

IWPCPS® - 12
twelfth International Workshop on Physical Characterization of
Pharmaceutical Solids

Lille, France
June 21-24, 2010

Monday June 21, 2010

assa® welcome

A. Rehfeldt, assa® Inc.; USA

Introduction

M. Bauer, Scientific Adviser to the R&D Direction of Sanofi-Aventis; France

Topological Tools to Determine the Stability Hierarchy of Drug Polymorphs From Suitable Experimental Data and Non Biased Thermodynamics

R. Ceolin, University of Paris; France

Characterization and Quality Control of Drug Product
Session Chair: Dr. Peter v. Hoof, Shering Plough; The Netherlands

Specification Setting and Quality Control of Physical Critical Attributes

P.v. Hoof; Shering Plough; The Netherlands

XRPD Quantification of Polymorph Impurities in Finished Drug Product

V.Kogan, Danalab; The Netherlands

Application of Multivariate Analysis in Understanding Polymorphic Transformation of Drugs – a Case Study With Carbamazepine

T. Rades, University of Otago; New Zealand

X-Ray Nanostructure Analytics as a Tool in Drug Development, Process and Quality Control

P.Laggner, Austrian Academy of Science, Graz; Austria

COFFEE BREAK

Story of a Generic Product

H. Brusova, Zentiva k.s.; Czech Republic

Specification Setting and Quality Control of Physical Critical Attributes

M. Scarzello, Shering Plough; The Netherlands

Discussion Round

Lunch

Interactive Pharmaceutical patents Session - from Invention to Litigation PART I

Session Chair: R. Whittock, Freshfields Bruckhaus Deringer; UK

The Case Study

R. Whittock, Freshfields Bruckhaus Deringer; UK

Identifying the Invention & Obtaining Patents

M. Feldstein, Finnegan, Henderson, Farabow, Garrett and Dunner LLP; USA

'The Work Around'

M. Dzwonczyk, Sughrue Mion PLLC;

Tuesday June 22, 2010

Interactive Pharmaceutical patents Session - from Invention to Litigation PART I

Session Chair: R. Whittock, Freshfields Bruckhaus Deringer; UK

Mock US Trial

M. Feldstein, Finnegan, Henderson, Farabow, Garrett and Dunner LLP; USA; **M. Dzwonczyk**, Sughrue Mion PLLC; USA; **R. Ceolin**, University of Paris; France; T. Threlfall, University of Southampton; UK; **M. Engelman**, Hardwicke Building, UK

COFFEE BREAK

Mock UK Trial

J. Ball, Norton Rose LLP; UK; **R. Whittock**, Freshfields Bruckhaus Deringer LLP; UK; **M. Engelman**, Hardwicke Building, UK

Discussion Round

Lunch

Solid State NMR for Pharmaceuticals
Session Chair: T. Larsson, Astra Zeneca; Sweden

Introduction to SSNMR
Applications of Solid-State NMR in Pharmaceutical Development
Applications of Magnetic Resonance Imaging to Pharmaceutical Development
NMR Powder Crystallography

T. Larsson, AstraZeneca; Sweden
S. Staffan, AstraZeneca; Sweden
L. Hughes, AstraZeneca; UK
L. Emsley, University of Lyon; France

COFFEE BREAK

High-Resolution ¹H Solid-State NMR Methods for Characterising Hydrogen Bonding in Pharmaceutical Compounds

S. Brown, University of Warwick; UK

New Perspectives of Multinuclear SS-NMR in the Characterization of API in Dosage Forms: Pseudopolymorphism and Polymorphism as Seen by ¹⁹F, ¹⁵N and ¹¹B SS-NMR Techniques

J. Brus, Academy of Science; Czech Republic

Discussion Round

Wednesday June 23, 2009

Sticking, A Serious Problem in the Tablet Manufacturing Process: Could We Comprehend This Phenomenon and Remedy
Session Chair: Michel Bauer, Scientific Adviser to the R&D Direction of Sanofi-Aventis and X. Pepin, Sanofi Aventis; France

Session Introduction
Sticking During Tablets Manufacture- Potential Origins
Theoretical Aspects on Adhesion and Cohesion
Analytical Tools to Anticipate Sticking

M. Bauer, Scientific Adviser to the R&D Direction of Sanofi-Aventis; France
X. Pépin, Sanofi-Aventis, France
P. Tchoreloff, University of Paris; France
N.A.

COFFEE BREAK

Sticking Issues in the Pharmaceutical Industry: Characterization and Troubleshooting - Case Study

U. Deodhar, Novartis; Switzerland

Sticking Issues in the Pharmaceutical Industry: Characterization and Troubleshooting - Case Study

P. Rivière, Sanofi-Aventis; France

Discussion Round

Lunch

Amorphous Pharmaceuticals

Session Chair: M. Descamp, University of Lille, France

Manufacture of Amorphous Solids at Industrial Scale in the Pharmaceutical Industry

J.R. Authelin, C. Bonvoisin, N. Midoux, S. Maret, Sanofi Aventis; France

How to Predict Physical Stability of Amorphous Dispersions?

S. Greco, M.A. Perrin, J.R. Authelin, Sanofi Aventis; France

Physical Stability Assessment of Amorphous Solid Dispersions

S. Qi, University of East Anglia; UK

AFM Studies of Amorphous and Co-Crystal Forms of Pharmaceutical Materials

W. Jones, University of Cambridge; UK

COFFEE BREAK

Addition of Surfactants in Amorphous Spray-Dried Dispersions: What Impact Does It Have on the Bioavailability and Physical Stability

S. Greco, Sanofi Aventis; France

Case Study on How to Develop Amorphous Drugs

T. Rades, University of Otago; New Zealand

The Potential of Milling to Produce New Glass Solutions: Associated Physical and Chemical Stability Problems

J.F. Willart, E. Dudognon, N. Dujardin, M. Descamps, University of Lille; France

Discussion Round

Thursday June 24, 2009

Solid State Characterization Methods and Physical Stability of API- Dispersions

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

Introduction to the Session

Solid-State Characterization Methods and Physical Stability of Glass Solutions

Formation, Stability and In Vitro Performance of Amorphous Drug-Drug Mixtures

The Influence of Excipients and Biomacromolecules on the Solid State of Mannitol

Characterization of Physicochemical Stability of Protein in Spray Dried Product

T. Rades, University of Otago; New Zealand

T. Rades, University of Otago; New Zealand

J. Aaltonen, University of Eastern Finland; Finland

H. Grohganz, University of Copenhagen; Denmark

A. Mingshi Yang, University of Copenhagen; Denmark

COFFEE BREAK

Visualizing Phase Changes in Amorphous Solids During Dissolution

Determining the Physical Stability of (Tox-)Suspensions Using Raman Spectroscopy

F. Tian, University of Copenhagen; Denmark

M. Scarzello, Shering Plough; The Netherlands

Discussion Round

Lunch

Solid State Phase transformations *Session Chair: Dr. Paul Luner, Pfizer Inc.; USA*

An Overview of Solid State Phase Transformation Mechanisms

Solid - Solid Transformations in Conglomerate-Racemic Compound Hydrate Conglomerate Systems

Solid State Transformations and Implication of Dynamic Disorder in Crystalline Polymorphism

Solid State Phase Transition Process by Powder X-ray Diffraction Structural Analysis

N.N.

Impact of Milling on a Low Solubility API and its Implications for Drug Product - A case study

G. Coquerel, University of Rouen; France

G. Coquerel, University of Rouen; France

M. Descamps, University of Lille; France

K. Terada, University of Toho; Japan

P. Luner, Pfizer R&D; USA

Discussion Round

Poster

Unbiased Melting Enthalpies of Pharmaceutical Solids With Non-Negligible Vapor Pressures	I. Rietveld, University Paris Descartes; France
Topological And Experimental P-T-X Diagram of the Camphor Enantiomers	I. Rietveld, University Paris Descartes; France
Pressure-Temperature Melting Curves of Molecular Solids of Pharmaceutical Interest	R. Ceolin, University Paris Descartes; France
Solid State Studies of Ternidazole, an Antiprotozoal Drug : Crystal Structure and P-T State Diagram	R. Ceolin, University Paris Descartes; France
Congruently Melting Molecular Solids	R. Ceolin, University Paris Descartes; France
Polymorphism of Progesterone : P-T Diagram from Topology and Experiment	R. Ceolin, University Paris Descartes; France