisfy regulatory requirements to establish the drug's safety and efficacy. This poster will outline and illustrate the important and necessary steps to evaluate topical use of drugs developed for oral use.