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Strategies for the bioequivalence assessment of topical drug products intended for local action

The assessment of Bioavailability/Bioequivalence (BA/BE) of topical products not intended to be absorbed into the systemic circulation presents a formidable challenge since the usual approach to assess BE by measuring drug concentration in blood/plasma/serum is deemed inappropriate. Although, various methods have been attempted as a surrogate to establish BA/BE of topical products for local action, to-date, only one such method, specifically for the assessment of the BE of topical corticosteroids, the Vasoconstrictor Assay (VCA) also known as the Human Skin Blanching Assay (HBSA), has been accepted by the FDA and by most other regulatory agencies. This presentation describes the VCA and its features and describes novel approaches to optimize dermatopharmacokinetic measurements using a tape stripping method for BE assessment by determining appropriate dose durations using the E_{max} model and standardization of skin thickness. An improved tape stripping method is described where BE data from test and reference (RLD) acyclovir creams and *in vitro* release results were used to establish *in vitro-in vivo* correlations (IVIVC). The application of Dermal Microdialysis (DMD) is also described and data showing its application for the BE assessment of an NSAID (ketoprofen gel) as well as its use to measure the diffusion and flux of a corticosteroid through the skin is discussed.

Biography

Isadore Kanfer completed his PhD at Rhodes University, South Africa and was a Visiting Professor at the University of California, San Francisco (1980) and the University of North Carolina, Chapel Hill, USA (1990). He is Emeritus Dean and Professor (Rhodes University) and Honorary Life Member of the South African Academy of Pharmaceutical Sciences and Fellow of the American Association of Pharmaceutical Sciences and of the Canadian Society for Pharmaceutical Sciences. He has supervised 41 Post-graduate students (MSc & PhD) and Post-doctoral fellows and contributed over 200 research publications and conference presentations and is Co-editor of 4 books in the series, Generic Drug Product Development.

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