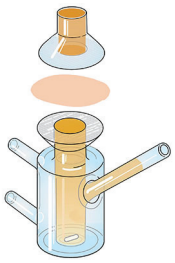
In vitro performance testing of topically applied and topically acting substances

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

The EMA Guideline on quality and equivalence of locally applied, locally acting cutaneous products will come into force on April 2, 2025. It provides specific guidance on a) the quality requirements for new marketing authorizations of cutaneous products and b) the equivalence testing of cutaneous products in lieu of therapeutic equivalence studies with clinical endpoints.

Such equivalence studies are typically performed for generic development projects as well as for scale-up and post-approval changes to avoid the need to conduct a clinical trial. The final guideline provides detailed guidance on in vitro release testing (IVRT) and in vitro human skin permeation testing (IVPT) that will be considered state of the art for submissions to the EMA or national authorities of Member States. In addition to in vitro methods, also in vivo penetration testing (tape stripping) as an additional option of performance testing will be presented.

In this online seminar, the anatomy of the skin and the principles of release,permeation and penetration will be explained. Based on this, the experimental design, development, validation and evaluation of IVRT, IVPT and tape stripping studies will be explained in detail, including differences to the previous EMA „Draft guideline on quality and equivalence of topical products“ from 2018.

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 pre-formulation 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 guideline bioequivalence versus FDA SUPAC-SS guideline
- model overview:
  - in vitro release testing
  - in vitro 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 EMA guideline
- General introduction and IVRT Method development
- IVRT method validation (according to new the final EMA guideline)
- Data evaluation and acceptance criteria (according to new the final EMA guideline) with examples
- Difference between new and previous EMA draft guideline as well as FDA requirements

Sascha Gorissen, RaDes GmbH, Germany

In vitro permeation testing (IVPT) based on the EMA guideline
- Relevant guideline fundamentals
- Penetration
- Permeation
- Franz cells
- Bioequivalence testing
- Differences between new and previous EMA draft guideline

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

In vivo tape stripping based on the EMA guideline
- General introduction and relevant guideline fundamentals
- Bioequivalence testing
- Differences between new and previous EMA draft guideline

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

Panel discussion with all speakers and conclusion

Programme subject to changes.

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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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