



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.



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

**Scientific Committee**

<b>Makrand Avachat</b> India, Industry	<b>Prof. Andrei Valentin Medvedovici</b> Romania, Academia
<b>Dr. Abha Doshi</b> India, Academia	<b>Prof. Constantin Mircioiu</b> Romania, Academia
<b>Dr. Samir Haddouchi</b> France, Industry	<b>Dr. Dalia Simona Miron</b> Romania, Academia
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<b>Prof. Dumitru Lupuleasa</b> Romania, Academia	<b>Dr. Salim Velji</b> India, Regulatory Authority
<b>Mr. Michel Magnier</b> Switzerland, Industry	

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<b>Prof. Laurian Vlase</b>	<b>Dr. Lavinia Vlaia</b>

**Sponsors of the Conference**



**Final program**

## Scientific Program - Day 1<sup>st</sup>: 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 2<sup>nd</sup>: 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 lipophilic 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: \_\_\_\_\_

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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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