Do you want to pioneer a new way for topical generic drug approval?

Current situation:
FDA approval for most topical generic drugs requires a clinical endpoint study to compare the therapeutic effect.

Our offer:
We are testing bioequivalence based on pharmacokinetics directly in the dermis using dermal open flow microperfusion (dOFM).

Your benefits
- One PK study instead of an expensive clinical endpoint study
- Less participants (<50 healthy subjects) instead of hundreds of patients
- Single center instead of multi center trial
- Reduce risk of failure due to placebo effects known in clinical endpoint studies
**Bioequivalence testing and clinical endpoint studies**

**Our approach – dermal Open Flow Microperfusion for dermal PK bioequivalence studies**

- Dermal Open Flow Microperfusion – dOFM – delivers time-resolved drug-concentration profiles by direct sampling in the dermis.
- PK profiles of generic and originator product (RLD) are compared in healthy subjects.
- Together with our clients, we design the best testing strategy for any dermal drug.

**Case study acyclovir: FDA funded research grant**

In a clinical study (n=20 healthy subjects) bioequivalence (BE) of two different acyclovir products was evaluated by using the average BE approach:\[6]\:

Product 1: Zovirax cream, 5 %,
applied on two adjacent sites (A and B)
Product 2: Acyclovir 1A Pharma cream, 5%,
was selected as a known non BE product (C)

**Results:**
- Zovirax cream is BE to itself
- Acyclovir 1A Pharma cream is not BE to Zovirax cream

\[6\] Mean dermal acyclovir concentration profiles for Product 1 (A, B) and Product 2 (C).
Our services with our partners

- One contact for all services
- Protocol and CRF development
- Submission to regular authorities and ethics committee
- Regulatory affairs management
- Site management
- Monitoring
- Safety lab
- GLP compliant bioanalytics
- Clinical data management
- Clinical statistics from sample size calculation, randomization to SAP development, programming and analysis
- Pharmacovigilance
- Medical writing: protocols, ICFs, clinical study reports

Our quality standards

- FDA 21 CFR part 11 compliant data management
- SDTM, CDISC, ADaM standard for data sets
- Full audit trail
- Fully validated software packages (sas®, OpenClinica)
- GLP certified bioanalytical lab
- GCP compliant study conduct

Publications


One single contact for all services:

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