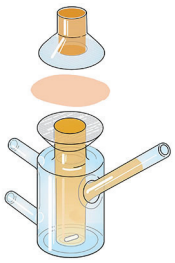
In-vitro performance testing for topically applied formulations

with a focus on the adopted „Guideline on quality and equivalence of locally applied, locally acting cutaneous products“ becoming effective April 2025



04 February 2024
Online Seminar

Course no. 7045

ONLINE SEMINAR

Research an Development

Zielgruppe

The course is designed for all scientists involved in In-Vitro Permeation testing and In-Vitro Release Testing of topically applied formulations.

APV
MAKING SCIENCE WORK

Research and Development

A seminar organised by the focus group for liquid and semi-solid dosage forms

Objectives

In order to be effective, topically applied drugs need to overcome at least the outermost layer of the skin. The skin is a complex and efficient barrier with various factors that can influence penetration. Paradigms of dermal bioavailability are different and at least partially less straightforward than in peroral drug delivery. And, there is not the single in vitro model that fits all purposes. Nevertheless, in vitro performance testing of topicals can be performed in a systematic manner. It is an important aspect of early projects for compound and formulation selection and overall program de-risking, and can support toxicological characterization. Most importantly, it is used to establish bioequivalence in generic development programs and post-approval changes. For this purpose, the respective regulatory guidelines must be taken into account.

This online course provides a comprehensive overview of in vitro performance testing by academic and industry experts. It begins with an introduction to skin anatomy, principles of dermal pharmacokinetics, and a general overview of release and penetration models. In vitro release testing (IVRT), an important model for demonstrating quality and equivalence of semi-solids, is introduced, as is in vitro permeation testing (IVPT), which is used for equivalence testing as well as exploratory development and toxicology. Finally, some important information on differences between draft guideline and final guideline will be discussed.

Moderators

Dr. Adina Eichner, IADP e. V. at Martin Luther University Halle-Wittenberg e. V.

During her pharmacy studies in Halle/Saale, Dr. Adina Eichner discovered her curiosity for scientific work. She received her doctorate grade under the supervision of Prof. Dr. Reinhard Neubert. Her thesis dealt with the structural investigation of stratum corneum lipid model membranes by neutron diffraction. Since 2022, she has been a lecturer at Martin Luther University Halle-Wittenberg. Currently, her focus is in the field of IVPT and regulatory affairs, which she carries out in the context of her activities for IADP e.V. (Institute for Applied Dermatopharmacy at Martin Luther University Halle-Wittenberg e. V., Germany).

Dr. Michael Herbig RaDes GmbH

Michael Herbig is co-founder and CEO of RaDes GmbH, Hamburg, Germany, a service provider for development & analytics of liquid and semi-solid formulations. He is a pharmacist and holds a PhD in drug delivery & formulation from ETH Zurich, Switzerland, and an MBA from OUBS, UK. Previously, he was Head of Pharmaceutical Development at Almirall Hermal, and held positions of increasing responsibility in preformulation and pharmaceutical development at Novartis, Basel. One focus of his work is the „rational design" of semi-solid and liquid formulations for topical use.

Sascha Gorissen RaDes GmbH

Sascha Gorissen is co-founder and head of laboratory of RaDes GmbH, Hamburg, Germany. He is a biotechnology engineer with extensive experience in preclinical development, pharmaceutical analytics and project management. In addition to his role as head of laboratory and project management, he is responsible for the in vitro models of release and skin penetration/permeation. Previously, he was group leader of "Analytics and Quality Control Pharmaceutical Development" at Almirall Hermal and research scientist in preclinical development at Schwarz Pharma AG.

Prof. Dr. Dominique Lunter Eberhard Karls Universität Tübingen

Dominique Lunter was appointed full professor of pharmaceutical technology and biopharmacy at the University of Tuebingen (Germany) in 2020. Her research interests are: sustained release dermal preparations, confocal Raman microspectroscopic investigation of the skin and skin penetration as well as 3D printing. She held a guest professorship at the Paracelsus private medical University of Salzburg (Austria) in 2019. In same year she received the Venia Legendi from the University of Tuebingen, where she did her PhD in pharmaceutical technology in 2012.

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Programme

Tuesday, 04 February 2025, 13:00 - 17:00 Uhr

Welcome address & introduction of the speakers
Dr. Adina Eichner, IADP e. V. – Institute for Applied Dermatopharmacy at Martin Luther University Halle-Wittenberg e. V., Germany
Sascha Gorissen, RaDes GmbH, Germany
Dr. Michael Herbig, RaDes GmbH, Germany
Prof. Dr. Dominique J. Lunter, University of Tübingen, Germany

Introduction to IVRT/IVPT with a focus on the adopted guideline
- anatomy of the skin
- regulatory background EMA draft guideline bioequivalence versus FDA SUPAC-SS guideline
- model overview:
  - in vitro release testing
  - in vitro penetration and permeation testing
- description of dermal pharmacokinetics

Prof. Dr. Dominique J. Lunter, University of Tübingen, Germany

Introduction to in vitro release testing (IVRT) based on the adopted guideline
- General introduction
- IVRT Setup
- IVRT method validation (considering EMA & FDA guidelines)
- Data evaluation and acceptance criteria (EMA & FDA) with examples

Sascha Gorissen, RaDes GmbH, Germany

In vitro permeation testing (IVPT) based on the adopted guideline
- relevant guideline fundamentals
- Penetration
- Permeation
- Franz cells
- Tape stripping
- Bioequivalence testing

Dr. Adina Eichner, IADP e. V. – Institute for Applied Dermatopharmacy at Martin Luther University Halle-Wittenberg e. V., Germany

Diffrences between draft guideline and final guideline
Sascha Gorissen, RaDes GmbH, Germany

Panel discussion with all speakers and conclusion

Programme subject to changes.

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7045

Date
04 February 2025, 13:00 - 17:00 h CET

Registration fee

Industry	400,00	EUR
Authority/University	200,00	EUR
Students*	50,00	EUR

(free of VAT according to § 4,22 UStG)

* Limited places for full time students available; written evidence must be submitted. .

Registration
If you have decided to attend the APV seminar, you can easily register online. We will process your registration immediately and will be happy to advise you on any questions you may have.

You will receive an invoice/registration confirmation by email after successfully registering online.

Seminarregistration:
apv-mainz.de/en/events/seminars/details/seminar/7045

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International Association for Pharmaceutical Technology

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