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Book Review: "Analytical Testing for the Pharmaceutical GMP Laboratory"

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Analytical Testing for the Pharmaceutical GMP Laboratory (Huynh-BA, K.; Holberg, W.; Lin, J.; Ng, L. L.; Gray, V. A.; Famili, P.; Cleary, S.; Wiley, 2022. ISBN 9781119120919) is an excellent and comprehensive book. It includes extensive, concrete instructions and examples of key documents. This book is a valuable resource for individuals entering the pharmaceutical industry, especially for those following an analytical, chemistry and controls (CMC), or development path. It is particularly useful for recent graduates and professionals working in small companies where access to experienced colleagues may be limited.

The book begins with a review of pharmaceutical laboratory regulations, with an emphasis on U.S. Food and Drug Administration (FDA) and International Council for Harmonisation (ICH) of Technical Requirements for Pharmaceuticals for Human Use requirements and their roles in drug development, registration, and control. Kim Huynh-Ba continues with a discussion on Good Manufacturing Practices (GMPs) and the roles and responsibilities of the quality control unit. Areas addressed include personnel qualification, instrument qualification, testing programs for release and stability, and documentation. The book also provides an overview of pharmaceutical quality systems.

Chapter 3 introduces several analytical techniques used in the GMP laboratory, including both chemical and microbiological testing. Successful use of analytical techniques requires good statistical control, which is the subject of chapter 4. Chapters 5 and 6 provide important guidance and practical advice for development, validation, and transfer of these analytical techniques.

Dissolution testing is unique to the pharmaceutical industry, so this technique warrants an entire chapter. This chapter covers not only the basics of United States Pharmacopeia (USP) apparatuses and method development, but also provides extensive practical information to help the reader avoid many of the potential pitfalls encountered in dissolution testing.

The book concludes with a chapter on the analytical laboratory, including critical subjects related to the pharmaceutical data such as documentation systems, stability programs, and LIMS/electronic data, and quality control.

Overall, *Analytical Testing for the Pharmaceutical GMP Laboratory* is a valuable training tool and reference. It is highly recommended as a complete and comprehensive introduction to testing in the GMP laboratory.