

Advisory Committee for Pharmaceutical Science
Meetings July 19-20, 2001

Day 1: July 19

Subcommittee Reports

Orally Inhaled and Nasal Drug Products Subcommittee

CDER Guidance for Industry, Bioavailability and bioequivalence studies for nasal aerosols and nasal sprays for local action, Draft Guidance, June 1999.

CDER Guidance for Industry. Allergic rhinitis: Clinical development programs for drug products. Draft Guidance, April 2000.

Optimal Applications of At-line Process Controls on Pharmaceutical Production

Hussain, A. S., Optimal Applications of In-Line or At-line Process Controls on Pharmaceutical Production. Memorandum to ACPS members, dated 14 June 2001.

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CDER/OPS Office of Testing and Research. Rapid chemical imaging of product quality characteristics: Preliminary data. Power point presentation. Undated

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The European Agency for the Evaluation of Medicinal Products, Concept paper on the development of a Committee for Proprietary Medicinal Products / Committee for Veterinary Medicinal Products (CPMP/CVMP) note for guidance on the use of near infrared spectroscopy by the pharmaceutical industry and the data to be forwarded in the Part II of the dossier for a marketing authorisation. 1 March 2001.

The European Agency for the Evaluation of Medicinal Products. Committee for Proprietary Medicinal Products. Note for guidance on parametric release. 1 March 2001.

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Hailey, P. A. et al. Automated system for the on-line monitoring of powder blending processes using near-infrared spectroscopy. Part I. System development and control. J. Pharm. Biomed. Anal. Vol. 14 pp. 551-559. 1996.

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Plugge, W. and C. van der Viles. Near-infrared spectroscopy as a tool to improve quality. J. Pharm. Biomed. Anal. Vol. 14, pp. 891-898. 1996.

Raju, G. K., MIT Pharmaceutical manufacturing initiative (PHARMI), MIT program on the pharmaceutical industry, Massachusetts Institute of Technology. Power Point presentation dated July 2001

Thosar, S. S. et al. A comparison of reflectance and transmittance near-infrared spectroscopic techniques in determining drug content in intact tablets. Pharm Dev. and Tech. Vol 6 No. 1 pp. 19-29. 2001.

Zannikos, P. N. et al. Spectrophotometric prediction of the dissolution rate of carbamazepine tablets. Pharm. Res. Vol. 8 No. 8 pp. 974-978. 1991.

Microbiology

Lewandoski, N. Is there time for rapid micro? Pharmaceutical Formulation and Quality. April/May 2001. pp. 17-22.

Reynolds, D. T. and C. R. Fricker. Application of laser scanning for the rapid and automated detection of bacteria in water samples. J. Appl. Micro. Vol. 86 pp. 785-795. 1999.

Wallner, G. et al. The ChemScan system: a new method for rapid microbiological testing of water. European Journal of Parenteral Science. Vol 2 No. 4 pp. 123-126. 1997.

Day 2: July 20

Clinical Pharmacology

Agatonovic-Kustrin, S. et al. Prediction of drug transfer into human milk from theoretically derived descriptors. Analytica Chimica Acta. Vol. 418 pp. 181-195. 2000.

Ito, S. Drug therapy for breast-feeding women. NEJM. Vol. 343 No. 5 pp.118-126. 2000.

Kari, F. W. et al. Active transport of nitrofurantoin across the mammary epithelium *in vivo*. Journal of Pharmacology and Experimental Therapeutics. Vol. 280. No. 2 pp. 664-668. 1996.

Oo, C. Y. et al. Active transport of cimetidine into human milk. Clinical Pharmacology and Therapeutics Vol. 56. No. 5 548-555.

Complex Drug Substances - Liposome Drug Products

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