

AAPS In Vitro Release and Dissolution Focus Group—First Meeting Highlights

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The AAPS In Vitro Release and Dissolution (IVRD) Focus Group has now been put in place and approved by AAPS. The first meeting was held November 10, 2004, at the AAPS Annual Meeting in Baltimore, MD, and 60 members were present. The mission of the focus group was reviewed and revised:

1. Explore new technologies/equipment for in vitro release testing of novel dosage forms
2. Provide a forum to discuss the specification-setting process
3. Identify current method development problems and the associated dosage forms—share solutions to these difficult problems
4. Explore the use of dissolution testing in applying the BCS/biowaivers
5. Explore in vitro release testing methods for dosage forms other than solid oral dosage forms
6. Discuss the calibration parameters of all official apparatus.
7. Explore how the test may be more relevant to the human physiology
8. Discuss validation principles for new and standard methods
9. Explore harmonization of ICH and Pharmacopeias
10. Evaluate statistics and modeling related to in vitro release and dissolution testing

The Chair and Chair-Elect were selected. Tahseen Mirza is now Chair, elected for a two-year term. The Chair-Elect is

Edward Ciolkowski; he will succeed Tahseen as Chair in November 2006. A Steering Committee was formed, with some members accepting specific tasks. The committee members are as follows:

Banu Zolnik—Website with AAPS, (University of Connecticut)
Tahseen Mirza—Chair, (Novartis)
Edward Ciolkowski—Chair Elect, (Pfizer)
Vivian Gray—Communications, (V. A. Gray Consulting and Dissolution Technologies)
Beverly Nickerson—Program (Pfizer)
Saji Thomas—Program (Barr)
Stephen Mayock—Liaison with APQ, (Cardinal Health)
Diane Worrell—Website with AAPS, (Quintiles)
Alger Salt, (GSK)
Margareth Marques, (USP)
Michael Likar, (Pfizer)
Chris Chabot, (Pfizer)
Alex Shlyankevich (Cardinal)
Kailas Thakker, (Analytical Solutions)
Jean-Louis Raton, (Sotax)
Charles Tong (Pfizer)
Jerry Yen (Alza)
Eda Montgomery, (Vertex)
Panjah Shah, (BMS)
Bryan Crist, (Varian)
Terry Wilke (Pfizer)
Brian Hill (Merck)
Peter Wuelfing (Merck)



Tahseen Mirza and Edward Ciolkowski

Plans include a workshop given by the Focus Group Members since there are many worthy topics and many volunteers to speak. With the time remaining a lively discussion took place on several topics—validation for manual versus automation comparisons, validation for deaeration, use of dissolution testing as the content uniformity test, method transfer, and volume correction and media replacement.

Since this first meeting, there was a teleconference of the Steering Committee on January 20, 2005. The plans to present an AAPS workshop on pertinent topics were discussed. A meeting of the focus group in April is in the planning stages.

For more information on the Focus Group, contact Tahseen Mirza at tahseen.mirza@pharma.novartis.com