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Human skin as an *in vitro* surrogate model for bioequivalence comparison of topicals

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Bioequivalence comparisons for transdermal patches can be done by pharmacokinetic data and considerations relating to skin adhesion and irritation. In contrast, systemic plasma levels are generally less important for topical dermatological products, except from a toxicological perspective. For dermatologicals, determination of drug levels in the skin (dermatokinetics) is desired, which is more difficult due to the invasive nature of such measurements. At this time, bioequivalence comparisons for topicals require clinical testing, which is both expensive and time consuming. Therefore, *in vitro* drug absorption into and across excised human skin mounted on diffusion cells can act as a powerful and sensitive tool. Although this method is not recognized by the FDA to get a waiver on clinical testing, such studies can guide the internal decision making for a company. The method can also provide guidance during formulation development and can provide a QbD approach for development of RLD and generics.

In vitro studies with human skin are simple but involve several scientific considerations. Decisions need to be made on what type of data should be generated, e.g., receptor sampling or skin assay at different time points by terminating the experiment at those pre-determined time points. For skin assay, drug levels can be determined in stratum corneum, epidermis or dermis. Q1/Q2/Q3 differences and site of action in the skin will also be important considerations. Other considerations involve choice of skin type (dermatomed or epidermis), spreadability of formulation vs. OECD guidelines, occlusion, and sink conditions in receptor.

Biography

Ajay K. Banga is Professor and Department Chair in the Department of Pharmaceutical Sciences at the College of Pharmacy and Health Sciences, Mercer University, Atlanta, GA. He also holds an Endowed Chair in transdermal delivery systems. He has a Ph.D. in pharmaceutics from Rutgers University, NJ. He has over 250 publications and scientific abstracts to his credit. He currently serves on the Editorial Board of 10 journals, as Associate Editor for one journal, and has served as the Editor-in-Chief for a drug delivery journal. He has written three single author books and over 10 book chapters in the areas of transdermal delivery and protein formulation/delivery. He is a Fellow of the American Association of Pharmaceutical Scientists.

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