

IWPCPS® - 10
**Tenth International Workshop on Physical Characterization of
Pharmaceutical Solids**

Bamberg, Germany June 8 - 13, 2008

Sunday June 8, 2008 PM

16:00 - 18:00

Registration

17:00

Seminar: XRPD for Pharmaceutical Applications

PANalytical; The Netherlands

Monday June 9, 2008

9:00

assa welcome

A. Zakrzewski, assa Inc.; USA

9:10

From Pharmaceutical Art to Pharmaceutical Science

M. Bauer, Scientific Advisor to Sanofi-Aventis;
France

Spectroscopic Characterization of Drug Substances and Drug Products

Chair: Dr. Stephen Byard, Sanofi-Aventis; UK

9:30

Introduction to the Session - Spectroscopic Characterisation of Pharmaceutical Solids

S. Byard, Sanofi-Aventis; UK

9:45

Structure & Dynamics of Pharmaceutical Solvates, Studied by NMR

R. Harris, University of Durham; UK

10:30

Application and Development of NMR Crystallography on Pharmaceutical Solids at Natural
Isotopic Abundance: Utilization of ^1H - ^1H and ^1H - ^{13}C (^{15}N) Dipolar Couplings for Structure
Refinement

J. Brus, Academy of Sciences; Czech Republic

11:00

Coffee Break

11:20

Utilization of Dielectric Techniques in Pharmaceutical R&D: Application to Amorphous Phases
and Solid Dispersions

M. Bauer, Scientific Advisor to Sanofi-Aventis;
France

11:55	X-Ray Based Spectroscopies for the Characterisation of Drug Substances and Products	S. Schroeder, University of Manchester; UK
12:25	New Possibilities for X-Ray Diffractometry	B. Hasse, J. Graf, T. Samtleben, J. Wiesmann, C. Michaelsen, Incoatec GmbH; Germany
12:55	Using XRF Spectrometry for Quality Control of Drug Products	D. Beckers, I. Campbell, L. Kempnaers, PANalytical B.V.;The Netherlands
13:20	Lunch	
15:00	The Role of MRI in Characterising Solid Dosage Forms	L. Gladden, University of Cambridge; UK
15:40	T.K.	A. Djemai, Merck Sharp and Dohme; UK
16:10	Applications of Terahertz Pulsed Spectroscopy to Pharmaceutical Solid State Analysis - An Overview	L. Ho, Teraview; UK
16:40	SPM Based Photothermal Spectroscopy: Principles and Applications	M. Reading, University of East Anglia; UK
17:10	assa welcome Coffee Break and Mixer	
17:45	Raman Spectroscopy: From Pre-Formulation to Product	A. Williams, University of Reading; UK
18:15	Discussion Round	

Tuesday June 10, 2008 AM

Advanced Characterization of Pharmaceutical Materials- Selecting the Best Tool for Your Analysis (Thermal Methods, IR, Raman)
Chair: Svenja Goth, Perkin Elmer USA

8:00	Studying Physical Forms in Formulated Systems	G. Buckton, University of London; UK
------	---	--------------------------------------

8:45	Differentiating Surface and Bulk Properties of Solids in Relation to Functionality	R. Pinal, Purdue University; USA
9:15	Large Sample Analysis with an Automated Confocal and Raman Atomic Force Microscope Combination	M. Kress, WITec GmbH; Germany
9:40	Morphology Influence on Thermal Behavior of Aripiprazole Monohydrate	M. Rajić Linarić, Ž. Jelčić, A. Kwokal, H. Cerić, N. Košutić Hulita, E. Meštrović, PLIVA Croatia Ltd.; Croatia
10:05	Coffee Break	
10:25	Rapid Raman Imaging of Pharmaceutical Tablets Using a Novel Continuous Readout Technique	T. Smith, I.P. Hayward, Th. Olschewski, Renishaw plc; UK
10:50	Prediction of Materials' Properties Based on Thermokinetic Evaluation of Dehydration and Decomposition Reactions	G.Kaiser, NETZSCH-Gerätebau GmbH; Germany
11:15	Discussion Round	
11:45	Lunch break	

Tuesday June 10, 2008 PM

Screening for and Characterization of Solid Forms Chair: Dr. Norbert Nagel, Sanofi-Aventis; Germany

13:15	How to select the Optimal Salt, Co-Crystal or Polymorph	R. Hilfiker, Solvias AG; Switzerland
14:00	Robotic Screening in Discovery: a Salt Screening Case Study	J. Menegotto, H. Duplaa, C. Ponthus, C. Picard; Sanofi-Aventis; France
14:25	Polymorph Screening and Selection: Conventional Approach or High-Throughput Screen?	G. Winter, Bayer-Schering; Germany
14:50	Diversity: A Principle of Efficient Solid Form Screening	R. Dam, Avantium; The Netherlands

15:15	High Resolution Real Time Tracking of Modified Release Dosage Form in the Gastrointestinal Tract	W. Weitschies, University of Greifswald; Germany
15:40	Coffee Break	
16:00	Structural Determination of Novel Metastable Form of Tolbutamide by Synchrotron X-Ray Powder Diffraction	T. Terada, University of Toho; Japan
16:25	Solid-State Characterization of Pharmaceutical Coatings - From Nanometers to Macroscopic Dimensions	S. Schantz, AstraZeneca R&D; Sweden
16:50	Assessment of the Impact of Crystal Form on Bioavailability Using Pharmacokinetic Modeling	P.E. Luner, K.Sagawa, Pfizer Global Research and Development; USA
17:15	News from Old Drugs: Investigations on the Polymorphism of Glucocorticoids	C. Näther, University of Kiel; Germany
18:00	Discussion Round	
18:30	<i>Seminar: Modern Thermal Analysis</i>	<i>Perkin Elmer; UK</i>

Wednesday June 11, 2008 AM

Patent and Litigation Support for Pharmaceutical Solids Chair: Dr. Robert Whittock; Freshfields Bruckhaus Deringer; UK

8:00	Overview of Patent Process for Pharmaceutical Solids	J. Lindemann, Nixon Paebody; USA
8:45	Applying Lessons from Litigation to Defining the Pharmaceutical Invention	M. Feldstein, Finnegan, Henderson, Farabow, Garrett and Dunner, LLP; USA
9:30	Case Example - Litigation in the USA	E. Longton, Milbank, Tweed, Hadley & McCloy; USA
10:15	Coffee Break	

10:45 On Being an Expert Witness T. Threlfall, University of Southampton; UK

11:30 How Basic Science Should Prevent from Deleterious Effects of Patent Litigations: A Case Study Regarding the Amorphous State R. Ceolin, University of Paris; France

12:15 Pharmaceutical Patents - Past, Present and the Future R. Whittock; UK

12:45 Discussion Round

13:15 PM **Lunch Break**

Wednesday June 11, 2008 PM

15:00 **Exhibitor Presentation Session** **Chair: H.**
Brusova; Zentiva; Czech Republic

Exhibition open until 6 pm

18:00 **Seminar: Fast Imaging RAMAN Technology** **Renishaw, UK**

Thursday June 12, 2008 AM

Amorphous Content in Pharmaceutical Material
Chair: Dr. Marc Descamps; University of Lille; France

8:00 Carbohydrates in Amorphous States: Molecular Packing, Nanostructure and Interaction with Water J.B. Ubbink, Nestle Research Center; Switzerland

8:45 Nucleation in Amorphous Pharmaceutical Compounds: Some Aspects M. Descamps, University of Lille; France

9:10 Excipient / API Glass Solutions: Impact of the Nature of the Excipients on the Ultimate Stability A. Aumelas*, J.R. Authelin **, M. Descamps*, *University of Lille; France; **Sanofi-Aventis; France

9:35 A Structured Approach to Investigate and Develop Amorphous Systems T. Rades, University of Otago; New Zealand

10:00 Micro/Nano Thermal Analysis of Pharmaceutical Dosage Forms M. Reading, University of East Anglia; UK

10:25 **Coffee Break**

10:45 Ordering and Disordering of Pharmaceuticals upon Mechanical Milling: The J.F. Willart, M. Descamps, N. Dujardin, E. Dudognon, University of Lille; France
Role of Tg

11:10 The Use of Amorphous Compounds in Drug Discovery and Early Development V. Cooper, Merck Sharp & Dohme; UK

11:35 Discussion Round

12:00 **Lunch Break**

Thursday June 12, 2008 PM

Detecting Process Induced Transformations in Solid State Formulations

Chair: Dr. Thomas Rades, University of Otago; New Zealand

13:30 Determination of Hydrate Formation During the Dissolution Process T. Rades, University of Otago; New Zealand

14:15 Simultaneous Detection of Dissolution and Solid State Properties of Solid Dosage Forms J. Aaltonen, University of Helsinki; Finland

15:00 Terahertz Pulsed Imaging as a Process Analytical Technique for Tablet Film Coating L. Ho, Teraview; UK and T. Rades, University of Otago; New Zealand

15:45 **Coffee Break**

16:15 Assessing Prediction Parameters for the Stability of Amorphous Pharmaceutical Compounds K. Graeser, University of Otago; New Zealand

17:00 Discussion Round

18:00 Seminar: Particle Size Analysis and its Pharmaceutical Applications Sympatec; Germany

Friday June 13, 2008 AM

Development and Validation of Quantitative Solid State Methods Chair: Dr. Peter V. Hoof, Organon; The Netherlands

9:00	Issues in Quantitative Solid State Method Development and Validation: Overview	An	P. Van Hoof, Organon; The Netherlands
12:50	Solid-State Method Development and Validation: The Rationale of a Staged Approach. What is Necessary from a "Submission" Point of View Related to the Different Stages of Development?	C. Field, Boehringer Ingelheim; USA	
9:45	Development and Validation of Quantitative Methods Using Solid State NMR	E. Munson, University of Kansas; USA	
10:10	Development and Validation of Quantitative Methods using XRPD	V. Kogan, Danalab; The Netherlands	
10:35	Development and Validation of Quantitative Methods Using SAXS, SWAXS and GISAXS	P. Laggner, Hecus X-Ray Systems; Austria	
11:00	The Determination of Amorphous Content Using Microcalorimetry	K.Jarring, AstraZeneca; Sweden	
11:25	Coffee Break		
12:00	Comparison of DSC, XRPD, SS-NMR and FT-Raman to Determine Amorphous Content	M. Scarzello, Organon; The Netherlands	
13:15	Discussion Round		
13:45	Lunch		

Poster Presentations

Modeling dissolution of drugs in stomach environment

B. Markun, I. Legen and K. Kočevar, Lek
Pharmaceuticals, Slovenia

Solid-state characterization of co-crystal prepared by co-grinding and co-precipitation methods	Ibrahim, A., Grimsey, I., Bonner, M. C., Blagden, N. and Forbes, R.T.
Study of Polymorphism in Ramipril	R. Chadha, P. Arora, S. Gupta and A. Sharma, Panjab University; Chandigarh.
Quantitative Determination of Crystal Modifications in Active Pharmaceutical Ingredients by FT-IR, NIR and XRPD	G. Klein, S. Graswinckel, M. Ruijken, P. Hoogkamer, M. ter Horst, J. Winder and P. Muijselaar, Solvay Pharmaceuticals; The Netherlands
Determination of Specific Surface and Particle Size Distribution by Small Angle X-Ray Scattering	D. Beckers, J. Bolze, PANalytical B.V., Almelo, The Netherlands
The Solvate Formation of Ethinyl Estradiol - A Rational Insight	N.W.C. Eeuwijk ¹ , C. Guguta ² , J.M.M. Smits ² , R. de Gelder ² , P.J.C.M. van Hoof ¹
Thermal Expansion of Crystals	C.J. Coles, T. Horton, M.B. Hursthouse, S. Huth, G. Tizzard and T.L. Threlfall, University of Southampton, U.K.