

Meeting Report: Workshop on “Dissolution Technology and Bioequivalence”

Held 10 and 11 March 2003 at the Mahidol University, Bangkok, Thailand
Prof. Hans E. Junginger, Scientific Secretary of Federation Internationale Pharmaceutique
(FIP, International Pharmaceutical Federation)

The workshop “Dissolution Technology and Bioequivalence” held 10 and 11 March 2003 at Mahidol University, Bangkok, Thailand followed the workshop held in India (January 23-24, 2001 in Mumbai, India and January 27-28, 2001 in Bangalore, India). This workshop was again organized by the chairman of the Special Interest Group on Bioavailability and Bioequivalence of the FIP Board of Pharmaceutical Sciences (BPS), Dr. Vinod Shah, CDER, FDA, USA, and current president of AAPS, together with the Dean of the Faculty of Pharmacy of Mahidol University, Prof. Sompol Prakongpan. This workshop was co-sponsored by WHO, the Pharmaceutical Association of Thailand, and Mahidol University, Bangkok, Thailand. Members of the Organizing Committee were Prof. Jennifer Dressman from the Goethe University of Frankfurt, Germany and Prof. Gordon Amidon, University of Michigan, Ann Arbor, Michigan, USA.

The workshop was opened by the Dean of the Faculty of Pharmacy, Prof. Prakongpan and the Vice Chancellor for Research of the same university who emphasized the necessity of improving the quality of pharmaceutical drug product development in Thailand and welcomed the initiative of the organization of such workshops in countries like Thailand. Prof. Hans Junginger, Scientific Secretary of FIP welcomed the participants on behalf of FIP and explained the initiative as taken by BPS to organize such workshops in developing countries to help them to improve their countries’ drug product quality, and to get updates on the latest developments in regulatory science. He also mentioned the financial involvement of BPS in organizing these types of workshops. More than 190 participants from academia, the pharmaceutical industry and the regulatory authorities of Thailand attended the workshop.

The first lecture was an overview of dissolution technology and bioequivalence, given in the Thai language by Prof. Prakongpan, to set the stage for the following lectures. Dr. Vinod Shah gave an introduction into the basics of the design of dissolution testing, which was followed by the lecture of Dr. Sandra Klein from Goethe University of Frankfurt who talked about the design of dissolution equipment as given in the pharmacopoeias and how to calibrate and troubleshoot dissolution equipment. Prof. Jennifer Dressman talked about the selection of a dissolution test medium especially for poorly soluble drugs and how to simulate the fasted and fed state in *in vitro* dissolution testing.

In the afternoon sessions the participants were able to practice “Hands-on Dissolution” experimentally with equipment, which was made available by the Erweka Company, Heusenstamm, Germany and its Thai subsidiary company Access. In this session, the participants also observed the latest developments in dissolution testing, including the use

of fiber optics to continually measure the dissolved drug amount. The participants were guided by Mr. Werner Mueller and Mr. Frank Wucher, both from the Erweka Company, and assisted by Dr. Sandra Klein. All the participants showed great interest in participating in ‘Hands-on Dissolution Testing’ and getting first hand experience in performing dissolution testing the right way. Simultaneously, the participants could ask the experts on dissolution methodologies, Dr. Shah, Profs. Amidon, Dressman and Kamal Midha from the University of Saskatchewan, Saskatoon, Canada and Dr. Horst Dieter Friedel from the Bayer Company in Leverkusen, Germany for more detailed information on dissolution technologies and for problem solving strategies. The workshop attendees participated extensively in this unique opportunity to get detailed information from world experts on dissolution testing.

The second day was dedicated to the topic “Dissolution and Bioequivalence” to give more details for the application of the science in dissolution testing. The first speaker of this session was Prof. Gordon Amidon speaking on the basic concepts and application to biowaivers of the biopharmaceutical classification system. Prof. Hans Junginger informed the audience about an initiative taken by the Dutch National Institute of Public Health and the Environment and supported by him, to establish an international database based on the biopharmaceutical classification of drugs (mainly drugs of the Essential Drug List of WHO) that will especially enable developing countries to get easy access to data of drugs for which only dissolution testing will be needed for registration. Dr. Horst Dieter Friedel illustrated in his talk the application of dissolution testing in the product development of an international company. The next lecture of this session was given by Prof. Kamal Midha, who talked on the fundamentals of average bioequivalence and showed proof of the concept. In the final lecture, Dr. Vinod Shah summarized the possibilities for application of dissolution testing with respect to SUPAC, biowaivers, profile comparison of dissolution curves and the QC vs. BE test.

The final panel discussion with all participants was quite interesting for both the panel and the participants because many of the questions came from the Thai regulatory authorities.

This workshop was the first one in which all participants received a certificate of attendance signed by the co-chairman of the workshop, Dr. Vinod Shah, Prof. Hans Junginger, and Prof. Prakongpan. This certificate, with the FIP logo and designed by FIP Headquarters, was well received by the participants.

At the end of the workshop Dr. Vinod Shah thanked Prof. Prakongpan for the excellent organization of the workshop and the great hospitality all overseas speakers were able to enjoy during their stay in Bangkok.