



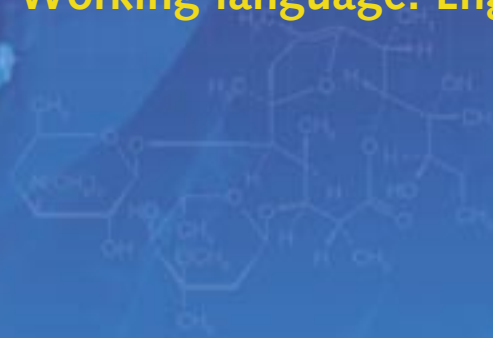
Copenhagen, Denmark, 5-6 May 2003

*Microbiological Control
Methods in the European
Pharmacopoeia:
Present and Future*

**International symposium organised
by the EDQM, European Pharmacopoeia**

Scientific Programme

Working language: English



MICROBIOLOGICAL CONTROL METHODS PRESENT

Monday, 5 May 2003

Opening Session

- **Welcome address**

8:30 Prof. Dr H. G. Kristensen, Chair of the European Pharmacopoeia Commission

Session I: International Harmonisation Update

Chair: Prof. Dr H. G. Kristensen, Chair of the European Pharmacopoeia Commission

- **Sterility**
- **Microbiological examination of non-sterile products: microbial enumeration tests, tests for specified micro-organisms**
- **Microbial limits for non-sterile dosage forms**
- **Mycoplasma testing and PCR**

8:40 Mr P. Castle, Secretary to the European Pharmacopoeia Commission

9:25 Discussion

Session II: Alternative Methods/New Control Methods

Chair: Dr K. Haberer, Compliance Advise & Services in Microbiology GmbH (D)

Implementation, validation and registration of rapid microbiological test methods

9:30 Dr P. Newby, Glaxo Wellcome (UK)

9:55 Discussion

Microbiological testing of water

10:00 Dr S. Guyomard, Aventis Pharma (F)

10:25 Discussion

10:30 Coffee break

Microplasma testing by PCR

- Development and validation

10:55 Dr L. Mallet, Aventis Pasteur (F)

- Application

11:15 Dr T. Hämmerle, Baxter Vaccine AG (A)

11:35 Discussion

Rapid identification of micro-organisms based on molecular biological method

11:40 Dr T. Sasaki, National Institute of Infections Diseases (J)

12:05 Discussion

Validation of alternative methods: a compendial approach

12:10 Dr D. Porter, Information and Standards Development, US Pharmacopeia (USA)

12:35 Discussion

12:40 Lunch

IN THE EUROPEAN PHARMACOPOEIA: AND FUTURE

Session III: Development of Culture Media

Chair: Dr H. Van Doorne, Universitair Centrum voor Farmacie – Rijksuniversiteit (NL)

Validation of existing formulas

14:00 Mrs J. Sobhane, Biomerieux (F)

14:25 Discussion

Culture media for biological testing: pitfalls, developments and quality control

14:30 Dr P. Van Netten, Merck KGaA (D)

14:55 Discussion

Development of an innovative medium with chromogenic characteristics

15:00 Dr F. Villeval, Biomerieux (F)

15:25 Discussion

Innovative selective media to detect specified micro-organisms. Why the pharmaceutical industry does not use them!

15:30 Mr C. Booth, Oxoid Ltd (UK)

15:55 Discussion

16:00 Coffee break

Session IV: Microbiological Testing of Raw Materials

Chair: Prof. Dr H. G. Kristensen, Chair of the European Pharmacopoeia Commission

A survey of current practice

16:30 Dr B. Alexander, Medicines Testing Laboratory (UK)

16:55 Discussion

Microbiological quality of herbal medicinal products

17:00 Dr L. Kabelitz, PhytoLab GmbH & Co. KG (D)

17:25 Discussion

Tuesday, 6 May 2003

Session V: Sterilisation Processes

Chair: Prof. J.C. Darbord, Pharmacie Centrale des Hôpitaux de Paris (F)

Biological indicators of sterilisation: standards and pharmacopoeial requirements

9:00 Dr K. Haberer, Compliance Advise & Services in Microbiology GmbH (D)

9:25 Discussion

Biological indicators of sterilisation: update on ISO/CEN activities

9:30 Dr K. Hahnen, 3M Laboratories (Europe) (D)

9:55 Discussion

The Fo-concept, its application and limitations

10:00 Dr H. Van Doorne, Universitair Centrum voor Farmacie – Rijksuniversiteit (NL)

10:25 Discussion

10:30 Coffee Break

The PIC/S position on parametric release

11:00 Dr L. Hamilton, Läkemedelsverket (S)

11:25 Discussion

Session VI: Final Round Table Discussion

11:30 - 12:30 Round table discussion dedicated to the following topics:

- International Harmonisation: Needs and perspectives
- Validation: Route to harmonisation or obstacle for improvement
- Batch release of non-sterile raw materials and finished products with an alternative method: experience from participants

With the participation of:

JP, Ph.Eur, USP representatives and representatives from the Industry, National Authorities, licensing and control laboratories (OMCLs)

Programme Committee

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P. Castle, EDQM, Council of Europe;
E. Charton, EDQM, Council of Europe;
J.-C. Darbord, Pharmacie centrale des Hôpitaux de Paris, F;
V. Fenton-May, SMPU, GB;
S. Guyomard-Devanlay, Aventis Pharma, F;
K. Haberer, Compliance Advise & Services in Microbiology GmbH, D;
F. Jolyon, BioMérieux, F;
H. G. Kristensen, Chair of the European Pharmacopoeia Commission;
H. Seyfarth, Boehringer Ingelheim Pharma KG, D;
H. Van Doorne, Rijksuniversiteit, NL.



Organisation

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