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Book Review

Dissolution Theory, Methodology, and Testing

Edited by Anthony Palmieri III

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I first heard of the upcoming book over two years ago. Anthony Palmieri, a well-respected professor of pharmacy, public speaker on dissolution, and inventor of the Palmieri basket apparatus for dissolution testing of suppositories, had assembled a dream team of authors. His goal was to create a new book covering the theory and methodology of dissolution testing. I reported on its announcement and waited with baited breath. Unfortunately, the publication date was delayed. I contacted Dr. Palmieri and was assured of its eventual release. Two year later, I was contacted and given the privilege to review this fine work of authorship.

Dr. Palmieri opens the book with an introduction, which establishes the history and foundation of dissolution testing. This section sets the tone for a book that builds very strongly on the rich history of this maturing field of testing. The first chapter, written by Arthur Kibbe, dives quickly into the theory of dissolution testing. This chapter traces the development of well-established formulas using the fields of thermodynamics, kinetics, and diffusion. This chapter explains the development of many models used to describe dissolution from the original Noyes-Whitney through decay-based mathematics to recent standard-moment analysis. This listing will be a useful resource for researchers attempting to find the best fit with one of the current theoretical expressions. William Brown from the USP was a logical choice to write Chapter 2 on the USP dissolution procedure. Mr. Brown traces the historical need for dissolution testing, the refinement of the apparatus, and the necessary creation of suitable calibrator tablets. The chapter touches briefly on the ongoing debate to replace calibrator tablet testing with a strictly mechanical check, falling on the side of showing reproducible holistic results based on actual testing. Bryan Crist, one of the best speakers on dissolution testing, discusses the equipment used for testing. This chapter is highly visual, relying much on photographs, diagrams, and figures to display the multitude of apparatus, methods, and variations in this highly unique test. The chapter not only discusses the compendial test from basket to flow-through cells but also includes rotating bottle apparatus, Franz cell, and my personal favorite, the mega paddle. This chapter helpfully includes a useful aberrant data investigation section.

Those working in regulated laboratories will benefit greatly from the fourth chapter, which deals with the issues of international harmonization of standards and methods. The authors also thoroughly address many of the ICH recommendations. Over 100 pages and dozens of data graphs makes Chapter 5, Dissolution of Oral Solid Dosage Forms, unique among all those in the book. In a field so dominated by this dosage form, Peng, Sun, and Shukla have created a resource covering the multitude of variations of tablets and capsules. The authors intelligently discuss formulation effects of fillers, lubricants, binders, disintegrants, and wetting agents, as well as processing factors, storage conditions, and physiochemical properties of the drug. Each of these variables is presented with data graphs displaying its impact on dissolution. While Chapter 5 covers immediate-release forms, Chapter 6 moves to modified-release oral dosage forms. Robert Williams and Judith Brown speak on this ever-increasing variation of delivery systems. This chapter contrasts with the previous in that its focus is on development of dissolution testing methods and regulatory issues associated with IVIVC. The gem of this chapter is the section summarizing the mathematical models used to describe drug dissolution curves.

The editor and Vivian Gray have teamed up to cover the evolving field of heterogeneous dosage forms in the next chapter. Although most of the compendial monographs for these do not contain a dissolution test requirement, it is likely that regulatory pressure will increase in the demonstration of these useful dosage forms. The authors have effectively shown that dissolution testing is an appropriate way to determine performance attributes for

these dosage forms. Chapter 8 may strike many by surprise. It deals with the dissolution of aerosols, which is a new concept to many. Many new drugs exploit the weakness of the protective mechanisms of the lungs. This chapter is rich in theoretical explanations of the subject of aerosol particle release, the respiratory tract, and drug solubilization in the airways. The last chapter of the book talks about the usefulness of dissolution in predicting bioavailability and bioequivalence. Dissolution has often been a useful means to correlate a relationship between a biological property and a physiochemical property of the same dosage form. Dr. Eley goes through each of the four classes of the Biopharmaceutics Classification System (BCS) and the three categories of in vivo–in vitro correlations (IVIVC), discussing the likelihood of developing a correlation in each of the unique situations. Dr. Eley clearly, yet concisely, outlines the methodology for the determination of BCS characteristics and also treats us to innovative IVIVC research.

Every good evaluation needs an area of constructive criticism to facilitate improvement and growth. Future editions could include a chapter on patches. However, this book in its present form is an excellent contribution to the field of dissolution science. With its strength in theoretical and computational aspects, this will be a useful textbook.