



3rd Workshop on the Characterization of Heparin Products

Symposium organized by United States Pharmacopeial Convention, the National Institute of Biological Standards and Control and the European Directorate for the Quality of Medicines and Health Care/Council of Europe

July 27-28, 2009

USP Headquarters, Rockville, Maryland, USA

Duration: 2 days, Working Language: English

~ PROGRAM ~

Day One: Monday, July 27, 2009

- 7:00 a.m. Registration/Continental Breakfast
8:00 a.m. Welcome and Introduction: R. Williams, USP

SESSION 1: LMW HEPARINS: STANDARDIZATION AND BIOSIMILARS

Chair: J-M Spieser, EDQM

Bioassay for LMW Heparins

- Replacement of the International Standard for LMW Heparins
8:10 a.m. Replacement of the 2nd IS for LMW Heparins (E. Gray, NIBSC)

Potency Assignment and Reference Standards

- 8:30 a.m. The Limit of Common RS for the Characterization of LMWH: The Case of Enoxaparin (P. Anger, Sanofi-Aventis)
8:50 a.m. Potency Assignment and Reference Standards, Low and Ultra-low Molecular Weight Heparins (P.C. Sainz-Ezquerro, Rovi, S.A.)
9:10 a.m. Enzymatic chromogenic assays-LMW Heparin (R. Lecky, LEO Pharma)
9:40 a.m. Panel Discussion

10:00 a.m. Morning Break

Biosimilars for LMW Heparins

- Regulatory and International Issues
10:30 a.m. EMEA update (E. Gray, NIBSC)
10:50 a.m. US regulatory update (G. Woollett, Engel & Novitt)



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Experiences with Biosimilar LMWH

- 11:10 a.m. Quality heparin for LMWH preparation (L. Li, Shenzhen Hepalink)
11:25 a.m. Immunogenicity of LMWH and their biosimilars (J.M. Walenga, Loyola University)
11:45 a.m. Manufacture of LMWHs-Gland's experience (G. Nadamuni, Gland Pharma)
12:00 noon Panel Discussion

12:30 p.m. Lunch & Poster Viewing

SESSION 2: LMW HEPARINS: CHARACTERIZATION AND STANDARDIZATION

Chairs: E. Gray and B. Mulloy, NIBSC

Physico-Chemical Characterization of LMW Heparins

- 2:00 p.m. Overview of LMWHs: Current characterization tests (P. Jongen, RIVM)
2:20 p.m. NMR Spectroscopy: Identity and Purity Test of LMWH (I. McEwen, MPA)
2:40 p.m. Oligosaccharides Isolated from LMWH Display Anti-Factor Xa Activity not Systematically Correlated with the Strength of their Affinity for Antithrombin (C. Viskov)
3:00 p.m. Panel Discussion

3:30 p.m. Afternoon Break

Physico-Chemical Characterization of LMW Heparins cont'd

- 3:45 p.m. Chromatographic Methods for Analysis and Control of Enoxaparin Sodium (I. Capila, Momenta)
4:10 p.m. Panel Discussion
4:50 p.m. Rapporteur Wrap-up (Z. Shriver, MIT)

5:00 p.m. Adjourn

Day 2: Tuesday, July 28, 2009

SESSION 3: UNFRACTIONATED HEPARIN (UFH) ISSUES

Chair: T. Morris, USP

- 7:30 a.m. Continental Breakfast

Replacement of UFH International Standard for Potency

- 8:00 a.m. Collaborative study results from the 6th IS (E. Gray, NIBSC)
8:20 a.m. How UFH Therapy and Neutralization of UFH by Protamine are Monitored in Clinical Practice (J. Harenberg, Ruprecht-Karls University Heidelberg)

Contamination of Heparin—Progress Report from the Licensing Authorities*

- 8:40 a.m. US: FDA (A. Al-Hakim)
9:10 a.m. Contamination of Heparin-Japan update (S. Uzu)
9:30 a.m. Panel Discussion



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10:00 a.m. Morning Break

Physico-Chemical Characterization of UFH

- 10:30 a.m. Utility of Anion Exchange HPLC Coupled with Depolymerization to Monitor New Contaminants (P. Anger, Sanofi-Aventis)
- 10:50 a.m. Capillary Electrophoresis of Impurities in Heparin (T. Wielgos, Baxter)
- 11:20 a.m. NMR Spectroscopy: Identity and Purity Test of UFH (I. McEwen, MPA)
- 11:40 p.m. Molecular Weight Distributions for UFH: A Potential Reference Material (B. Mulloy, NIBSC)
- 11:50 a.m. Panel Discussion

12:00 noon Lunch & Poster Viewing

Pharmacopeias—Heparin Monograph Revisions & Global Harmonization

- 1:00 p.m. USP Heparin Monograph Revisions- Stage 2 and Beyond (A. Szajek)
- 1:20 p.m. EP Update (J-M. Spieser)
- 1:40 p.m. JP: Revision of Heparin Sodium and Heparin Calcium Monographs (N. Kawasaki)
- 2:00 p.m. Panel Discussion

2:30 p.m. Afternoon Break

Industry Implementation of the Proposed USP Heparin Monographs

- 3:00 p.m. TGA Update on Contamination of Heparin (via conference call)
- 3:20 p.m. Heparin Sodium Analytics: 2008 and Beyond (E. Kellenbach, Schering-Plough)
- 3:40 p.m. Heparin Impurities Testing (E. Moore, Baxter)
- 4:00 p.m. Consequences of OSCS Crisis on Heparin Compliance to USP Proposed Monograph (C. Viskov)
- 4:20 p.m. Panel Discussion
- 4:50 p.m. Rapporteurs Wrap-up (K. Johansen, Zealand Pharma & P. Jongen, RIVM)

5:00 p.m. Adjourn



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