

# Highlights of the Annual Meeting for the AAPS In Vitro Release and Dissolution Testing Focus Group

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**O**n November 9, 2005, at the annual AAPS meeting at Nashville, the second annual meeting of the In Vitro Release and Dissolution Testing Focus Group took place. There were about 75 attendees with about 40 new members signing up. In the absence of the Chair (Tahseen Mirza), Vivian Gray, Bryan Crist, and Steve Mayock each took a turn at running the meeting.

The meeting began with a review of the activities over the past year. Since the focus group was formed at the 2004 annual meeting, this was the one-year anniversary. The first face-to-face meeting was held on April 19, 2005, at the Pfizer site in Groton. The meeting was almost a full day of facilitated discussion on a variety of topics including validation, method development of novel dosage forms, and new equipment. One important outcome of the meeting was a list of questions that will be forwarded to FDA for consideration. In fact, these questions will be given to the four FDA speakers who will be presenting in the workshop sponsored by the focus group on May 1-3, 2006 in Arlington, Virginia. The other main activity of the group was the planning and submission of the program for this workshop on current pressing dissolution issues.

We spent some time reviewing the program for the May 1-3, 2006 workshop. The title of the 2½ day workshop is "Dissolution in the 21<sup>st</sup> Century." For a detailed description, go to <http://www.aapspharmaceutica.com/meetings/meeting.asp?id=63>. Since the Focus Group is the only sponsor for the workshop, all members are encouraged to attend and bring colleagues from other sections. All equipment manufacturers are welcome to exhibit. The workshop content will be as follows: First day discussion topic will be PAT issues involving dissolution, with speakers from Industry, FDA, and USP. On the second day, a discussion of Dissolution of Novel Dosage Forms will be in the morning; in the afternoon, the discussion topic will be Challenges in Dissolution Testing. Third day session is half day and will be a discussion of Dissolution Hot Topics including calibration. Representatives from FDA will speak at each session. There will be a panel discussion after each morning and afternoon session. We may consider having a web-seminar with this workshop. We also discussed the certainty that some publication will come out of this workshop, either a white paper, book, or both.

There will be a symposium on IVIVC topics in the 2006 AAPS annual meeting program. Several speakers from the Focus Group and some from PDD will participate in this symposium. The group is encouraged to get involved in AAPS annual meeting programming. Vivian is the APQ Program chair for the 2007 annual meeting, and she encouraged people to come forward with programming for that event.

The Steering committee met by teleconference every month in 2005, and the minutes are available on the website. Please sign up to the list server for the focus group if you haven't already done so.

Steve Mayock took over the meeting with the purpose of seeing if there was interest in writing a review article about the industry perspective on the recent upsurge of criticism regarding USP Apparatus 2. Some of the participants found that the apparatus was quite appropriate for most of their products, though there were always some case-by-case exceptions and those problem products were dealt with in the method development stage. The paper would include a review of the literature using Apparatus 2 as the tool of choice. We would look at what we have and then what might be improved. Steve took down the names of those interested in working on this paper. There were at least 10 who signed up. It was mentioned that many of us received an invitation to the formation of a Dissolution Testing Consortium sponsored by Fernando Muzzio at Rutgers University. At least three members planned to attend and will report back.

One participant brought up the fact that the testing of comparator products is sometimes troublesome. How is the industry approaching this, and what is the feedback from FDA? It was pointed out that there will be a talk on the subject of comparators on day 2 of the May 2006 workshop and that the FDA speakers may be on the panel. Several people expressed an interest in off-line discussion on comparators.

The meeting ended with a technical discussion lead by Bryan Crist. We decided that we would not necessarily end such discussions with "rules" but with more of a consensus. The first topic was loss through evaporation of medium when testing product for long periods of time. The problem should be evaluated during the method development stage. Some said that they would deter-

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mine the rate of evaporation and replenish the medium based on that calculation, or weigh the vessel before and after the dissolution testing. Dissolution vessel covers have been used with some success. Topic two was the use of speeded up dissolution for long in situ dosage units. Some believed that the kinetics could be demonstrated in a few hours of testing either by heating the vessels higher than 37 °C, more likely to 45–55 °C, or involving alcohol in the medium. Other topics such as the need to always obtain 80% Q, reducing the number of samples from 6 to 3, comparison of fiber optics and NIR, and small sample volumes were briefly addressed in the remaining time allotted.