

Book Review

Dissolution Technologies Questions and Answers

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I learned of this book from Ms. Vivian Gray, who is the managing director of Dissolution Technologies. To the best of my knowledge, Dissolution Technologies is the only peer-reviewed publication dedicated to dissolution testing. The journal provides a forum and a platform for people who work in this area to receive and exchange information. A special feature of this journal is the Question and Answer section, which has been in every issue since 1999. This book, Dissolution Technologies Questions and Answers, is a compilation of these Question and Answer sections supplemented with updated information and an index.

The readers of Dissolution Technologies are professionals who either work with dissolution testing or conduct research in related areas. The many questions from these professionals in the drug dissolution field indicate that from theory to practice, dissolution testing is complicated in nature. Despite the fact that the United States Pharmacopeia (USP) defines several dissolution apparatus, monographs, and media, every dissolution testing project is unique considering the variability in API, formulation, dosage form, and so forth. Thus, every dissolution test presents its own challenges, from design to successful execution. When facing these challenges, how fantastic it is for one to discuss his/her confusion and questions with field experts who have many years of hands-on experience and profound knowledge! After reading this book, I felt that the experts were sitting right next to me. They not only answer my questions but also inspire me to think more. Resources for finding additional information are also provided.

The experts are Dr. Marques and Mr. Brown, who are the editors of this book and are on the editorial advisory board of Dissolution Technologies. Dr. Marques and Mr. Brown have been hosting the Question and Answer section of Dissolution Technologies since 1999. They sorted all the questions and answers into ten different sections that cover almost every aspect of dissolution

testing, such as acceptance criteria and results interpretation, equipment qualification, regulatory aspects and USP, dissolution media, and dissolution apparatus. Updates were provided in those cases where policies and USP requirements were revised after the answers had been given. After reading this book, it made me think that my years of study on hydrodynamics and its impact on dissolution testing would have been more fruitful if I had read this book before I started my work.

The longest section among the ten is Section 8, Running the Dissolution or Disintegration Test. Questions in this section are very representative of those that may be raised by dissolution analysts whose day-to-day work is dissolution testing and data interpretation. Some are about tiny but critical details such as determination of sink conditions for a particular compound, deaeration of dissolution media, sampling amounts and procedures, introduction of the dosage form into the dissolution vessel, selection of the proper sinker, and comparison of manual and auto sampling. Many questions are very interesting, sometimes beyond one's imagination. The answers are presented with details and sound rationale. For example, it was asked if it is acceptable to use multiple dosage units in a single vessel for products with very low strength. The answer recommended not doing so because high variability could be introduced from the different ways the units could contact the dissolution medium. On top of that, alternative ways to achieve better results were provided. One can also find in-depth answers and discussions on testing uncommon dosage forms such as chewable tablets, ocular inserts, and implants. Such information is rarely discussed elsewhere.

This book in its present form is very valuable to the dissolution testing community. I sincerely hope that Dissolution Technologies will continue to include the Question and Answer section. When the second edition of this book is published one day, I am sure that it will include additional valuable information.