



EUROPEAN FEDERATION
FOR PHARMACEUTICAL
SCIENCES

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EUFEPS & COST B25 Conference on

Bioavailability (BA) and Bioequivalence (BE): Focus on Physiological Factors and Variability

*A unique discussion forum for scientists from the pharmaceutical industry,
regulatory agencies and academic institutions*



October 1-2 • 2007 • Royal Olympic Hotel • Athens • Greece

This Conference is jointly Co-organised by EUFEPS
and the COST Working Group I of Action B25
and it is Co-sponsored by FIP Board of Pharmaceutical Sciences (BPS)



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EUFEPS & COST B25 Conference on

Bioavailability (BA) and Bioequivalence (BE): Focus on Physiological Factors and Variability

October 1-2 • 2007 • Royal Olympic Hotel • Athens • Greece

This Conference opens on Monday, October 1, at 08:45 (Pre-registration on Sunday, September 30) and it closes on Tuesday, October 2, at 16:00.

Scope & Aim

There are concerns about highly variable drugs and drug products. Physiologically based approaches to understand drug absorption and the bioavailability of drugs and drug products have gained major interest over the recent years. This is why physiology and factors of variability affecting the oral absorption and the systemic availability of drugs and drug products will be addressed in this Conference.

It will also provide good insight in current thinking as to the design and analysis of bioavailability and bioequivalence studies of highly variable drugs and drug products, as viewed by pharmaceutical industry, academia and regulators. It is anticipated that the outcomes of the Conference will contribute significantly to the harmonisation of regulatory policies. Speakers – and delegates – of the Conference include experts in all relevant fields.

Sessions will include

- Physiological factors affecting drug absorption
- Role of pre-systemic effects on bioavailability
- Impact of variability in BE studies
- Unresolved issues in BA/BE Regulations

Format & Preliminary Programme

Using a similar format to previous EUFEPS conferences, key segments of the process are broken down into a number of sessions, each with lectures and discussions, and general discussion sessions for conclusions and recommendations.

Conference Planning Committee

Co-chairs: *Henning H Blume*, Oberursel DE; *Panos Macheras*, Athens GR; *Vinod P Shah*, North Potomac MD USA; and *Achiel Van Peer*, Beerse BE
Additional members: *Melin Babaoglu*, Ankara TR; *Daan JA Crommelin*, Leiden NL; *Hans H Lindén*, Stockholm SE; *Constantin Mircioiu*, Bucharest RO; *José A Morais*, Lisbon PT; *Tomas Salmonson*, Uppsala SE; *Victor A Voicu*, Bucharest RO

Exhibition

Companies are welcome to participate as an exhibitor at this Conference. The Conference delegates are academics, industrialists, regulators and students which will create a unique opportunity to meet experts in your field. The exhibition offers every opportunity to promote and position your company, your products, your services, your expertise and your specialists, facilitating your contact with them, predicting their needs and shaping future collaboration.

Sponsorship Opportunities

To sponsor this Conference and by this enable additional quality meetings on key topics, contact the Executive Director, Hans H Lindén (hans.linden@eufeps.org) or the Project Manager, Annika Nyman (annika.nyman@eufeps.org).

Oral and poster contributions

Scientific contributions relating to the scope and aim of the Conference will be welcome and considered for poster presentations. Abstracts should be submitted to the EUFEPS Secretariat, both as an email attachment and as a hard copy. For editorial instructions, please visit the Conference Website EUFEPS Online at: www.eufeps.org. Submission deadline is August 30, 2007.

Language

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

Organisers

EUFEPS 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 there are more than 600 individual members of EUFEPS. For more information on EUFEPS and its activities, please visit the Conference Website EUFEPS Online at: www.eufeps.org.

COST, the European cooperation in the field of scientific and technical research, was established in 1971. COST is an intergovernmental European framework for international co-operation and now has 34 member countries and one cooperating state. Rather than funding research itself, COST brings together research teams in the different countries working on specific topics, and supports networking, conferences, short-term scientific exchanges and publications. The Action B25 enables scientists from Academia, Industry and Governmental to interact and transfer knowledge in the area of Physiologically based Pharmacokinetics and Dynamics. For more information on COST and its activities, please visit the COST Website at www.cost.esf.org.

Preliminary Programme

Monday, October 1, 2007

Welcome, Introduction and Opening Remarks

Daan JA Crommelin, EUFEPS President, Leiden NL

Panos Macheras, Conference Co-Chair, University of Athens, Athens GR

Session I: Physiological Factors affecting Drug Absorption

Session Leaders: *José A Morais*, University of Lisbon, Lisbon PT &

Victor A Voicu, Romanian Academy & University of Medicine and Pharmacy

Carol Davila, Bucharest RO

- Complexity of GI physiology and impact on drug absorption
Clive G Wilson, Strathclyde Institute for Pharmacy and Biomedical Sciences, Glasgow Scotland UK
- Site dependent drug absorption and impact on BA/BE assessment
Frank Donath, SocraTec R&D, Oberursel DE
- Impact of food on drug absorption
Werner Weitschies, University of Greifswald, Greifswald DE
- Formulation effects on drug absorption
Marcus Brewster, Johnson & Johnson, Beerse BE

Discussion – moderated by: *José A Morais*, University of Lisbon, Lisbon PT & *Victor A Voicu*, Romanian Academy & University of Medicine and Pharmacy
Carol Davila, Bucharest RO

Session II: Role of Pre-systemic Effects on Bioavailability

Session Leaders: *Constantin Mircioiu*, University of Medicine and Pharmacy, Bucharest RO & *Achiel Van Peer*, Johnson & Johnson, Beerse BE

- Integrating the complexities of physiology and biology of GI tract into modelling the interindividual variability of oral drug absorption
Amin Rostami-Hodjegan, University of Sheffield and Simcyp Ltd, Sheffield UK
- Assessment of intestinal and hepatic first-pass: Necessity to measure metabolites?
Henning H Blume, SocraTec, Oberursel DE
- Prediction of intestinal first-pass drug metabolism from *in vitro* data
Geoffrey T Tucker, University of Sheffield, Sheffield UK
- BCS and BDSS
Leslie Z Benet, University of California, San Francisco CA USA

Discussion – moderated by: *Constantin Mircioiu*, University of Medicine and Pharmacy, Bucharest RO & *Achiel Van Peer*, Johnson & Johnson, Beerse BE

Demo Get-together: Delegates and Software Developers and Poster Session

Welcome Reception

Tuesday, October 2, 2007

Session III: Impact of variability in BE studies

Session Leaders: *Vinod P Shah*, International Pharmaceutical Federation (FIP), North Potomac MD USA & *Meir Bialer*, Hebrew University of Jerusalem, Jerusalem IL

- Within subject variability: Design, determination, demonstration
Kamal K Midha, University of Saskatchewan, Saskatoon CA
- Design considerations: Single versus multiple dose studies to assess variability?
Achiel Van Peer, Johnson & Johnson, Beerse BE
- Can statistics address the BE for highly variable drugs?
Panos Macheras, University of Athens, Athens GR
- Current thinking of EMEA position on BE of Highly Variable Drugs
Tomas Salmonson, Medicinal Products Agency, Uppsala SE
- Current Thinking of FDA on BE of Highly Variable Drugs
Barbara M Davit, FDA, Rockville MD USA

Discussion – moderated by: *Vinod P Shah*, International Pharmaceutical Federation (FIP), North Potomac MD USA & *Meir Bialer*, Hebrew University of Jerusalem, Jerusalem IL

Session IV: Unresolved issues in BA/BE Regulations

Session Leaders: *Henning H Blume*, SocraTec, Oberursel DE & *Panos Macheras*, University of Athens, Athens GR

Panel Members: *George Aislaitner*, National Organisation for Medicines, Athens GR, *Alfredo Garcia-Arieta*, Spanish Agency for Medicines and Health Care Products, Madrid ES & *Jan Welink*, Medicines Evaluation Board, The Hague NL

Conclusions, recommendations and closing remarks

Panos Macheras, University of Athens, Athens GR





Location

The Conference will take place at the Royal Olympic Hotel, 28-34 Ath. Diakou Str, GR-11743 Athens, Greece,
Tel +30 210 9288400, Fax +30 210 9230331

How to get there

from Athens International Airport 'Eleftherios Venizelos':

Board the Metro from the Airport's Station and get off at 'Syntagma Station'. At 'Syntagma Station', switch lines in the direction of Agios Dimitrios and get off at the first station which is the 'Acropolis Station'. From the 'Acropolis Station' the Hotel Royal Olympic is 100 m away, walking along Ath. Diakou Street. The approximate time from the Athens International Airport to the hotel is approximately 30 minutes at a cost of EUR 10.

Taxi in about 25 minutes at an approximate cost of EUR 30.

Registration

Please visit the Conference Website of the EUFEPS Online at www.eufeps.org to register through Congrex Sweden AB or use the enclosed registration form when registering for the Conference and for hotel reservations during the Conference. The registration fee (EUFEPS Membership 10% reduction) includes all conference documentation, all coffee breaks, two lunches and one Welcome buffet. The cost for hotel accommodation and travel is not included in the registration fee. Additional registration forms can be obtained by photocopying the one in this brochure, or (as PDF) on the Conference Website at the EUFEPS Online www.eufeps.org.

Students

Participants applying for student fees should include proof of their student status (a photocopy of the university identity card).

Confirmation

In order to receive confirmation of registration by email, please make sure to indicate the email address on the registration form! Confirmation will be sent upon receipt of payment. For payment details please see page 9.

Alterations

Alterations to your registration must be made in writing and sent to Congrex Sweden AB by email or fax.

Inquiries

Congrex Sweden AB has been contracted for registration and administration support. Please direct all inquiries regarding registration, accommodation or payment to Congrex Sweden AB at:

Email bae.registration@congrex.com

Phone +46 8 4596600 Fax +46 8 6619125

Conference Registration Fees

	EUFEPS	EUFEPS	EUFEPS	EUFEPS
Conference Registration Fees EUR	Members before August 30, 2007	Non-Members before August 30, 2007	Members after August 30, 2007	Non-Members after August 30, 2007
Industrial Delegate	1080	1200	1400	1550
Academic Delegate	540	600	700	775
Government Delegate	540	600	700	775
PhD and Student Delegate	200	220	250	275

The registration fee will be waived for every second SME delegate from the same SME (Small and Medium-Sized Enterprise, employing fewer than 250 persons), when registering at the same time. This means that you will get two SME delegates per one Industrial Delegate Fee (equalling 50 % reduction). When registering, tick the "SME Delegate" box, on the Registration Form.

Hotel Reservation

Hotel reservations can be made on-line or on the attached hotel reservation form. A number of hotel rooms have been reserved at hotels at preferential rates for the Conference. The hotels are all situated in the city centre of Athens and the Conference venue is accessible with public transportation or by foot. The rates below are per room, per night and including breakfast.

Hotel accommodation will be reserved and confirmed only when Congrex Sweden AB has received your credit card number as a guarantee on the registration form. Congrex Sweden AB reserves the right to book another hotel if the desired accommodation should be fully booked. To ensure that the hotel reservation will be made as required, please indicate your credit card number on the registration form. After August 30, accommodation and rates will be confirmed according to availability.

The hotel reserves the right to charge you for all nights reserved and guaranteed on the registration form, should you check out before confirmed departure date or in case of no-show.

All reservations are handled by Congrex Sweden AB. Possible changes of your hotel reservation as well as cancellation must be made in writing to Congrex Sweden AB. Please do not contact the hotel directly.

Hotel Rates				
	Single room	Double room	Breakfast	Rate available until
Royal Olympic Hotel	€ 160	€ 175	included	August 30, 2007
Novotel Athenes	€ 132	€ 141	included	August 30, 2007
Esperia Palace	€ 110	€ 137	included	August 30, 2007

Payment of Registration Fee and Hotel Accommodation

Please indicate **your name and the payment reference number 0791** on all money transfers.

Congrex Sweden AB will not be responsible for identifying funds transferred directly into the account when the name of the participant or invoice number is not mentioned, nor will Congrex Sweden AB accept charges of bank fees associated with the transfer.

Payment should be made in advance by one of the following methods:

- American Express, Visa or Eurocard/Mastercard may be used for all charges. Please indicate card number and expiry date on the registration form.
- Transfer to Handelsbanken, Box 7190, SE-103 88 Stockholm, Sweden, BIC/SWIFT-Code: HANDSESS, Account no. 6137-0434 84239, IBAN No SE24 6000 0000 0000 4348 4239 in EUR to Congrex Sweden AB.
- Scandinavian residents may pay by bank or postal giro transfer. Bank giro 224-7021, or Postal giro 9052-2.

As from 3 weeks before the Conference we only accept credit card as payment. Registrations will be confirmed when Congrex Sweden AB has received payment. Admission to the Conference is granted only if Congrex Sweden AB has received the registration fee. Delegates, who have made late payments,

should bring a proof of payment to the Conference. Failure to produce this on request gives Congrex Sweden AB the right to charge the amount to your credit card.

Cancellation of Registration

Notification of cancellation must be made in writing and sent to Congrex Sweden AB. Cancellation of registration will be accepted until August 30, 2007, up to which date the total amount will be refunded less EUR 50 for administrative expenses. For cancellations made after August 30, 2007 we regret that no refunds can be made.

Cancellation of Hotel Reservation

Notification of cancellation must be made in writing and sent to Congrex Sweden AB. Cancellation of any hotel reservation will be accepted until August 30, 2007, up to which date the hotel deposit will be refunded less an administration fee of EUR 50. We regret that after August 30, 2007, we will charge you for the whole stay.

General Information

Badges

Each participant will receive a name badge upon registration. For security reasons all participants are requested to wear their name badge during all the Conference activities.

Currency

The currency in Athens is EUR.

Disclaimer/Liability

The Organising 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.



The Congrex Group works internationally with subsidiaries in the Netherlands, the United States and Sweden as well as licensed partners throughout Europe and Latin America.

Website

For the latest information about the Conference, please visit the Conference Website of the EUFEPS online at: www.eufeps.org



Conference Registration and Hotel Reservation

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Email: bae.registration@congrex.com
Website: <http://www.congrex.com>

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Conference Venue

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GR-11743 Athens, Greece
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Website: <http://www.royalolympic.com>

Sverige
Porto Betalt
Port Payé

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Acropolis



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