Program of the ASST/SCPI/ERWEKA

Dissolution Workshop

Damascus, Syria, 8 and 9 October 2008

Wednesday, 8 October 2008

09.00 Opening of the Workshop by representatives of ASST and the chairman of the Workshop

09.15 – 10.00 Dissolution Testing: from the Past to Future Applications in Bioequivalence Testing
Prof. Hans E. Junginger, Marburg, Germany

10.00 -10.45 Practical Aspects of Dissolution Testing A) Selection of an Adequate Test Equipment and B) Overcoming Typical Problems in Dissolution Testing
Dr. Sandra Klein, University of Frankfurt, Germany

10.45 – 11.15 Coffee Break

11.15 – 12.00 Standard methods for Dissolution Testing of oral Drug Products A) for highly soluble drugs in IR dosage forms and B) for poorly soluble drugs in IR dosage forms
Dr. Sandra Klein, University of Frankfurt

12.00 – 12.45 in vitro- in vivo Correlation (ivivc)
Prof. Hans E. Junginger, Marburg, Germany

12.45 – 14.15 Lunch Break

Representative from ERWEKA, Heusenstamm, Germany and Dr. Sandra Klein, University of Frankfurt

14.00 – 16.00 Talk with the Experts. Group 2

16.00 – 16.15 Coffee Break
16.00 – 18.00 Hands-on-Dissolution Experiments Demonstration: Mechanical Calibration, Testing and Practical Aspects. Group 2
Representative from ERWEKA, Heusenstamm, Germany and Dr. Sandra Klein, University of Frankfurt

16.00 – 18.00 Talk with the Experts. Group 1

Thursday, 9. October 2008

09.00 – 09.45 Regulatory Aspects of Dissolution as a Surrogate for in Vivo Bioequivalence Testing in Western Countries,
Dr. Dirk. M. Barends, Bilthoven, The Netherlands

09.45 – 10.30 Biorelevant Dissolution Test Methods for Modified Release Products
Dr. Sandra Klein, University of Frankfurt

10.30 – 11.00 Coffee Break

11.00 – 11.45 Application of Dissolution Testing in Industrial Product Development (Quality by Design)
Dr. Kerstin Pauli, Leverkusen, Germany

11.45 – 12.30 Practicality of Dissolution as a surrogate for in vivo Bioequivalence Testing: the Biopharmaceutics Classification System (BCS) and the Biowaiver monograph series.
Dr. Dirk M. Barends, Bilthoven, The Netherlands

12.30 – 14.00 Lunch Break

14.00 – 14.45 Identification of the Optimal Drug Form for further Development by applying Dissolution Kinetics – Analytical Perspective
Dr Kerstin Pauli, Leverkusen, Germany

14.45 – 16.00 Discussion of all topics of the Workshop

16.00 Closing of the Workshop