JOANNEUM RESEARCH HEALTH

Pharmacokinetics of dermal drug products

using dermal open flow microperfusion (dOFM) and sensors in Phenion® reconstructed skin models

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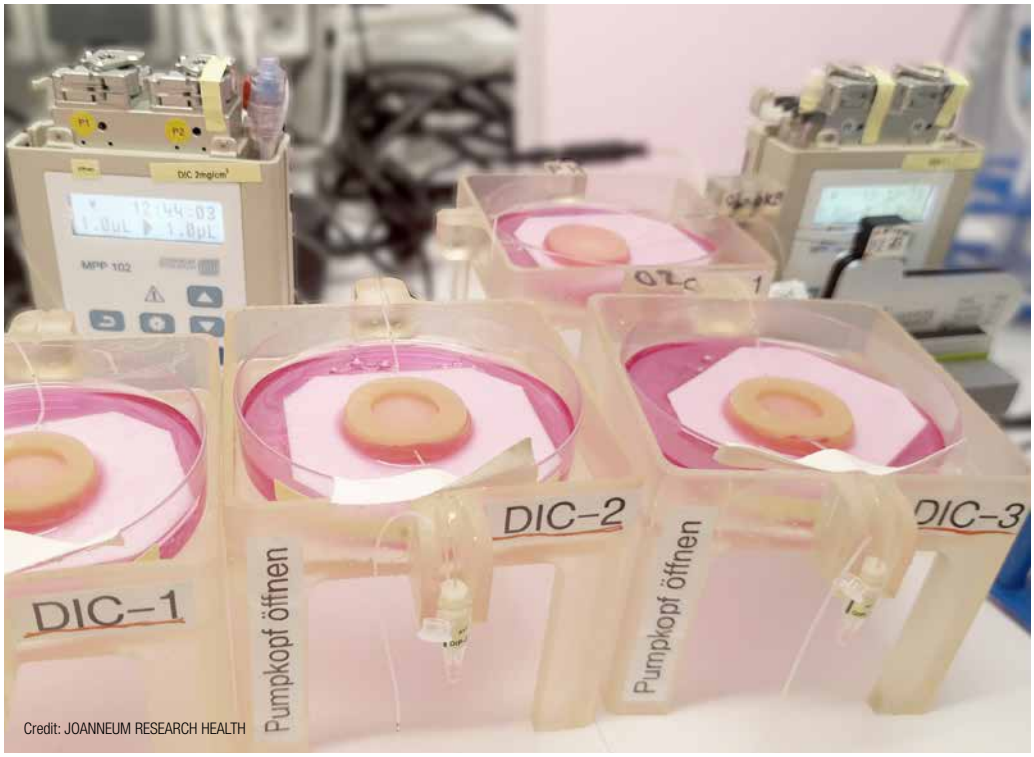

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Background and Aims

The institute HEALTH at Joanneum Research supports drug development from candidate screening, ex-vivo studies in explanted skin, preclinical trials to clinical studies.

The aim of the present work was to create an alternative to human and ex vivo studies by combining the Phenion® FT LARGE Skin Model with the CE-certified dOFM technology. This cost-effective combination delivers reliable pharmacokinetic (PK) profiles directly from dermal tissue.

Methods

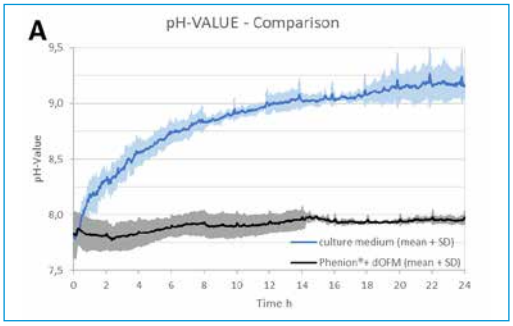
dOFM probes (https://www.openflowmicroperfusion.com) were implanted in Phenion® FT LARGE Skin Model. The drugs aciclovir, lidocaine and prilocaine were topically applied as cream and data were compared to results from skin explant studies and clinical studies. Sensors from Pyroscience and Jobst were integrated to deliver reliable data on tissue condition (pH, oxygen), metabolism (glucose, lactate) at flow rates of just 1 µl/min.

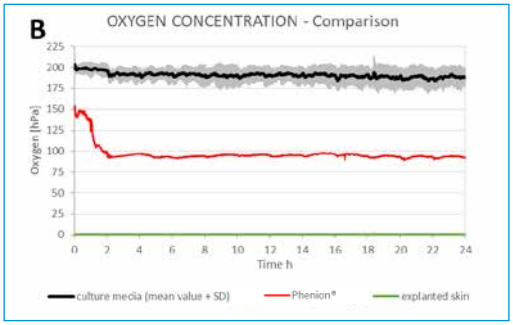
Conclusion/ Results

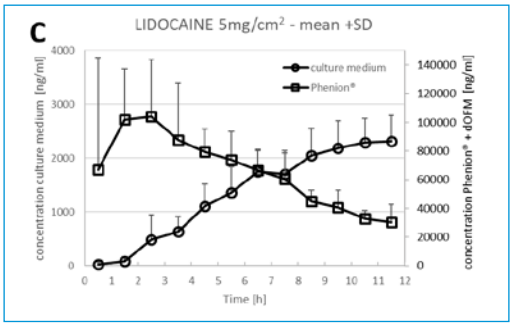
- The Phenion® FT LARGE Skin Models along with dOFM probes and sensors can be an in vitro alternative for PK determination in skin explants and clinical studies to support your drug development.
- The sensor system supports optimal operation of the Phenion® FT LARGE Skin Model.
- All data confirmed that topically applied active substances/ ingredients penetrate the skin models in a time- dependant pattern as expected for human skin.

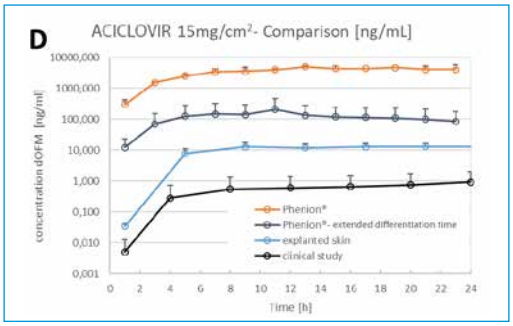
In detail:

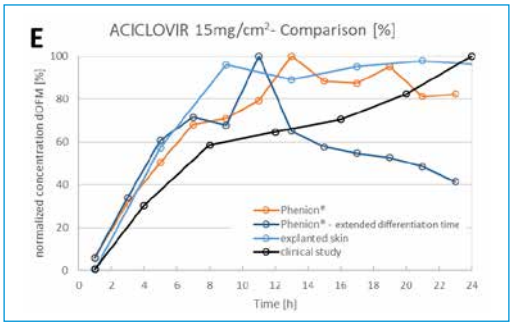
- Sensors confirmed a nearly constant pH value in the Phenion® FT LARGE Skin Model while the pH value increased in the culture medium (Figure A) when cultured at ambient air.
- Oxygen concentrations in the Phenion® FT LARGE Skin Model were lower than oxygen concentrations in the culture medium while there was no oxygen in the explanted skin (Figure B).
- The combination of dOFM sampling and the Phenion® FT LARGE Skin Model showed a penetration profile with decreasing lidocaine concentrations correlating to increasing levels in the culture medium over time (Figure C).
- Aciclovir concentration found during clinical studies, in explanted skin and Phenion® FT LARGE Skin Models differed significantly from each other due to tissue specific barrier properties (Figure D).
- For aciclovir the curve shape of the product concentration found with dOFM and the Phenion® FT LARGE Skin Model was very similar to curves found in clinical studies and explanted skin (Figure E).











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