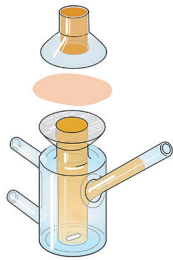
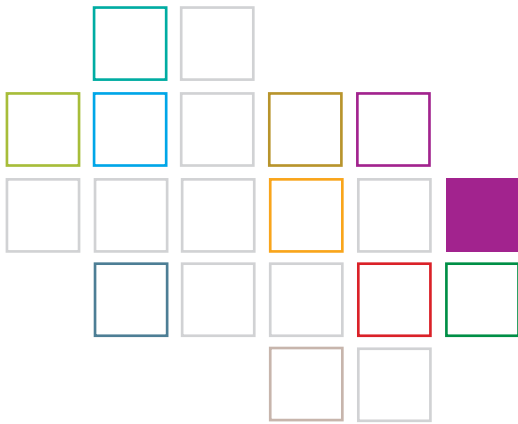


In-vitro performance testing for topically applied formulations



08 December 2023
Frankfurt am Main, Germany

Course no. 6964



Research and Development

Target group

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



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 course/workshop 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. Raman microscopy as a novel tool to study skin penetration will be presented as well as the Hamburg model of skin penetration as a tool to study cutaneous biodistribution. Finally, some important aspects of analytical method development for in vitro studies will be discussed. The workshop will conclude with a panel discussion.

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.

Programme

Friday, 08 December 2023, 08:30 - 16:30 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

- 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)

- 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)

- 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

Raman spectroscopy to monitor skin permeation

- Principles of Raman spectroscopy
- Raman spectroscopy in skin penetration analysis
- Comparison to conventional IVPT methods

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

Determination of cutaneous biodistribution of actives in formulations development

- The „Hamburg model of skin penetration“
- Obtaining biodistribution profiles and information on metabolism in viable skin
- Correlation human vs. porcine skin
- Case studies on formulation design and optimization

Dr. Michael Herbig, RaDes GmbH, Germany

Challenges of analytical methods for IVRT / IVPT

- General differences in the analysis of IVRT and IVPT samples
 - Concentration range; type of equipment
 - Matrix effects
 - Extraction procedure & sample preparation
- Guidelines for analytical methods

Sascha Gorissen, RaDes GmbH, Germany

Panel discussion with all speakers and conclusion

- Pros and cons of different bioequivalence methods
- Innovative formulations – how to use IVPT approaches

Programme subject to changes.

Registration by fax +49 6131 97 69 69 or by email apv@apv-mainz.de



Location

Holiday Inn Alte Oper Frankfurt
Mainzer Landstraße 27
60329 Frankfurt am Main
Phone: +49 69 255156500
Mail: hifrankfurt@ihg.com
Web: www.ihg.com/holidayinn

Registration fee

Industry 990 EUR
Authority/University 495 EUR
Students 200 EUR
(free of VAT according to § 4,22 UStG)

Coffee breaks, luncheon and
electronic proceedings included

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

Registration

APV-Geschäftsstelle
Kurfürstenstraße 59
55118 Mainz/Germany
Phone: +49 6131 97 69 0
Fax: +49 6131 97 69 69
Mail: apv@apv-mainz.de
Web: www.apv-mainz.de

You will receive a confirmation of
your registration with the invoice.

I herewith repealable authorise the
organizers to use my e-mail address
to send me relevant material including
current programme information. My
acceptance can be cancelled at any
time in writing.

Hotelreservation

Holiday Inn Alte Oper Frankfurt
Mainzer Landstraße 27
60329 Frankfurt am Main
Phone: +49 69 255156500
Mail: hifrankfurt@ihg.com
Web: www.ihg.com/holidayinn

Single room incl. breakfast from
129 €/night. Participants should make
their own hotel reservation using the
„promotional code“: **APV - Pharma-
zeutische Verfahrenstechnik**.
Room rates valid until 09 November
2023

Date

Course No. 6964
from 08 December 2023 08:30 h
to 08 December 2023 16:30 h

IVPT for topically applied formulations , 08 December 2023, Frankfurt am Main, Course no. 6964

Registration

As soon as you have found a seminar of your interest,
it is very easy to register for it via fax, e-mail or online.
We will process your registration promptly and
certainly are available for any questions that may arise.

Registration confirmation

After your registration was successfully processed, you
will receive a confirmation.

Before the event

A few days before the event starts, you will receive
important information about the seminar, such as
time, date, addresses etc.

After the event

You will receive a certificate confirming your
participation. Furthermore, we would like to ask you
to fill-in our evaluation sheet to make sure we get
better every time.

Follow-up

After the event, we are open to receive any suggestions
and critique that might arise during the seminar and
will certainly help you with further questions you may
have.

Declaration of consent in respect of data protection

- By registering for this seminar, I agree that
the APV uses my data for the purpose
of processing the order and provides
me with all relevant information.
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Your data will not be shared with third
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APV-Geschäftsstelle
Kurfürstenstraße 59
55118 Mainz/Germany

Phone: +49 6131 97 69 0
Fax: +49 6131 97 69 69
Mail: apv@apv-mainz.de