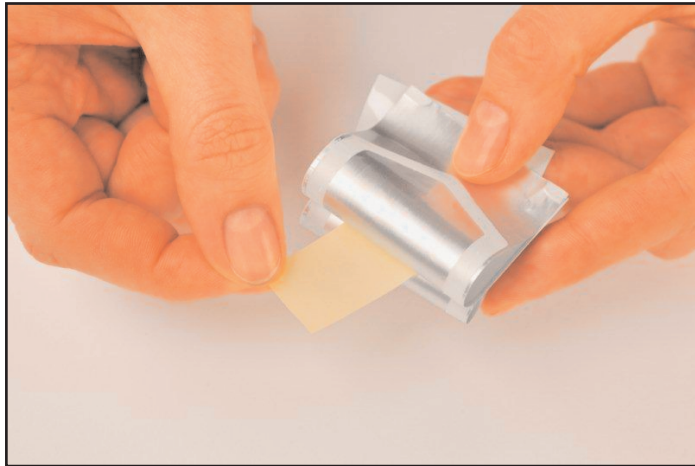


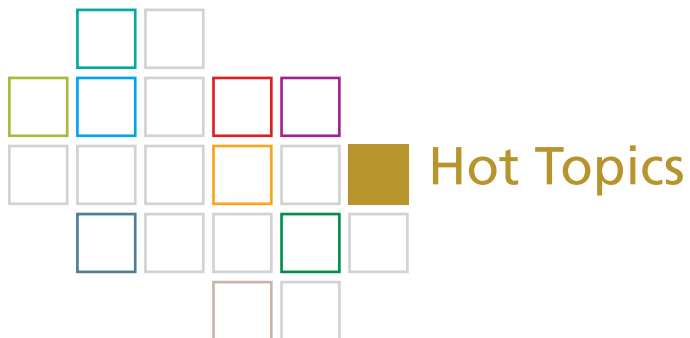
ODx and MBx - Orodispersible and Mucoadhesive Buccal Formulations

New products, novel technologies and tailored specifications



29 to 30 January 2015
Innsbruck, Austria

Course no. 6580



Target Group

- Pharmacists and other scientists
- Engineers and technicians working on ODx and MBx
- Everyone working in:
 - Pharmaceutical Development
 - Manufacturing
 - Regulatory Affairs
 - Quality Control
 - Business Development



Arbeitsgemeinschaft für Pharmazeutische Verfahrenstechnik e.V.
Gemeinnütziger wissenschaftlicher Verein
International Association for Pharmaceutical Technology



Dear colleagues,

various orodispersible drug formulations (ODx) and muco-adhesive buccal drug formulations (MBx) have been recently introduced into the pharmaceutical market. These innovative medicinal products are either based on orodispersible tablets (ODTs), films (ODFs), lyophilisates (ODLs) or granules (ODGs), or on mucoadhesive buccal tablets (MBTs) or films (MBFs). New dosage forms like orodispersible mini-tablets (ODMTs) already appear on the horizon.

The new dosage forms are intended to release the active pharmaceutical ingredient(s) for local action, e.g. corticosteroids or local anesthetics, or systemic availability by absorption through the oral mucosa, e.g. antiemetics or and pain killers. Still, there is confusing wording in scientific literature, pharmacopoeial monographs and the labels of the existing products.

This seminar will reflect on the recent developments and innovations in formulation development, manufacturing and quality control, biopharmaceutical methods for characterization and regulatory issues.

We are looking forward to meeting you in Innsbruck, which calls itself the "capitol of the Alps".



Dr. Kathrin Bartscher
NextPharma Waltrop



Prof. Dr. Jörg Breitzkreutz
Heinrich-Heine-University



Dr. Michael Horstmann
transdermalpharma UG

Programme

Thursday, 29 January 2015, 09:00 to 18:15 h

Welcome and Introduction

Dr. Kathrin Bartscher
NextPharma Waltrop, Waltrop, Germany
Prof. Dr. Jörg Breitzkreutz
Heinrich-Heine-University, Düsseldorf, Germany
Dr. Michael Horstmann
transdermalpharma UG, Neuwied, Germany

Part 1: Definitions and Overview of Orodispersible dosage forms (ODx)

Orodispersible tablets (ODTs), minitables (ODMTs) and granules (ODGs) – History and current products

Dr. Joachim Herrmann
Dr. Willmar Schwabe GmbH & Co. KG, Karlsruhe, Germany

Oral lyophilisates (melting tablets) – History and current products

Leon Grother
Catalent Pharma Solutions, Swindon, United Kingdom

Orodispersible films (ODFs) – History and current products

Dr. Armin Breitenbach
tesa Labtec GmbH, Langenfeld, Germany

Part 2: Definitions and Overview of Mucoadhesive Buccal Formulations (MBx)

Mucoadhesion and mucoadhesive buccal preparations

Prof. Andreas Bernkop-Schnürch
University of Innsbruck, Innsbruck, Austria

Mucoadhesive buccal films (MBFs)

Mark Schobel
Monosol Rx, Portage, IN, United States

Part 3: Processing Technologies and Materials

Formulation development and manufacturing of ODTs

Dr. Dieter Lubda
Merck Millipore, Darmstadt, Germany

Formulation development and manufacturing of ODFs and MBFs

Dr. Andreas Krekeler
Hexal AG, Holzkirchen, Germany

ODx and MBx - Orodispersible and Mucoadhesive Buccal Formulations

API printing technologies

Dr. Carole Planchette
RCPE GmbH, Graz, Austria

Packaging of ODFs and MBFs

Johannes Jansen
Optima life science GmbH, Schwäbisch Hall, Germany

Discussion

Networking dinner

Friday, 30 January 2015, 09:00 - 13:30 h

Part 4: Biopharmaceutical and Clinical Evaluation of ODx and MBx

Drug permeation through oral mucosa

Prof. Dr. Eva Roblegg
Karl-Franzens-University, Graz, Austria

Requirements for bioequivalence assessment in case of ODx and conditions for biowaiver applications

Prof. Dr. Henning Blume
SocraTec R&D GmbH, Oberursel, Germany

Part 5: Quality Control and Regulatory Affairs

Pharmacopoeial specifications of ODFs, MBFs and ODTs

(follow-up of APV seminar in Dortmund 2013)

Prof. Dr. Jörg Breitzkreutz
Heinrich-Heine-University, Düsseldorf, Germany

Analytical testing of ODx and MBx

Dr. Maren Preis
Sapiotec GmbH, Würzburg, Germany

Regulatory perspectives on ODx and MBx

Speaker from authority to be confirmed

Discussion, summary and closing

Dr. Kathrin Bartscher
Prof. Dr. Jörg Breitzkreutz
Dr. Michael Horstmann

Programme is subject to change

Table-top presentations

There is limited space available for table-top presentations in front of the meeting hall. If you are interested to present news and recent products from your company, please ask APV-Office (ah@apv-mainz.de) for further information.

Be quick, as the exhibition was sold out at our previous seminar on ODFs.

How to get to Innsbruck?

Right in the heart of Europe, Innsbruck is very conveniently located. A well-developed road and rail network connects the Tyrolean capital to the world: A 12 autoroute (toll sticker required) leads from East (Munich, Salzburg, Brenner) to West (Arlberg arena).

Innsbruck may be reached by plane through Innsbruck airport or Munich airport. Convenient airport shuttles are available from both airports. In the winter season, there are many direct flights to Innsbruck airport, e.g. from Amsterdam, Berlin, Düsseldorf, Eindhoven, Frankfurt, London Gatwick, Moscow Domodedovo, Rotterdam, or Vienna.

Book early as there are numerous skiing tourist who fly to Innsbruck and move on to the very near, world-famous skiing resorts.

Location

Austria Trend Hotel Congress
Innsbruck
Rennweg 12a
6020 Innsbruck, Austria
Phone: +43 512 2115
Fax: +43 512 2115-550

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

Date

Course no. 6580
from 29 Jan. 2015 09:00
to 30 Jan. 2015 13:30

Registration fee

APV member 1160 EUR
Non-member 1290 EUR
(free of VAT according to § 4,22 UStG)

Special rate for students with an APV membership available on request.

Coffee breaks, lunch, dinner and proceedings included.

Registration

APV-Geschäftsstelle
Kurfürstenstraße 59
55118 Mainz/Germany
Phone: +49 6131 9769-0
Fax: +49 6131 9769-69
e-mail: apv@apv-mainz.de

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

Members of authorities pay half of the APV member's and non-member's registration fee respectively.

Hotel reservation

Austria Trend Hotel Congress
Innsbruck
Rennweg 12a
6020 Innsbruck, Austria
Phone: +43 512 2115
Fax: +43 512 2115-550

Participants should make their own hotel reservation referring to the APV seminar.

Deadline for special conference rate: 01 December 2014.

Special rate:
Single room incl. breakfast buffet from 100 EUR per night.

Mainz, October 2014

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.

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Technology

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