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Assessing the bioavailability and bioequivalence of topical dermatologic drug products with multiple surrogate tests

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Progress in the development of surrogate methods to evaluate the bioavailability and bioequivalence of drugs applied to the skin has resulted in the generation of a sufficient body of data to justify their use as alternatives to clinical trials for the approval of generic topical drug products. They can also be used during the formulation development phase of both new and generic topicals to assess the relative bioavailability of various test formulations. A number of these (excised skin permeation assay, stratum corneum tape-stripping, microdialysis, transepidermal water loss) have been shown to successfully duplicate the results of clinical trials and demonstrate the bioequivalence of generic products approved by the FDA with an AB rating. Though each of these surrogate tests may not have been sufficiently validated to the satisfaction of regulatory authorities, and each can be criticized as potentially having significant shortcomings, they do not all have the same potential limitation and the results of one can effectively complement the results of another. Selected pairings of these surrogate methods, depending on the therapeutic product class in question, in conjunction with a membrane rate of release assay and irritation/sensitization testing, can offer a scientifically justified, efficient pathway to the approval of generic topical drug products.

Biography

Thomas J Franz received an MS in Biochemistry and an MD from the University of Oregon Medical School and completed a residency in Dermatology at the University of Washington School of Medicine. He has worked in the fields of cutaneous pharmacology and toxicology for over 40 years, both within academia and the pharmaceutical industry, as well as at the Food and Drug Administration. His special focus is in percutaneous absorption as it relates to issues of BA/BE and he is the developer of the Franz Cell. He has published more than 70 papers in peer reviewed journals and books.

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