



PROFESSIONAL  
EDUCATION

The United States Pharmacopeia, in conjunction with Erweka, is pleased to announce a two-day course:

## Effectively Using the *USP-NF* & Fundamentals of Dissolution

Club Mahendra Resort, Goa, India | October 4 - 5, 2006

NIPER, Mohali, Chandigarh, India | October 9 - 10, 2006

The first part of this two-day course - **Effectively Using the *USP-NF*** - provides insight into how USP operates and establishes standards, how to use the *USP-NF*, and how to take part in the standards-setting process. The second part - **Fundamentals of Dissolution** - provides focused, relevant instruction on the fundamentals of pharmaceutical dissolution testing, as described in USP General Chapter <711>. Participants will gain an overview of the theory, practice, and history of dissolution. These topics are discussed throughout the two days.

The course is intended for laboratory scientists, lab managers, and compliance staff in the pharmaceutical and allied industries.



### COURSE TOPICS :

- Introduction, history of *USP-NF*
- USP Reference Standards and the Standards-setting process
- Theory & History of Dissolution Testing
- Design of Dissolution Test
- Dissolution - Biowaivers

### INSTRUCTORS:

**Barbara B. Hubert** Barbara joined USP in 1980 and has over 30 years of experience in analytical chemistry, including over 25 years of experience developing dissolution test methods. Her research experience and interests include the development of analytical methods, compendial dissolution and drug release standards for conventional and modified release dosage forms and the establishment of purity standards for USP monographs. Barbara has published papers and lectured around the world on drug purity and quality, dissolution and bioavailability of drugs and the USP Standards development process.

**Robert Tyler** Rob is an experienced analytical chemist with laboratory experience. Rob joined USP in 2002 and is Sales Manager. He has been an instructor in the Pharmacopeial Education Program since joining USP.

**Vinod P Shah, Ph.D.** Dr. Shah is a pharmaceutical consultant. Dr. Shah retired from US FDA (Food and Drug Administration) as a Senior Research Scientist after 30 years of service in July 2005. He has received several FDA Awards for Leadership Excellence, Team Excellence and Excellence in Communication, FDA Award of Merit, FDA Scientific Achievement Award and FDA Distinguished Career Service Award. Dr. Shah is the Scientific Secretary and a member of the Executive Council of International Pharmaceutical Federation (FIP), 2003-2007. Dr. Shah is an Adjunct Professor at University of Kentucky, Lexington KY, 2001-present. Dr. Shah is author/co-author of over 200 scientific papers and is a co-editor of two books. Dr. Shah was the President of American Association of Pharmaceutical Scientists (AAPS) in 2003.

**Sandra Klein, Ph.D.** Sandra Klein is a pharmacist and got her Ph.D. from the Johann Wolfgang Goethe University of Frankfurt where she has worked in the group of Professor Jennifer B. Dressman since 2000. Before starting graduate studies, she worked for Fresenius AG, a leading manufacturer of parenteral and nutrition products for four years. Presently she is working on the development of biorelevant dissolution test methods for dosage forms with modified release and on the improvement of the bioavailability of poorly soluble drugs. Sandra Klein maintains membership in AAPS, APV and CRS and has been invited several times by the FIP, APV and CRS to present lectures in dissolution workshops.

**Frank Wucher** Frank Wucher studied process engineering with focus in biotechnology at the technical-academy in Bingen, Germany. Since April 2000 he works at ERWEKA GmbH. Presently he is the head of the customer support department. He has more than 5 years experience in calibration of testing equipments and represents the company ERWEKA in the "USP Project team No. 5: Dissolution Calibrators".



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October 4-5, 2006, Club Mahendra Resort, Goa, India.  
October 9-10, 2006, National Institute of Pharmaceutical Education  
and Research, (NIPER), Mohali, Chandigarh

### Day 1:

**Check In and Breakfast - 8:00 - 8:30 a.m.**

#### Session I - 8:30 a.m.

Welcome address & Introduction, *Kumud Sampath, USP-India & Werner Mueller, Erweka*  
USP History and Organization, *Barbara Hubert, USP*  
Effectively Using the USP-NF, *Robert Tyler, USP*

**Break for Lunch - 12:30 - 1:30 p.m.**

#### Session II - 1:30 p.m.

Effectively Using Pharmacopeial Forum, *Robert Tyler, USP*  
USP Reference Standards - an Overview, *Barbara Hubert, USP*  
Theory and History of Dissolution Testing, *Barbara Hubert, USP*  
Validation of Dissolution Tester, *Frank Wucher, Erweka*

**Adjourn 5:30 p.m.**

### Day 2:

**Check In and Breakfast - 8:00 - 8:30 a.m.**

#### Session III - 8:30 a.m.

Design of a Dissolution Test and its Importance, *Vinod P Shah, Consultant*  
Selection of Dissolution Media, *Sandra Klein, Univ. of Frankfurt*  
Biorelevant Drug Release Test for Modified-release Dosage Forms, *Sandra Klein, Univ. of Frankfurt*  
Dissolution Biowaivers and Profile Comparisons, *Vinod P Shah, Consultant*

**Break for Lunch - 12:30 - 1:30 p.m.**

#### Session IV - 1:30 p.m.

Physical and Mechanical Inspection of Dissolution System, *Robert Tyler, USP*  
Dissolution Procedure Demonstration Videos, *Barbara Hubert, USP*  
Dissolution Tester Demonstration, *Frank Wucher, Erweka*

**Adjourn 5:00 p.m.**



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**ERWEKA**  
Quality through Experience  
Since 1952

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and Research, (NIPER), Mohali, Chandigarh

### CONTACT INFORMATION

Last Name		First Name	
Title	Educational Qualifications	Organization	
Address			
City	State	Zip Code	
Phone	Fax	E-Mail	
Name for Badge			

### PAYMENT INFORMATION

**Fee (in Indian Rupees): 8500 per participant. If four or more, 7500 per participant. This fee is inclusive of Service Tax @ 12.24%.**

Full payment must accompany the registration form before it can be processed. One registration per form. Please copy the form for additional registrations.

Please mail the registration forms along with Check/Pay Order to:

**United States Pharmacopeia-India Private Limited,**  
ICICI Knowledge Park, Turkapally,  
Shameerpet, Hyderabad 500 078

Attention: K Satya Kameswari  
Ph. +91 40 2348 0088  
Fax: +91 40 2348 0089.  
Email: [ksk@usp.org](mailto:ksk@usp.org)

Enclosed is my check/pay order for INR \_\_\_\_\_  
(Check must be at par checks or Demand Draft in INR.)

- Drawn in favour of United States Pharmacopeia-India Private Limited, Payable at Hyderabad.
- Note: Registration will be closed on or before 25 September 2006.

I Would like to attend in

Goa

Chandigarh

Questions? Please contact K. Satya Kameswari, [ksk@usp.org](mailto:ksk@usp.org), at 040 2348 0088, Extn. 105 or A.V.Murali Krishna, [avm@usp.org](mailto:avm@usp.org), at 040 2348 0088, Extn.103., Ashok Dang, [ad@usp.org](mailto:ad@usp.org), at 094172 73102

Attendees should make their own lodging arrangements.



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For more information and to register contact:

**United States Pharmacopeia-India (P) Limited**

ICICI Knowledge Park, Genome Valley, Labs - 7-10, Phase III,  
Turkapally, Shameerpet, R.R.Dist. Hyderabad 500 078, A.P., India,

Ph. +91 40 2348 0088 Fax. +91 40 2348 0089

email: [ksk@usp.org](mailto:ksk@usp.org), [www.usp.org](http://www.usp.org).