

# Meeting Report: Workshop on “Hands on Dissolution and Bioequivalence”

Held 13 and 14 March 2003 at the University of Medicine and Pharmacy, HoChiMinh City, Vietnam  
Prof. Hans E. Junginger, Scientific Secretary of Federation Internationale Pharmaceutique (FIP, International Pharmaceutical Federation)

Directly after the workshop “Dissolution Technology and Bioequivalence” in Thailand a slightly modified workshop with the title “Hands-on-Dissolution and Bioequivalence” was organized 13 and 14 March 2003 in HoChiMinh City, Vietnam. This workshop was sponsored by FIP and WHO and was organized by the Faculty of Pharmacy in HoChiMinh City (HCMC) together with the Vietnam Pharmaceutical Companies Association and the Institute of Quality Control of HCMC.

The Co-chairs of the workshop were Dr. Vinod Shah from FDA, USA and current president of AAPS, Professor Le Quan Nghiem, Dean of the Faculty of Pharmacy in HCMC and Prof. Le van Truyen, former Vice-Minister of Health and currently Chairman of the Vietnam Pharmaceutical Companies Association. Members of the Organizing Committee were Professor Jennifer Dressman, Goethe University, Frankfurt, Germany, Dr. Martin Siewert from Aventis Pharma AG, Germany, Dr. Nhan Tran Le, from FDA, USA, Dr. Truong Van Tuan and Dr. Quang Cao Minh, both from the University of Medicine and Pharmacy, HCMC, Vietnam. Unfortunately no representative from WHO could be present at the workshop. 177 participants from academia, the pharmaceutical industry and the Vietnamese Regulatory Authority attended the workshop

At the beginning of the first day, all participants and the overseas speakers were welcomed by the Dean of the Faculty of Pharmacy, Professor Nghiem and Professor Le van Truyen. Both emphasized the necessity of having this type of international workshop in Vietnam. This was the first international pharmaceutical meeting since the end of the Vietnam War. The Chair of the workshop, Dr. Vinod also welcomed the participants as did Professor Hans Junginger, Scientific Secretary of FIP, who also gave a short introduction into FIP and the aims of the Board of Phar-

maceutical Sciences of FIP in organizing such meetings.

Professor Le van Truyen opened the workshop with a short lecture on drug quality improvements with respect to Bioavailability. Dr Vinod Shah explained in his lecture the basic facts of the design of dissolution testing and the possibilities of application to quality control tests in comparison to bioequivalence tests. Dr Sandra Klein from Goethe University, Frankfurt, Germany gave an overview of dissolution testing methods as described in the major pharmacopoeias including calibration and trouble shooting. Professor Jennifer Dressman talked about the selection of dissolution test media especially for poorly soluble drugs and how to simulate the fasted and fed state in dissolution testing.

In the afternoon sessions, the participants were able to practice “Hands on Dissolution” experimentally with equipment that was made available by the Erweka Company, Heusenstamm, Germany. The participants in the “Hands on Dissolution” sessions also had the opportunity to see the use of fiber optics for the measurement of 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 tests in the right way. Simultaneously, the participants could ask the experts on dissolution methodologies, Dr. Shah, Professor Gordon Amidon from the University of Michigan, USA, Professor Jennifer Dressman and Professor Kamal Midha from the University of Saskatchewan, Saskatoon, Canada and Dr. Horst Dieter Friedel from Bayer AG in Leverkusen, Germany for more detailed information on dissolution technologies and

problem solving strategies. All the workshop attendees actively participated in this unique opportunity to get detailed information from world experts on dissolution testing.

The second day was dedicated to the topic on “Dissolution and Bioequivalence” to give more details for the application of the science in dissolution testing. The first speaker of this session was Professor Gordon Amidon speaking on the basic concepts and application to biowaivers of the biopharmaceutical classification system. Professor Hans Junginger informed the audience about an initiative taken by the Dutch National Institute of Public Health and the Environment to establish an international database based on the biopharmaceutical classification of drugs (mainly drugs of the Essential Drug List of WHO). This database will give developing countries access to data on drugs that only require dissolution testing for registration. Dr Horst Dieter Friedel from Bayer AG, Leverkusen, Germany illustrated in his talk the application of dissolution testing during product development at an international company. Professor Kamal Midha, Vice President of FIP, lectured on the fundamentals of average bioequivalence and he illustrated proof of the concept.

During the final panel session, the participants actively discussed dissolution testing aspects and related problems with the international experts. This workshop was the first one in which all the participants received a certificate of attendance signed by the chairman of the workshop, Dr. Vinod Shah, Professor Hans Junginger as the official FIP representative and the co-chair of the workshop, Professor Le Quan Nghiem, Dean of the Faculty of Pharmacy in HCMC. This certificate with the FIP logo and designed by the FIP Headquarters was well received by the participants.

At the end of the workshop Dr. Vinod

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Shah thanked the Dean of the Faculty of Pharmacy, Prof. Le Quan Nghiem for the excellent organization of the workshop. Most of the English slides of the overseas presentations have been translated into the Vietnamese language and both the English and Vietnamese version was given to all attendants. In addition, Dr. Shah thanked Professor Le Quan Nghiem for the warm hospitality shown to all the overseas speakers during their stays in HoChiMinh City and during the 3 days excursion to Nha Trang.