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Dissolution Testing

Development / Quality Control and *in vivo* Relevance

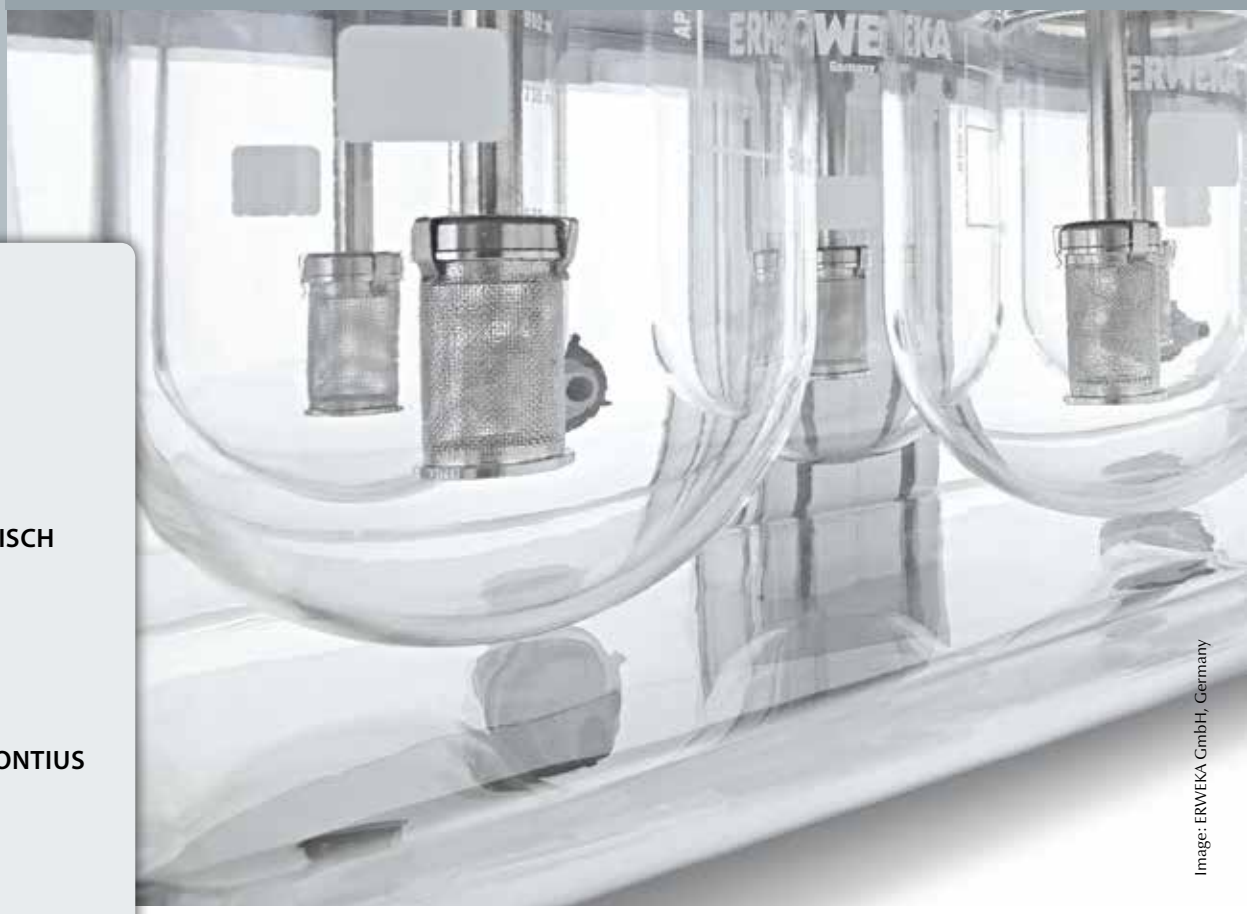

Image: ERWEKA GmbH, Germany

SPEAKERS

DR KERSTIN HARTISCH
Bayer AG

DR ALEXANDER PONTIUS
Bayer AG

DR JOCHEN SCHER
Boehringer Ingelheim

DR FERDINAND STEIERHOFFER
Boehringer Ingelheim

19 – 20 February 2019, Prague, Czech Republic

HIGHLIGHTS:

- Importance of Dissolution Testing in Drug Development and for a Commercial Product
- In vivo Relevant Dissolution Testing
- Importance of Biowaiving in Drug Product Development
- Discriminatory Power of a Dissolution Method
- Regulatory Requirements (Pharmacopoeias, Required Data for Application of Marketing Authorisation)
- Country-specific Challenges: Japan, Korea, Taiwan, China etc.
- Automation of Dissolution Methods
- Mechanical Qualification and Performance Verification Testing (PVT)
- Development of Dissolution Methods
  - How to Set Specifications?
  - Analytical Validation
  - Practical Recommendations
- OOS Results in Dissolution Testing
- Dissolution Profile Comparison

This course is recognised for the ECA GMP Certification Programme „Certified Quality Control Manager".
Please find details at www.gmp-certification.eu

Dissolution Testing

19 – 20 February 2019, Prague, Czech Republic

Objectives

This GMP Education Course on Dissolution Testing aims at providing delegates with a sound understanding of the principles and best practices in dissolution testing.
As Dissolution represents a very interdisciplinary topic, a broad variety of areas within the development and commercial phase will be discussed.

Dissolution testing:
- to characterize formulations
- to support formulation and process development
- to evaluate the impact of formulation and process parameters changes
- to control the quality (QC tool) of clinical trial supplies and the commercial product
- to support drug product stability testing
- to justify formulation/production changes (e.g., according to SUPAC, Biowaivers)
- to predict in vivo performance

Due to the wide range of applications and the sensitivity of dissolution testing, sound method development and validation is of essential importance. Furthermore also knowledge on dissolution apparatus qualification, dissolution specification setting, dissolution profile comparison and handling of OOS/OOE results will be trained and discussed.

Background

The dissolution test is a key test parameter for assessing the performance of solid and semi-solid dosage forms in both drug development and quality control. In these fields it is used to assure batch-to-batch quality as well as providing process control information as part of the approach to Process Validation.

Dissolution testing is usually connected to in vivo performance because the API must be released from the formulation in the gastrointestinal tract (GIT) before in vivo absorption can occur. Therefore dissolution testing is generally employed during Drug Product development and optimization. A dissolution test should therefore have adequate discriminatory power to detect relevant Drug Product changes.

Where dissolution testing data can be shown to be correlated to in vivo performance, clinical trials may be avoided by in vitro dissolution studies under certain circumstances, thereby reducing development time and costs.

There are many dissolution guidances and associated guidelines (e.g. FDA, EMA and the Pharmacopoeias) dealing with Scale-up and Post-Approval Changes, Bioequivalence studies, Waiver of in vivo Bioavailability and Bioequivalence Studies. Additionally, there are some country-specific dissolution requirements which are very challenging for global pharmaceutical companies.

This GMP Education Course will, therefore, cover the following topics:
- physicochemical and biopharmaceutical foundations
- dissolution method development,
- validation of the dissolution methodology
- approaches for setting specifications
- OOS and OOE Results in dissolution testing
- statistical methods for comparing dissolution profiles
- approaches for substitution of BE-studies (biowaiver) and
- approaches to establish in vitro in vivo correlations (IVIVC)
- country-specific dissolution requirements and challenges

In addition, the expectations of the European Medicines Agency (EMA) and of the pharmacopoeias (Ph.Eur. 2.9.3 and USP Chapters <711> and <1092>) including USP Reference Standard Tablets and Mechanical calibration for the dissolution apparatus qualification will be discussed.

The objective of this course is to cover all aspects of dissolution testing with a focus on practical examples. Workshops are also part of the course in order to encourage the exchange of experience and to allow interactive and in depth discussions of the subject.

Moderator

DR JOCHEN SCHER, *Boehringer Ingelheim Pharma GmbH & Co. KG, Biberach, Germany*

Programme

Fundamentals of Dissolution Testing: From Physicochemistry to Bioavailability

- Mechanism and theories of solid dissolution (e.g. diffusion layer model)
- Intrinsic dissolution rate
- Sink conditions
- Kinetics of drug release
- Relationship between dissolution and bioavailability
- Quality control dissolution testing and in vivo predictive dissolution testing
- Biopharmaceutics Classification System
- Fraction of a dose absorbed classification system
- Hurdles and limitations of dissolution testing

DR JOCHEN SCHER, *Boehringer Ingelheim*

Dissolution Testing throughout the Drug Product Development Lifecycle

- Use of dissolution testing during Drug Product development
- What is Biorelevance? Meaning and Misconceptions
- How to establish a link between dissolution and bioavailability
- The role of IVIVC
- Setting biorelevant dissolution specifications
- BCS based biowaivers
- Waivers based on proportional similarity
- Country specific regulatory differences
- Case studies

DR JOCHEN SCHER. *Boehringer Ingelheim*

Dissolution Testing – Regulatory Guidelines

- Prerequisites of international and mostly harmonized pharmacopeia (USP, EP, Pharm Jap)
- Miniaturization of dissolution tests
- General guidelines for dissolution testing
- Contents and differences in Chinese pharmacopeia
- Validation of dissolution test methods
- Bioequivalence considerations
- Special in vitro bioequivalence applications in Japan
- Waiving dissolution tests by disintegration tests

DR ALEXANDER PONTIUS, *Bayer AG*

Development of Dissolution Methods - The balancing Act between Quality Control and Clinically Relevance

- Method development for Immediate Release, Extended Release and Delayed Release Formulations
- Regulatory recommendations
- Dissolution apparatus and medium selection
- Use of surfactants
- Adequate discriminatory capability
- Standard Dissolution Test Conditions
- Evaluation of bio-relevance
- Dissolution methods for developing an IVIVE/C to gain regulatory flexibility
- Case studies

DR FERDINAND STEIERHOFFER, *Boehringer Ingelheim*

Mechanical Calibration & Performance Verification Test (PVT)

- Regulatory basis
- Fundamentals of instrument qualification
- Qualification and calibration of dissolution apparatuses
- Mechanical calibration
- USP Performance Verification Test (PVT)
- Deviations and OOC

DR ALEXANDER PONTIUS, *Bayer AG*

Setting Specifications for Dissolution Methods

- How to set adequate dissolution specifications for various types of formulations
- Requirements of different Pharmacopoeias and Guidelines
- Specifics and exceptions

DR KERSTIN HARTISCH, *Bayer AG*

Programme (cont'd)

WORKSHOP I
How to Set Specifications: Sharing Information of the Learned Theories
- Presentation of Case Studies and discussion of potential results
- Q&A Session

Moderator: Dr Kerstin Hartisch, Bayer AG

OOS Results in Dissolution Testing
- Regulatory aspects
- Dissolution methods having appropriate discriminatory power
- General OOS procedure for dissolution testing
- Defining and handling of OOS results including CAPA
- OOS evaluation for immediate release products, for capsules, for modified-release products
- OOT/OOE results: Evaluating stability effects by applying dissolution testing

DR ALEXANDER PONTIUS, *Bayer AG*

Automation in Dissolution Testing
- Why and when is automation valuable?
- Various types of dissolution systems
- New products on the market

DR KERSTIN HARTISCH, *Bayer AG*

Analytical Validation of Dissolution Testing Methods
- Pharmacopoeial and Regulatory Recommendations (e.g., ICH Q2 (R1),USP <1092>, RDC No. 166/2017)
- Validation characteristics:
  - Specificity, Linearity, Precision, Accuracy and Robustness
  - Validation of automated procedures
- Some practical recommendations for performing the validation and recommended acceptance criteria
- Dissolution method transfer

DR FERDINAND STEIERHOFFER, *Boehringer Ingelheim*

WORKSHOP II
Analytical Validation of Dissolution Methods
Putting theory to work (case studies):
- Develop validation protocol for validation of dissolution methods for solid oral dosage forms
- Pitfalls in performing the experiments

Moderator: Dr Ferdinand Steierhoffer, Boehringer Ingelheim

Dissolution Profile Comparison; Approaches and Issues
- Importance of dissolution profile comparisons during drug product development and for a commercial product
- Regulatory requirements concerning dissolution profile comparison
- Different approaches to compare dissolution profiles: Model dependent and independent approaches
- Examples

DR JOCHEN SCHER, *Boehringer Ingelheim*

Case Study: Application of Dissolution Testing in Industrial Drug Product Development
- Discussion of various case studies occurring during product development

DR KERSTIN HARTISCH, *Bayer AG*

Conference Exhibition
Leading suppliers of Dissolution apparatus and Dissolution systems are invited to exhibit their products. Please contact Mr Niklaus Thiel for further information on the opportunity to exhibit at the conference: Phone ++49-(0)62 21-84 44 43, Fax ++49-(0)62 21-84 44 34, thiel@concept-heidelberg.de

Speakers

DR KERSTIN HARTISCH

Bayer AG, Berlin, Germany

Kerstin Hartisch studied Food Chemistry and Pharmacy at the University of Bonn and received her PhD in Pharmaceutical Analytics. In her position as head of Analytical Development within Bayer, Chemical and Pharmaceutical Development she is responsible for all aspects regarding special analytical techniques in product development, i.e. dissolution testing, particle identification, packaging materials, excipient testing and also sample and data management (LIMS). She is specialised in the area of dissolution testing including all aspects of automation (Robot Technology).

DR ALEXANDER PONTIUS

Bayer AG, Leverkusen, Germany

Alexander is a pharmacist by training and did his PhD graduation in biopharmaceutical analytics. He was heading a QC group in the global pharmaceutical development division and was responsible for all aspects of the dissolution methodology. This work covered the development and validation of dissolution methods, bio-pharmaceutical evaluations, dossier submission of innovative drug products, handling of post approval changes as well as support of life cycle management and patent protection of market products. At present, Alexander is working as Quality System Manager within the enterprise-wide Corporate Quality function. He is responsible for the regulation management within the overarching Quality Management System at Bayer.

DR JOCHEN SCHER

Boehringer Ingelheim Pharma GmbH & Co. KG, Biberach, Germany

Dr Jochen Scher is a pharmacist by training and received a PhD in natural product chemistry at the University of Saarland. He joined Boehringer Ingelheim Pharma GmbH & Co. KG in 2005 and worked for 12 years in different areas of Drug Product Analytics (including 3 years as dissolution lab head and 3 years as Drug Product Analytics group manager at the development site in Kobe (Japan). Since 2017 he joined the global R&D Project Management at Boehringer Ingelheim.

DR FERDINAND STEIERHOFFER

Boehringer Ingelheim Pharma GmbH & Co. KG, Biberach, Germany

Dr Ferdinand Steierhoffer is a pharmacist by training and conducted his PhD at the Martin-Luther-University Halle-Wittenberg in cutaneous gene therapy. Dr Steierhoffer joined Boehringer Ingelheim Pharma GmbH & Co. KG in 2007 where he started in the quality control department. He is currently heading a dissolution lab within the Analytical Development Department at Boehringer Ingelheim in Biberach and acts as a deputy head of quality control for investigational medicinal products.

Social Event

We are looking forward to welcome all participants and speakers to a nice evening in a relaxed atmosphere after the first course day.

After a sightseeing tour of Prague we will have dinner at a nice restaurant..

Easy Registration

Reservation Form:
CONCEPT HEIDELBERG
P.O. Box 10 17 64
69007 Heidelberg
Germany

Reservation Form:
+ 49 6221 84 44 34

e-mail:
info@concept-heidelberg.de

Internet:
www.gmp-compliance.org

Date
Tuesday, 19 February 2019, 9.00 h – 18.00 h
(Registration and coffee 8.30 – 9.00 h)
Wednesday, 20 February 2019, 8.30 h – 16.00 h

Venue
Corinthia Hotel Prague
Kongresova 1
14069 Prague, Czech Republic
Phone + 420 261 191 111
prague@corinthia.com

Fees (per delegate plus VAT)
ECA Members € 1,490
APIC Members € 1,590
Non-ECA Members € 1,690
EU GMP Inspectorates € 845
The conference fee is payable in advance after receipt of invoice and includes conference documentation, dinner on the first day, lunch on both days and all refreshments. VAT is reclaimable.

Accommodation
CONCEPT HEIDELBERG has reserved a limited number of rooms in the conference hotel. You will receive a room reservation form/POG when you have registered for the event. Reservation should be made directly with the hotel.
Early reservation is recommended.

Registration
Via the attached reservation form, by e-mail or by fax message.
Or you register online at www.gmp-compliance.org.

Conference language
The official conference language will be English.

Organisation and Contact
ECA has entrusted Concept Heidelberg with the organisation of this event.
CONCEPT HEIDELBERG
P.O. Box 10 17 64
69007 Heidelberg, Germany
Phone +49 (0) 62 21/84 44-0
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Do you have any questions?
For questions regarding content please contact:
Dr Günter Brendelberger (Operations Director) at
+49 (0)62 21 / 84 44 40, or per e-mail at
brendelberger@concept-heidelberg.de.

For questions regarding reservation, hotel, organisation etc. please contact:
Mr Niklaus Thiel (Organisation Manager) at
+49 (0)6221/84 44 43, or per e-mail at
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19 – 20 February 2019, Prague, Czech Republic

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1. We are happy to welcome a substitute colleague at any time.
2. If you have to cancel entirely we must charge the following processing fees: Cancellation
- until 2 weeks prior to the conference 10 %,
- until 1 weeks prior to the conference 50 %
- within 1 week prior to the conference 100 %.

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The cancellation fee will then be calculated according to the point of time at which we receive your message.
In case you do not appear at the event without having informed us, you will have to pay the full registration fee, even if you have not made the payment yet. Only after we have received your payment, you are entitled to participate in the conference (receipt of payment will not be confirmed)! (As of January 2012).

German law shall apply. Court of jurisdiction is Heidelberg.

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