



Romanian Academy
Section of Medical Sciences



Romanian Society for
Pharmaceutical
Sciences



University of Medicine and
Pharmacy "Carol Davila"
Bucharest



Society for Pharmaceutical
Dissolution Science
(SPDS)



Advances and applications in Dissolution Science

Bucharest, Romania

October 20-21, 2016

The mission of Society for Pharmaceutical Dissolution Science (SPDS) is to promote and disseminate globally the science and advancement in the field of dissolution. SPDS is the only professional society dedicated to dissolution science. Disso Europe Romania 2016 International Conference is the first such conference in Europe discussing advances and practical applications in dissolution science. This will be an excellent opportunity for the participants to interact with the global leaders and discuss their views on the advancement of dissolution science.

President: Prof. Victor A. Voicu, General Secretary of the Romanian Academy.

Vice President: Vijay Kshirsagar, Society for Pharmaceutical Dissolution Science.

General Secretary: Dr. L. Ramaswamy, Society for Pharmaceutical Dissolution Science.

Program Chair: Dr. Vinod Shah, Ex-US FDA, Pharmaceutical Consultant, USA.

Program Co-chairs: Prof. Padma Devarajan, ICT, N. P. Marg, Mumbai, India.

Prof. Jean-Michel Cardot, Université d'Auvergne, Clermont-Ferrand, France.

Dr. Flavian Rădulescu, University of Medicine and Pharmacy, Bucharest, Romania.

Final program



Advances and applications in Dissolution Science
Bucharest, Romania
October 20-21, 2016
Ramada Plaza Bucharest Convention Center

Scientific Committee

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Sponsors of the Conference



Final program

Scientific Program - Day 1st: October 20, 2016

08.30-09.15 Registration

09.15-09.30 Welcome

*Romanian Academy, Romanian Society of Pharmaceutical Sciences,
Vijay Kshirsagar and L. Ramaswamy, SPDS,
Vinod P. Shah Conference Chair,
Jean-Michel Cardot and Flavian Rădulescu Conference Co-Chairs.*

09.30-10.00 BCS, biowaivers and dissolution test methodologies

Vinod P. Shah

10.00-10.30 Selection of the most suitable dissolution technique for development and link to QC

Jean-Michel Cardot

10.30-11.00 Coffee break

11.00-11.30 Strategies for developing a dissolution method

Johannes Krämer

11.30-12.00 Drug dissolution and drug release: applications using the flow through cell apparatus

Samir Haddouchi

12.00-12.30 Rationale for using biorelevant media in dissolution testing

Christos Reppas

12.30-13.30 Lunch

13.30-14.00 Utilization of dissolution in regulating dose proportional formulations

Atilla Hincal

14.00-14.30 Roadmap to approval -

Enabling BCS based biowaivers for immediate release oral dosage products

Vatsala Naageshwaran

14.30-15.00 Investigation and root cause analysis of OOS and OOT results obtained in dissolution

Vijay Kshirsagar

15.00-15.30 Coffee break

15.30-16.00 Use of QbD principles in drug development and dissolution studies

Vijay Kshirsagar

16.00-16.30 Regulatory requirements of dissolution for generic drug products

Om Anand

16.30-17.30 Panel Discussion

Scientific Program - Day 2nd: October 21, 2016

09.30-10.00 Challenges and Unique Applications of IVIVC in Drug Development

Umesh Banakar

10.00-10.30 Can dissolution predict food and alcohol effects?

Imre Klebovich, István Antal

10.30-11.00 *Coffee break*

11.00-11.30 A science based approach to topical drug classification system (TCS) and its implications

Vinod P. Shah

11.30-12.00 In vitro drug release from semisolid dosage forms and its regulatory applications

Flavian Rădulescu

12.00-12.30 *Q&A Session*

12.30-13.30 *Lunch*

13.30-14.00 Drug release methodologies for nanomedicines: Addressing challenges

Padma Devarajan

14.00-14.30 Dissolution testing automation: principles and benefits

Michel Magnier

14.30-15.00 The transition to enhanced mechanical qualification for the Dissolution Apparatus

Bryan Crist

15.00-15.30 *Coffee break*

15.30-16.00 Application of liophilic additives in RPLC mobile phases

Andrei Valentin Medvedovici

16.00-16.30 Correlation between in vitro dissolution of clopidogrel and pharmacokinetics of its metabolites carboxyclopidogrel and 2-oxoclopidogrel

Constantin Mircioiu

16.30-17.00 Electron Microscopy - promoting in situ solutions in the pharmaceutical drug discovery research

Iulian Boerașu

17.00-17.30 *Panel discussion*

With the participation of the regulators, speakers and industry's representatives

17:30 *Closing Remarks*

Registration form

Title: _____ Family name: _____ First name: _____

(the name and title you provide here will be printed on your badge)

Institution: _____

Address: _____

Postal/Zip code: _____, City: _____, Country: _____

Telephone: _____, E-mail: _____@_____.

Do you plan to present a poster at this conference?

Yes No

Preliminary poster title / topic: _____

Registration fee (please check one):

 PhD and Master students: 50 EUR, Academia representatives: 100 EUR, Industry representatives: 150 EUR.

By sending in this registration form, I acknowledge that I commit myself to the immediate payment of the fee upon reception of the registration confirmation.

Date: ____/____/____, Signature: _____.



Fees will be paid in the following accounts

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