

2006 EDQM SYMPOSIUM**NEW IMPURITIES CONTROL: SETTING SPECIFICATIONS
FOR ANTIBIOTICS AND SYNTHETIC PEPTIDES****Duration: 1,5 days, Location: Council of Europe, Strasbourg, France****Working language: English**

PROGRAMME**THURSDAY 21 SEPTEMBER 2006****8:00 - 9:00 Registration****OPENING SESSION****9:00 - 9:10 Opening Remarks****Dr Michael Morris**, Chair of the European Pharmacopoeia Commission**9:10 - 9:30**

How the European Pharmacopoeia policy on impurities was set out

- General monograph on 'Substances for pharmaceutical use'

- General Chapter 5.10 on 'Control of impurities and specific monographs'

Mr Peter Castle, Secretary to the European Pharmacopoeia Commission (EDQM,
Council of Europe)**SESSION I: ANTIBIOTICS****Moderator: Dr Michael Morris**

Chair of the European Pharmacopoeia Commission

9:30 - 10:00 Monograph specifications (case studies)**Dr Jan W.H. Smeets**, DSM Anti-Infectives BV (NL)**10:00 - 10:30** Regulatory assessment and expectations**Dr Cornelia Nopitsch Mai**, BfArM (D)**10:30 - 11:00 Coffee break****11:00 - 11:30** Manufacturer's approach to specifications**Dr Hanno Binder**, Sandoz GmbH Quality Management (A)**11:45 - 12:30** Workshop: How to limit unknown impurities

Delegates will be divided into two parallel working groups.

Workshop 1, Room 1 Moderators:- **Dr Bernhard Wolf**, Merckle GmbH (D)- **Mr Philippe Villatte**, Sanofi Aventis (F)*Workshop 2, Room 10* Moderators:- **Mrs Katjusa Kreft**, LEK Pharmaceuticals dd (SLO)- **Prof Dr Jos Hoogmartens**, Katholieke Universiteit Leuven (B)**12:30 - 14:00 Lunch break****14:00 - 14:45** Workshop: How to limit unknown impurities (continued)**14:45 - 15:15 Coffee break****15:15 - 16:00** Workshop conclusions**Presented by the four moderators****16:00 - 17:30** Round-table Discussion

With the participation of:

Dr Michael Morris, Chair of the European Pharmacopoeia Commission, **Dr Jean-Louis Robert**, Chair
QWP (EMA) and Chair of the Steering Committee of the Certification Procedure (EDQM, Council of
Europe); **Prof. Alain Nicolas**, President of the European Pharmacopoeia Group of Experts No. 7;**Mr Peter Castle**, Secretary to the European Pharmacopoeia Commission (EDQM, Council of Europe)

FRIDAY 22 SEPTEMBER 2006**SESSION II: SYNTHETIC PEPTIDES****Moderator: Mr Peter Castle****Secretary to the European Pharmacopoeia Commission (EDQM, Council of Europe)**

9:00 - 9:20 Monograph specifications (case studies)
Dr Peter Jongen, RIVM (NL)

9:20 - 9:40 Toxicological aspects of peptide - related impurities
Dr D. J. Van den Dobbelaere, NV Organon (NL)

Manufacturer's approach to specifications

9:40 - 10:10 . Towards the identification of related peptides impurities and interpretation of the monographs
Dr Silvia Arrastia and **Dr Sergi Pavon** BCN Peptides SA (E)

10:10 - 10:40 *Coffee break*

Manufacturer's approach to specifications

10:40 - 11:10 . Manufacturers' approach to control impurities in peptide manufacturing; a proposal to set specifications for peptide API's
Mr Bernard van Genugten and **Dr Ivo Eggen**, Diosynth BV (NL)

11:10 - 12:00 Round-table Discussion

With the participation of:

Dr Michael Morris, Chair of the European Pharmacopoeia Commission, **Dr Jean-Louis Robert**, Chair QWP (EMA) and Chair of the Steering Committee of the Certification Procedure (EDQM, Council of Europe);

Dr Jan Willem Dorpema, President of the European Pharmacopoeia Group of Experts No. 6 Biological Substances; **Mr Peter Castle**, Secretary to the European Pharmacopoeia Commission (EDQM, Council of Europe)

12:00 Final addresses and Closure of the meeting

12:15 - 13:30 *Lunch break*

DEBRIEFING MEETING

Important: A restricted meeting with national authority participants.

13:30 - 16:30 This meeting is open to national authority participants ONLY.

FOR MORE INFORMATION PLEASE VISIT THE WEBSITE : <http://www.pheur.org>