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BOOK REVIEW
Poorly Soluble Drugs: Dissolution and Drug Release

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This book will be a valuable training or reference addition for everyone involved with development or application of dissolution tests for poorly soluble drugs. It is comprehensive in its scope, providing practical information from the beginning stages—solubility determination—to selection of appropriate method conditions through early phases of product development, including various formulation approaches for poorly soluble drugs, to evolving trends, including rationale and approaches for biorelevant dissolution and clinically relevant dissolution. Even those who have been developing dissolution methods for years will find valuable information, since this text goes well beyond the basics of dissolution development for poorly soluble drugs.

Various sources consistently estimate that poorly soluble drugs constitute over 70% of the drugs currently in development. This provides challenges for new product development both on the formulation side and on the performance testing side. The editors of the book have a long history of analytical support for pharmaceutical product development and a host of publications of their own to back this up. They have gathered input from experts across the field to compile information that will empower those tasked with developing dissolution methods for these poorly soluble compounds that will address current regulatory and scientific concerns.

The book walks through the lifecycle of a dissolution method for a poorly soluble compound, starting with solubility and intrinsic dissolution, including use of surfactants, has chapters that address several of the strategies used for formulation development and the staged approach to development of dissolution methods, provides chapters on alternatives to the traditional USP dissolution Apparatus 1 and 2, including Apparatus 3 and 4 and noncompendial approaches, then moves to some of the most interesting information describing biorelevant dissolution, clinically relevant dissolution, QbD approaches, and regulatory considerations.

Drug solubility is often considered to be very straightforward, and perhaps that is the case for compounds with good solubility over the physiological range. For poorly soluble compounds, this can be significantly more challenging, and the authors meet the challenge with chapters on common solubility determination methods, use of surfactants, and discussion on intrinsic dissolution evaluation. The information presented has the potential to improve the knowledge and understanding of the method developer from the basic "shake-flask" approach to a much fuller understanding of solubility, which is extremely valuable in developing a dissolution method.

The chapters on biorelevant dissolution, clinically relevant dissolution, QbD approaches to method development, and regulatory consideration, as a suite of chapters, set the stage for understanding current and emerging expectations for regulatory dissolution methods. We can trace the evolution of dissolution methods from simple buffers to biorelevant media, which are much more indicative of the physiological environment in which dissolution occurs in the body. More recently, the concept of clinically relevant dissolution has emerged. Coupled with QbD concepts, the focus is shifting to factors that actually affect the patient. It is likely that the industry will continue to move in this direction, and it is very helpful to understand the drivers and have some practical advice on how to accomplish the goals.

One area that was not covered in depth in the book was dissolution testing for modified- or extended-release products. While this allowed the authors to provide in-depth coverage of the topics that were addressed, perhaps they will follow up with another book that will address these products.

Overall, this is a book that I strongly recommend for everyone involved in dissolution method development. It goes into much greater detail than similar texts and provides practical information that will prove helpful in addressing the concepts presented, both from a scientific and a regulatory perspective.

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