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Dermal Open Flow Microperfusion (dOFM) for the bioequivalence assessment of topical products based on skin PK

The availability of generic topical dermatological drug products may be constrained by the limited methods currently accepted for the assessment of topical Bioequivalence (BE). Therefore, the development of pharmacokinetics-based BE approaches has been proposed. Dermal Open Flow Microperfusion (dOFM) is one such *in vivo* methodology to continuously assess the cutaneous kinetics of topically administered drugs (as well as endogenous analytes) directly in the dermis. We evaluated whether dOFM performed with healthy human subjects could appropriately characterize the kinetics (rate and extent) of intradermal Bioavailability (BA) of *acyclovir* from identical vs. different 5% *acyclovir* creams. A single-center clinical study (EudraCT No. 2013-005062-19) was performed with 20 healthy subjects in a pivotal study (7 women, 13 men, 28±5 years). A marketed 5% *acyclovir* cream was used as a reference product (R), and a different marketed 5% *acyclovir* cream with different composition and inequivalent *in vitro* release characteristics was used as a test product (T). Three (3) small product application sites on each thigh were treated with either the R product in duplicate (R₁, R₂) or the T product to compare the *in vivo* BA of the R product with itself (R₁ vs. R₂) and to compare the *in vivo* BA of the T vs. R products. This was performed twice on each subject, once on each thigh (dosed as R₂-R₁-T and T-R₁-R₂). Two (2) certified dOFM probes per product application site profiled intradermal *acyclovir* kinetics for 36 h. *Acyclovir* in the perfusate was quantified by UHPLC-MS/MS. The equivalence (R₂ versus R₁) and inequivalence (T versus R₁) of *acyclovir* BA was evaluated statistically based on log (AUC_{0-36 h}) and C_{MAX}. The BA of *acyclovir* from R₂ vs. R₁ was found to be equivalent. The BA of *acyclovir* from T vs. R₁ was found to be non-equivalent.

Biography

Frank Sinner has completed his PhD in 2002 at University of Innsbruck, Austria. He is the Director of Joanneum Research HEALTH, an Institute for Biomedicine and Health Sciences. He has published more than 25 papers in reputed journals and has been serving as an Editorial Board Member of repute.

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