Development of Oral Liquid Forms

05 to 06 November 2018
Düsseldorf, Germany

Course no. 6751

Research and Development

Target group

Particularly formulation scientists, who have only limited experiences with liquid dosage forms, or those who strive for gaining a more holistic insight into the development of oral liquid forms should take benefit from this course.

MAKING SCIENCE WORK

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

Introduction and objectives

Oral liquids have been used since decades as preferred dosage forms for children. Since the regulation for pediatric development were set in force by EMA and FDA, age appropriate formulations have received increased relevance. Hence, also oral liquid forms are more frequently developed as pediatric dosage form. The scope of applications will be extended to NCEs, to highly potent drugs, to new fields of indications, and more often to long term treatments.

In addition to the classical field of OTC medications and antibiotics new requirements to oral liquids will play a role. Although solid, single unit dosage forms such as oral disintegrating tablets and dispersible tablets have clear advantages as pediatric formulation in terms of stability, oral liquids as multidose dosage forms provide the clear advantage of flexible dosing, which is particularly important for highly active compounds with narrow therapeutic window.

The seminar should provide an overview of all relevant aspects in the context of developing oral liquid dosage forms, such as oral solution and suspension including also formulations of powder for constitution thereof.

Programme

Monday, 05 November 2018 **10:00-18:30 h**

Welcome coffee

Introdcution
Rene Holm, Janssen R&D – a devision of Janssen Pharmaceutica NV, Belgium
Peter Kühl, F. Hoffmann-La Roche AG, Switzerland
Susanne Page, F. Hoffmann-La Roche AG, Switzerland

Setting the Scene

Regulatory expectations for oral liquid drug products:
CTD module 3
- What information should be submitted
- Typical deficiencies
- API PSD changes in suspensions

Pediatric Drug products
- Excipient acceptability
- Palatability
- Use of devices

Specifics of Combination product
Marcus Savsek, BfArM, Germany

Biopharmaceutical aspect of oral liquid drug products:
- Need for biobridging between different liquid forms and to solid forms when to apply waiver
- Reflection of biopharmaceutical classification system, GI physiology
- Excipients considered to impact drug absorption

Georgios Aislaitner, BfArM, Germany

Formulation development

Preformulation:
- Solubilities: use of cosolvents and surfactants, pH dependence
- pH dependent solution stability
- Solid form screening: potential poorly soluble salts and hydrates
- API PSD: requirements for dose accuracy and physical stability of suspensions

Rene Holm, Janssen R&D – a devision of Janssen Pharmaceutica NV, Belgium

Development of Oral Liquid Forms

Clinical formulation development:
- Decision solution versus suspension
- Physical stability testing of suspensions
- Physical stabilization of suspensions: sedimentation and viscosity, prevention form caking, PSD (Oswald ripening)
- Chemical Stabilization: antioxidants, pH adjustment
- Decision on Powder for constitution (PfC) vs. ready to use (RtU)

Under consideration of ADIs and limitation in use of surfactants and cosolvents particularly in pediatric use.
Peter Kühl, F. Hoffmann-La Roche AG, Switzerland

Commercial formulation development:
- Process definition and scale up (avoid overlap with "Granulation technologies for PfC")
- Accelerated stability studies to predict shelf life/in-use period
- Primary stability batches – ICH requirements for stability testing & manufacturing aspects

Roger Embrechts, Refoso consultancy, Belgium

Microbial stability and preservation:
- Requirements of RtU vs. PfC for multidose containers
- Selection of preservative type and amount
- Microbial qualification of in-use time: tests and requirements
- Definition of an in-use period
- Acceptability of preservatives in children

Sabine Ingelbrecht, Janssen R&D – a devision of Janssen Pharmaceutica NV, Belgium

Networking Dinner

Tuesday, 06 November 2018 08:30-16:30 h

Formulation development

Granulation technologies for PfC:
- Fluid bed granulation
- Roller compaction
- Specific processing aspects for high amounts of highly soluble excipients

Susanne Page, F. Hoffmann-La Roche AG, Switzerland

Palatability and taste:
- Taste assessment: preclinical and clinical, pediatric palatability studies
- Taste masking: particle coating, (resins), use of flavors
- Flavors: selection of flavor, specific regulatory aspects of flavor use; Masking of API taste: which flavors to take for which API taste, relevance of "improved taste " for pediatric populations

Sabine Ingelbrecht, Janssen R&D – a devision of Janssen Pharmaceutica NV, Belgium

Packaging and devices

Container closure systems:
- Overview of systems for oral liquids
- Bottles and caps: stability requirements and optimization, material qualification, child resistant tests
- Consider 2-compartment systems, safety aspects of high potent drugs

speaker requested

Dosing devices:
- Dosing accuracy of spoons and dispensers
- Compliance and usability
- Qualification requirements
- concept for age dependent dose volumes, safety aspects for highly potent drugs

speaker requested

Human factor aspects:
- Risk assessments
- Reconstitution procedures: home versus pharmacy
- Instruction for use and leaflet
- Use studies

Gereint Davies, F. Hoffmann-La Roche AG, Switzerland

Manufacture of drug products

Bottle filling lines:
- Principles of powders and liquid dispensation
- Capping
- Manufacturing controls
- Design for highly for potent drugs

speaker requested

Product cases:
- Example for the production of RtU solution/ suspension
- Example for a powder for constitution solution/ suspension

Roger Embrechts, Refoso consultancy, Belgium

Questions & Answers and Wrap-up
Rene Holm, Janssen R&D – a devision of Janssen Pharmaceutica NV, Belgium
Peter Kühl, F. Hoffmann-La Roche AG, Switzerland
Susanne Page, F. Hoffmann-La Roche AG, Switzerland

Registration by fax 0049 6131 97 69 69 / by e-mail apv@apv-mainz.de

Location

Holiday Inn Düsseldorf City
Toulouser Allee 5
40211 Düsseldorf
Germany
phone 0049 211 20541 100
fax 0049 211 20541 899

Date

Course No. 6751
from 05 November 2018 10:00 h
to 06 November 2018 16:30 h

Registration fee

Industry	1490 EUR
Authority/University	745 EUR
Students*	178 EUR

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

Coffee breaks, luncheon, dinner and electronic proceedings included.

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

Registration

APV-Headquarters
Kurfürstenstraße 59
55118 Mainz/Germany
phone 0049 6131 97 69 0
fax 0049 6131 97 69 69
Eemail 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.

Hotel reservation

Holiday Inn Düsseldorf City
Toulouser Allee 5
40211 Düsseldorf
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phone 0049 211 20541 100
fax 0049 211 20541 899

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

Deadline for special conference rate: 07 October 2018.

Special rate:
Single room incl. breakfast from 129,00 € per night.

Mainz, June 2018

Development of Oral Liquid Forms, Düsseldorf, 05-06 November 2018, Germany, Course no.: 6751

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

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