

# Revision of BE Requirements for Modified Release Products

*February 23-24 • 2011 • Hotel Majestic • Barcelona • Spain*



## **Scope & Aim**

A concept paper was recently published by the European Medicines Agency on the need for revision of the CPMP Note for Guidance on modified release oral and transdermal dosage forms. The aim of this open forum is to discuss the relevant issues on specific regulations and open questions for the assessment of bioequivalence of modified release products in order to contribute scientifically to the development of the forthcoming draft guideline. The scientific community is invited to share their experience with the scientists of regulatory agencies. The intention of this conference is therefore to give scientists from pharmaceutical industry and academia the chance to present their views – including experimental results – during the discussions. Based on the existing experience derived from bioavailability and bioequivalence (BA/BE) studies performed by pharmaceutical companies with their development products, the scientific rationale for appropriate requirements for the approval of medicinal products in the European Union should be defined.

The Open Discussion Forum will open on Wednesday, February 23, 2010 at 9 am, and it will close on Thursday, February 24, 2010, at 5 pm.

## **Who should attend?**

This Forum is designed to meet the requirements and expectations of professionals from academia, generic and research based industry, CRO and regulatory authorities. Heads of department, project managers, scientists and consultants in R&D, formulation development, quality control, regulatory affairs, pharmacokinetics, or clinical studies should attend in order to share their experience in the field with regulatory scientists from the European Agencies. All participants will have the chance to contribute actively to the scientific discussions in order to achieve consensus in open issues in BA/BE, or to learn facts and trends in the field from presentations and discussions.

## Conference Co-chairs

Henning Blume, SocraTec R&D, Oberursel DE  
Jan Welink, Medicines Evaluation Board, The Haag NL

## Scientific and Planning Committee & BABP Network Leadership

Gerald Beuerle, ratiopharm, Ulm DE  
Henning Blume, SocraTec R&D, Oberursel DE  
Erich Brendel, Bayer Schering Pharma, Wuppertal DE  
Andrzej Dzierbicki, Polpharma, Warsaw PL  
Hilda Koeszegi-Szalai, National Institute of Pharmacy, Budapest HU  
Hans H. Lindén, EUFEPS, Stockholm SE  
Henrike Potthast, BfArM, Bonn DE  
Tomas Salmonson, Medical Products Agency, Uppsala SE  
Hans Schaefer, Boehringer Ingelheim, Biberach DE  
Clive G. Wilson, University of Strathclyde, Glasgow UK

## Programme Information

For update and more detailed programme, as available, see this website, or contact the Organisers (full address below).

## Language

English will be the language of the Workshop. No simultaneous translation will be provided.

## Conference Venue & Location

The Conference will take place at the Majestic Hotel & Spa, Barcelona, Spain. The Majestic Hotel & Spa is located in the very centre of Barcelona, on Paseo de Gracia in walking distance to the Ramblas.

From the Airport, e.g. take the Airport Train towards the city and get off at train station Passeig de Gràcia. The Hotel Majestic is within walking distance, located on the same street one block away.

## Registration and Hotel Reservation

Please visit the Forum Website at [www.eufeps.org](http://www.eufeps.org) to register for the Forum and for hotel reservation.

	EUFEPS	EUFEPS		
Discussion Forum Registration Fees (incl VAT)	Members on/before December 13, 2010	Members after December 13, 2010	Standard on/before December 13, 2010	Standard after December 13, 2010
Industrial Delegate	EUR 950	EUR 1050	EUR 1200	EUR 1300
Academic Delegate	EUR 450	EUR 550	EUR 550	EUR 650
Government Delegate	EUR 450	EUR 550	EUR 550	EUR 650
PhD and Student Delegate	EUR 200	EUR 200	EUR 250	EUR 250

Rates include daily, tea and coffee breaks and lunches as well as a welcome reception buffet dinner on Wednesday February 23, 2011.

A number of rooms have been pre-blocked at the Majestic Hotel Barcelona and the Hotel Inglaterra for your convenience. The room blocks are available for booking until December 13, 2010. On/after this date, the room blocks will be released and availability and rates can no longer be guaranteed.

## Hotel Rates

Hotel Rates in EUR incl VAT	Single occupancy	Double occupancy	Breakfast	Availability until
Majestic Hotel & Spa 5*	EUR 160/night	EUR 180/night	Included	December 13, 2010
Hotel Inglaterra 3*	EUR 109/night	EUR 129/night	Included	December 13, 2010

Pre-Invited delegates may make their hotel reservation directly on the on-line registration form.

Registering delegates are recommended to make their reservation at any of the above hotels on the available booking form. Please note that there is a limited number of rooms available at each hotel, and allocation is made on a first-come first-served basis. Delegates are instructed to quote "EUFEPS" when making the reservation. Further details are available on the on-line registration link at the Forum Website at [www.eufeps.org](http://www.eufeps.org). Please note that all room blocks will be released on **December 13, 2010**.

A confirmation will be sent to you once your registration and accommodation request has been processed. Please read this carefully as it contains useful information and a summary of your booking.

Notification of cancellation must be made in writing to Congrex. Cancellation of registration will be accepted until **December 13, 2010** up to which date the total amount will be refunded less EUR 50 for administrative expenses. For cancellations made after **December 13, 2010** we regret that no refunds can be made. Substitutions will be allowed at any time.

## Disclaimer/Liability

The Scientific and Planning Committee, and Congrex Sweden AB accept no liability for any injuries/losses incurred by participants and/or accompanying persons, nor loss of, or damage to any luggage and/or personal belongings.

### Forum Registration and Hotel Reservation

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Congrex Sweden AB  
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### EUFEPS Meetings & Events

Veddesta Business Center  
175 72 Järfälla  
(Stockholm)  
Sweden  
Tel +46 8 50582040  
Fax +46 8 4113217  
Email [conference@eufeps.org](mailto:conference@eufeps.org)  
Website [www.eufeps.org](http://www.eufeps.org)

### Forum Venue

Majestic Hotel and Spa  
P<sup>a</sup> de Gracia, 68  
08007 Barcelona  
Spain  
Tel +34 93 4881717  
Fax +34 93 4879790  
Website [www.hotelmajestic.es](http://www.hotelmajestic.es)

## Preliminary Programme

Wednesday, February 23, 2011
<b>Welcome and Introductions</b>
Goals, objectives and structure of the Forum <i>Co-chairs</i>
<b>Session I: In-vitro vs. in-vivo characterisation of MR preparations</b> <b>Session Co-Chairs:</b> <i>Henrike Potthast</i> , BfArM, Bonn DE and <i>Erich Brendel</i> , Bayer Schering Pharma, Wuppertal DE
In-vitro dissolution testing: Method development and importance of biorelevant test conditions <i>Sandra Klein</i> , University of Greifswald, Greifswald DE
Setting specifications for dissolution testing of modified-release formulations <i>Alexander Pontius</i> , Bayer Schering Pharma, Berlin DE
Establishing in-vitro/in-vivo correlations: Concepts and improvement (average IVIVC vs. individualised approach) <i>Clive G. Wilson</i> , University of Strathclyde, Glasgow UK
Dissolution data supporting variations: Opportunities and limitations <i>Theresa A. Shepard</i> , MHRA, London UK
Dissolution testing in case of MR products: Current regulatory perspective and open issues <i>Henrike Potthast</i> , BfArM, Bonn DE and <i>Alfredo Garcia</i> , AEMPS, Madrid ES
<b>Session II: Assessment of bioequivalence for special MR preparations</b> <b>Session Co-Chairs:</b> <i>Henning Blume</i> , SocraTec R&D, Oberursel DE and <i>Juergen Schomakers</i> , BfArM, Bonn DE
Transdermal Delivery Systems: Pharmaceutical equivalence – bioequivalence – therapeutic equivalence <i>Juergen Schomakers</i> , BfArM, Bonn DE
Bioequivalence of transdermal delivery systems: Necessity for replicate design and assessment of product-specific within-subject variability? <i>Andrzej Dzierbicki</i> , Polpharma, Warsaw PL
TTS with different dose strengths: Dose proportionality and extrapolation of BE data <i>Christian Zurth</i> , Bayer Schering Pharma, Berlin DE
Assessment of bioequivalence of MR products for parenteral administration, e.g. liposomal preparations: Determination of free vs bound/encapsulated compound <i>Henning Blume</i> , SocraTec R&D, Oberursel DE
Assessment of bioequivalence of implants: Appropriate study design, parameters and acceptance criteria <i>Helmut Schuetz</i> , BEBAC, Vienna AT
Future perspective in BE assessment of parenteral modified release preparations <i>José Morais</i> , University of Lisbon, Lisbon PT

Thursday, February 24, 2011
<b>Session III: Food effect studies and enteric-coated products</b> <b>Session Co-Chairs:</b> <i>Jan Welink</i> , Medicines Evaluation Board, The Haag NL and <i>Clive G. Wilson</i> , University of Strathclyde, Glasgow UK
Understanding ‘dose dumping’ assessment and interpretation of significant increase of plasma concentrations after high fat meals <i>Werner Weitschies</i> , University of Greifswald, Greifswald DE
Food effect studies: Improvement by body weight adjusted meal size and restrictive standardisation of meal schedule on study days <i>Barbara Schug</i> , SocraTec R&D, Oberursel DE
Requirements for drugs with specific administration recommendations (e.g. after meal) and interactions with drugs affecting gastro-intestinal function <i>Hans Lennernäs</i> , Uppsala University, Uppsala SE
In-vivo characterisation of enteric-coated products: Single unit vs. multiple unit forms and food effects <i>Erich Brendel</i> , Bayer HealthCare, Wuppertal DE
Food effect studies and characterisation of enteric-coated products: Current regulatory thinking and open issues <i>Jan Welink</i> , Medicines Evaluation Board, The Haag NL
<b>Session IV: Pharmacokinetic characteristics for MR products and assessment of bioequivalence</b> <b>Session Co-Chairs:</b> <i>Monica Edholm</i> , Medicines Product Agency, Uppsala SE and <i>Gerald Beuerle</i> , ratiopharm, Ulm DE
Pharmacokinetic parameters for modified-release drug products <i>Laszlo Endrenyi</i> , University of Toronto, Toronto CA
Necessity of multiple dose studies: Reliability and limitations of extrapolations based on single dose data <i>Corina Becker</i> , Bayer Schering Pharma, Wuppertal DE
Design requirements, acceptance criteria for bioequivalence assessment of MR formulations <i>Susana Almeida</i> , Tecnimed, Abrunheira Sintra PT
MR products with different dose strengths: Extrapolation between strengths, bracketing concept and selection of strength(s) to be tested <i>Gerald Beuerle</i> , ratiopharm, Ulm DE
Bioequivalence requirements for MR products: Current regulatory thinking and open issues <i>Christoph Baumgaertel</i> , Austrian Medicines and Medical Devices Agency, Vienna AT
<b>Wrap-up and closing</b> <i>Co-chairs</i>



## EUFEPS and BABP Network



**EUFEPS** (European Federation for Pharmaceutical Sciences) was founded in 1991. Its mission is to advance excellence in the pharmaceutical sciences and innovative drug research and to represent the interests of scientists engaged in drug research and development, drug regulation and drug policymaking. Currently, it links scientific societies and associations in 24 European Countries, and 15 member institutions. There are around 500 individual members, and EUFEPS Networks are growing in numbers. The purpose of the networks is to join scientists together. A mission of the **BABP Network** is to provide an opportunity for EUFEPS members to get to know each other, to explore important issues in bioavailability, bioequivalence and biopharmaceutics through conferences and workshops and ultimately to propagate learning through various published media. The effect of these activities will be to help Europe to lead debate rather than work in a reactive mode, confident that resolutions are well-rehearsed and strongly scientifically justified.

## EUFEPS Member Societies



Academy of Pharmaceutical Sciences of Great Britain



Czech Pharmaceutical Society



Israel Society of Clinical Pharmacy and Biopharmaceutics



Polish Pharmaceutical Society



Spanish Society of Pharmaceutics and Pharmaceutical Technology



Association de Pharmacie Galenique Industrielle (APGI)



Finnish Pharmaceutical Society



Italian Society for Pharmaceutical Sciences



Portuguese Society for Pharmaceutical Sciences



Swedish Academy of Pharmaceutical Sciences



Austrian Pharmaceutical Society



German Pharmaceutical Society (DPhG)



Netherlands Association of Pharmaceutical Sciences



Romanian Society of Pharmaceutical Sciences



Swiss Society of Pharmaceutical Sciences



Belgian Society of Pharmaceutical Sciences



Hellenic Society of Medicinal Chemistry (HSMC)



Norwegian Pharmaceutical Society



Slovak Pharmaceutical Society



Turkish Pharmaceutical Technology Scientists' Association (TÜFTAD)



Croatian Pharmaceutical Society



Hungarian Society for Pharmaceutical Sciences (HSPS)



Pharmaceutical Society of Denmark



Slovenian Pharmaceutical Society

## EUFEPS Sponsors



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