



Dissolution Technique and Method Development Current Issues & Challenges

Registration Fee: £795

Date: May 5-6, 2010

Course Duration: Two Day 9am-4:30pm

Course Description

Developing discriminating dissolution methods is paramount in the modern pharmaceutical laboratory. Dissolution methods that show fast dissolution profiles do not give the practitioner any tools for predicting the performance of the drug in vivo or in vitro. This course will discuss ways to develop the dissolution method so that it is accurate and meaningful. The course will begin with a history of dissolution testing along with providing the relevant international regulatory documents information available. Equipment performance and sources of error will be covered. Conventional method development will be discussed, and then methods for the more challenging dosage forms will be explored. Since poorly soluble drug absorption is limited by the dissolution rate, drug products in this class, Class 2 (low solubility/high permeability) in the Biopharmaceutics Classification System, are good candidates for an in vivo and in vitro correlation; a practical approach will be considered. The course will conclude with method validation and setting specifications and pharmacopeial harmonization.

Key Topics

Fundamentals of Dissolution Testing

- General overview/Theory
- Role of Pharmacopeias in Dissolution Testing
- Regulatory Agencies Role in Dissolution and Guidances, Other Regulatory Guidances, and Additional Resources
- Harmonization
- Utility of Dissolution Testing
- Equipment Review, Compendial and Non-compendial
- Sources of Error During Calibration and Sample Testing
- Calibration Method Issues, including Calibrator Tablets, Mechanical Calibrations, and In-house Calibrators
- Following cGMP's in the Dissolution Laboratory, including preparing for an FDA inspection
- Method Validation
- Method Transfer
- Automation Considerations, including fiber optics

Method Development

- Biopharmaceutics Classification System (BCS)-US, EU, and Japan
- Selecting Test Conditions, including media, apparatus, timepoints
- Poorly Soluble Compounds Method Development



- Novel Delivery Systems Method Development
- Calibration of Non-Compdial equipment
- Encapsulated Products/Comparators
- Liquid filled Capsules, including crosslinking
- Bioequivalence, including discussion of F2
- Review of New Technology in Equipment Design and Dissolution Testing

Methodology in the Literature, including USP dissolution tests and FDA guidances

- Design of Experiments (DOE)
- In Vitro and In Vivo Correlations/Relationships
- ICH Specifications, Decision Tree
- Setting specifications
- Trend analysis and future challenges of Dissolution Testing
- Resources

Faculty

Vivian A. Gray,

Vivian has spent the last 30 years involved in all aspects of dissolution testing and evaluating new dissolution technology. At the United States Pharmacopeia, she enjoyed a long career serving first as a bench chemist, supervisor and lastly as a liaison to various expert USP committees, including the Biopharmaceutics and Dissolution Expert Committee. In 1997, Vivian joined the DuPont Pharmaceuticals Company Analytical Research and Development Section as the Head of the Dissolution Group. In that position, she gained experience in developing discriminating dissolution methods, writing SOP's and a variety of documents, adhering to strict cGMP practices, and filing CMC aspects of dissolution methods and specifications with regulatory agencies.

Vivian has been an invited speaker for conferences on 38 occasions (Six of these were International invitations), lecturing especially in the areas of calibration, dissolution equipment, sources of error in dissolution testing, method development and validation, new technology, and regulatory topics. She is a proactive participant in the field as demonstrated by 47 publications (including 5 book chapters), writing and revising USP Chapters, initiating change in USP methods, organizing workshops, serving on the USP Biopharmaceutics Expert Committee, the FIP Dissolution Working Group, and the Editorial Board for *Dissolution Technologies*. She served on the PhRMA Dissolution Committee from 1997 to 2001. Vivian received the American Society of Hospital Pharmacists Research and Education Foundation 1982 Research Award for co-authoring an article on packaging using USP calibrator model tablets and received an FDA Commissioner's Special Citation for involvement in the FDA task force on Gelatin Crosslinking. Vivian has co-authored a book on dissolution testing called "Handbook of Dissolution Testing", Third Edition, published in 2005.

In 2002, she formed her own consulting business in dissolution testing and related areas. The company name is V. A. Gray, Consulting, Inc. In June of 2003, she became Managing Director and owner of *Dissolution Technologies*, a peer-reviewed journal dealing specifically with dissolution testing issues.



CERTIFICATE OF ATTENDANCE AND COURSE MATERIAL

- All participants will receive a certificate of attendance upon completion of the course.
- The participants will be receiving specially prepared course manual

Location

Park Inn – Central London

Just a stone's throw from the **British Museum** and within walking distance to **Covent Garden & Oxford Street**, the Park Inn is nestled between London's financial district and the West End.

Conveniently located within the heart of **historic Bloomsbury**, the Park Inn is situated between Russell Square and Holborn tube stations and is within easy reach of Kings Cross and Euston Train stations.

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www.parkinn.co.uk

Registration

Please refer to the **register** tab on the CATD website (www.catdglobal.com) or click on the title of the course on the conferences/meeting or home page to register on line.

If you have any problem registering please do not hesitate to contact us at info@catdglobal.com or call us at + 44 (0) 20 8485 1234 or fax us at + 44 (0) 20 8485 1234

***Registration Fee Includes:**

Presentation Materials, Luncheon, and Refreshment

***Please indicate any special Dietary requirements when registering for the course**

Contact for More Information

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