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Book Review: *The Handbook of Dissolution Testing*, 4th Edition

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The 4th edition of *The Handbook of Dissolution Testing*, revised and expanded by Bryan Crist, Vivian Gray, and Royal Hanson (ISBN: 979-8-89412-327-1), presents a comprehensive and well-structured overview of the dissolution testing process, offering critical insights for both novice and experienced analysts (*1*). Covering topics from theoretical underpinnings to routine implementation and troubleshooting, the *Handbook* serves as a valuable reference for pharmaceutical laboratories and regulatory professionals involved in oral dosage form testing.

Chapter 2 establishes a theoretical foundation that informs subsequent sections on compendial methodologies. The text effectively transitions into detailed discussions of standard practices, regulatory expectations, and special dosage forms—often a source of complexity for analysts who are unfamiliar with modified or nontraditional delivery systems.

Chapter 5 is especially useful, compiling relevant compendial and regulatory documentation references, including United States Pharmacopeia (USP) and International Council for Harmonization (ICH) guidelines. This serves as a convenient reference point for those who are engaged in compliance and method alignment activities.

The authors provide practical guidance in Chapter 6 on apparatus variability, an often-overlooked source of error in dissolution testing. Chapter 7 offers a step-by-step checklist for apparatus qualification, which is particularly beneficial for ensuring operational consistency in quality control settings.

Chapter 8 introduces dissolution method development, emphasizing the importance of defining the Analytical Target Profile and assessing the method's discriminatory power—an essential but sometimes underappreciated element of robust method design.

The section on method validation addresses the unique challenges of dissolution testing, particularly its dynamic, time-dependent nature and the mechanical complexity of test apparatus. The discussion on automation acknowledges both the potential benefits and the additional complexity it introduces, making it a relevant resource for laboratories integrating new technologies.

The final Chapter 11 focuses on the investigation of test failures and high result variability. Given the multifactorial nature of dissolution testing, this discussion is timely and well-developed, covering common root causes and offering structured approaches to root cause analysis.

In sum, *The Handbook of Dissolution Testing, 4th Edition* is a thorough, technically sound resource that balances theoretical context with practical application. It is suitable for training purposes, method development, regulatory reference, and quality troubleshooting. Its structured approach and inclusion of regulatory context make it a significant contribution to the available literature on pharmaceutical testing practices.

The 4th Edition of the *Handbook* can be purchased on the Dissolution Technologies website at dissolutiontech.com/ordering.php.

REFERENCE

1. Crist, B.; Gray, V.; Hanson, R. *The Handbook of Dissolution Testing*, 4th ed.; Dissolution Technologies, Inc., 2024. DOI: 10.14277/DT2024DisHDBK.