ODx and MBx - Orodispensible 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
Dear colleagues,

various orodispersible drug formulations (ODx) and mucoadhesive 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 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 Breitkreutz
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 Breitkreutz
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), minitablets (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 - Orodispensible 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 Breitkreutz
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 Breitkreutz
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.

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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
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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