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Investigations into the impact of oleic acid purity on human skin penetration by terbinafine hydrochloride using MALDI-MS imaging

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MALDI-MS imaging has been successfully applied to demonstrate its utility for developing claims substantiation data on targeted drug delivery studies via topical applications. Data from trans-epithelial permeation (TEP) assays and microscopy demonstrated that super-refined oleic acid caused significantly less damage and disruption to human skin, compared to its standard grade counterpart, which was attributed to its significantly less potentially harmful impurities (e.g., aldehydes). The aim of this study was to see whether the reduction in degree of disruption to the skin structure impacted upon the permeation of an antifungal agent (terbinafine hydrochloride) using MALDI-MSI. Good quality 'heat map' images showing the degree of penetration of API into human skin (previously treated with solutions in two grades of excipient) were generated by MALDI MSI. This active could be detected with both excipients, even at low concentrations. Moreover, no significant difference was observed in the degree of penetration between the two grades of oleic acid. This data further supports the use of super-refined oleic acid in topical applications, in demonstrating the benefits of minimizing skin irritation without negatively impacting its permeation properties. Furthermore, additional studies in which penetration/permeation studies are combined with this imaging technique and histological measurements on potential changes to skin surface structure would also provide further insights into how different excipient/active combinations achieve effective penetration and permeation.

Biography

Stephen Rumbelow is the Research and Technology Manager at Croda Inc., managing research programs in Health Care and Analytical Chemistry. He developed his expertise, through providing claims substantiation data supporting the development of high performance excipients for the pharmaceutical industry. In this role, he is responsible for developing an integrated R&D program provide timely data, technical support, and industry presence advancing Croda's reputation within the pharmaceutical industry. The integration of both teams facilitates the selection, development and application of new methods and measurement techniques critical to value creation and retention.

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