

First Circular



October 19-20, 2006
Hungarian Academy of Sciences,
Budapest, Hungary

**INTERNATIONAL REGULATORY
WORKSHOP ON
BIOEQUIVALENCE AND DISSOLUTION**



Organized by the



Hungarian Society for Experimental and Clinical Pharmacology (HSECP)



in co-operation with the

Pharmaceutical Complex Committee of the Hungarian Academy of Sciences (HAS)



and the

Hungarian Society for Pharmaceutical Sciences (HSPS),



under the auspices of the

American Association of Pharmaceutical Scientists (AAPS)



International Pharmaceutical Federation (FIP)



and the

European Federation for Pharmaceutical Sciences (EUFEPS)

Co-Chairs

Prof. Dr. Imre Klebovich, Budapest, Hungary

Prof. Dr. Vinod P. Shah, North Potomac, MD, USA

Local Organizing Committee

Dr. István Antal

Lajos Hegedűs

Prof. Dr. Imre Klebovich (Chair)

Prof. Dr. Tamás L. Paál

Dr. Imre Szentpéteri

Prof. Dr. Kornélia Tekes

Dr. György Thaler

Dr. Romána Zelkó

Welcome to Workshop

Welcome to the International Regulatory Workshop on Bioequivalence and Dissolution. The Organizing Committee is delighted to welcome you in the center of Europe to this event in which participants can meet leading scientists and learn of new directions in the bioequivalence/dissolution discipline.

The venue of the Workshop, the home of the Hungarian Academy of Sciences was built in 1865 in neo-renaissance style. The HAS itself was founded in 1825 and has served as one of the most distinguished institutions in Hungary.

We hope you will find the Workshop a stimulating opportunity for meeting colleagues and friends, old and new, and that you will return home with pleasant memories of the scientific event as well as of Hungary.

Main topics of the Workshop

Regulatory Concerns in BA/BE/Dissolution in Hungary

Prof. Dr. Tamás L. Paál, National Institute of Pharmacy, Budapest, Hungary

Concerns of Healthcare Practitioners and Patients

Prof. Dr. Leslie Benet, University of California, USA

Regulatory Requirements for Oral Drug Products

Prof. Dr. Vinod P. Shah, FIP, North Potomac, USA

The Fundamentals of Average Bioequivalence, Proof of Concept

Prof. Dr. Kamal K. Midha, University of Saskatchewan, Canada

Food-Drug Interactions and Their Regulatory Aspects

Prof. Dr. Imre Klebovich, Semmelweis University, Hungary

Assessment of Bioequivalence of Highly Variable Drugs

Prof. Dr. Laszlo Endrenyi, University of Toronto, Canada

Bioequivalence Metrics: Computational and Clinical Issues

Dr. László Tóthfalusi, Semmelweis University, Hungary

Cell Culture Model as a Screening Tool for Possible Prediction of Drug Absorption

Prof. Dr. Hans Junginger, Naresuan University in Thailand, Thailand

Extending the Role of Dissolution in Regulating Pharmaceutical Drug Products

Prof. Dr. Vinod P. Shah, FIP, North Potomac, USA

Quality Aspects of the Comparability of Product Performance

Dr. Hilda Kószegei-Szalai, National Institute of Pharmacy, Hungary

BCS - Concepts and Applications for Biowaivers

Prof. Dr. Gordon Amidon, University of Michigan, USA

Biowaivers for BCS Class 2 Drugs

Prof. Dr. Panos Macheras, University of Athens, Greece

In Vitro-In Vivo Correlation

Prof. Dr. Hans Junginger, Naresuan University in Thailand, Thailand

Pharmaceutical Equivalence of Biologics - Is It Feasible?

Prof. Dr. Solomon Stavchansky, University of Texas, USA

Justification of Biosimilarity in 2006

Dr. János Borvendég, National Institute of Pharmacy, Hungary

Formulation of Biotech Products Including Biopharmaceutical Considerations

Prof. Dr. Arto Urtti, University of Helsinki, Finland

Bioanalytical Methodology (New Regulatory Aspects of Bioanalytics)

Prof. Dr. Kamal K. Midha, University of Saskatchewan, Canada

Practical Aspects of Conducting and Analysing BE Studies

Prof. Dr. Atilla Hincal, University of Hacettepe, Turkey

Venues

Workshop and exhibition: Hungarian Academy of Sciences,
H-1051 Budapest, Roosevelt Sq. 9., 2nd floor.

Lunches: Hungarian Academy of Sciences,
H-1051 Budapest, Roosevelt Sq. 9., groundfloor, Academic Club Restaurant.

Gala dinner on 19 October, 2006, 20:00^h: Hotel Sofitel Budapest,
Ball Room, H-1051 Budapest, Roosevelt Sq. 2.

**Traditional Hungarian Dinner with folklore program on 20 October, 2006
19:30^h:** chartered boat to 'Ladik Csárda' of Hajógyári Island

Website of the Workshop

You will find the newest details on the website entitled www.bew.sote.hu

Language of the Workshop

The official Workshop language is English.
No simultaneous translation will be provided.

Exhibition

An exhibition of bioanalytical, analytical and pharmaceutical technology instrumentation is planned in connection with the Workshop. Analytical and bioequivalence CRO-s are also expected and welcomed for introduction.

Workshop Secretariat

Hungarian Society for Experimental and Clinical Pharmacology (HSECP)
c/o: Semmelweis University, Department of Pharmaceutics
H-1092 Budapest, Hőgyes E. St. 7., Hungary

Zsuzsanna Ábrám
Workshop Secretary

Phone/Fax: +36 1 217 0914 E-mail: abram@hogyes.sote.hu

Bank data of the Workshop:

Bank Name:	OTP Bank Rt.
Bank Address:	H-1095 Budapest, Tinódy St. 9-11., Hungary
Account No.:	11709002-20334956
Account Owner:	Hungarian Society for Experimental and Clinical Pharmacology
SWIFT Code:	OTPVHUHB
IBAN No.:	HU23 1170 9002 2033 4956 0000 0000

Schedule

Deadline for registration and payment: September 18, 2006

Scientific program: October 19, 2006, 08:30^h Start of the Workshop
October 20, 2006, 18:00^h End of the Workshop

Social programs (including gastronomic and cultural tour):
October 19, 2006, 20:00^h Gala dinner
October 20, 2006, 19:30^h Traditional Hungarian dinner
with folklore program

Workshop fee

370 € for participants (including registration fee, Workshop documentation, lunches and dinners, coffee breaks, VAT)

220 € for accompanying persons (lunches, dinners, ladies programs, VAT)

Accommodation - Recommended hotels

Prices - room/night - include breakfast and taxes.
In the case of double rooms, two breakfasts will be invoiced.

Hotel Sofitel Budapest****: (central location of the Workshop, 3 min walk)	single: 195 €;	double: 220 €
Hotel Mercure Korona****: (20 min by bus from the Workshop)	single: 115 €;	double: 130 €
Hotel Mercure Duna***: (15 min by tram from the Workshop)	single: 99 €;	double: 105 €
Hotel Ibis Centrum***: (20 min by bus from the Workshop)	single: 85 €;	double: 95 €

Rooms in the above mentioned hotels are available through the Workshop Secretariat in a limited quota, the **deadline** being **18 September, 2006**. Booking requests will be filled in the order of receiving them. Accommodation fees should also be sent to the Workshop Secretariat.

Location of Workshop and recommended Hotels in Budapest





**Application Form for the
International Regulatory Workshop on Bioequivalence and Dissolution
October 19-20, 2006, Budapest, Hungary**

Please type or use block letters and return the Application Form by post,
fax (+36 1 217 09 14), e-mail (abram@hogyes.sote.hu) or on-line at www.bew.sote.hu
before September 18, 2006.

Title: Ms. Mrs. Mr. Dr. Prof.

Name:

Affiliation:

Address:

.....

Postal code: City:

Country: E-mail:

Phone: Fax:

- I intend to participate **as attendant**. If prevented, I will inform you accordingly in written form.
- I intend to participate **as exhibitor**. Please, send me further information.
- My companion intends to participate on the **social and ladies program**.
Name:.....

Hotel requests:

Name of hotel:

Date of arrival:..... Date of departure:.....

No. of rooms:

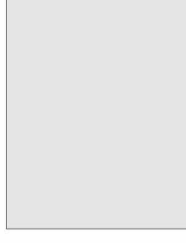
Type of rooms: single double

I understand that registration will be accepted if payments are made and certified to the Workshop Secretariat not later than September 18, 2006. In case of cancellation, the transferred Workshop and accommodation fees (subtracting bank charges) can be repaid only before September 18, 2006. No further reimbursements are possible.

Date:

Signature





**International Regulatory Workshop on
Bioequivalence and Dissolution
Secretariat**

**Hungarian Society for Experimental and Clinical Pharmacology
c/o: Semmelweis University Department of Pharmaceutics**

**H-1092 Budapest
Högyes E. St. 7.
Hungary**