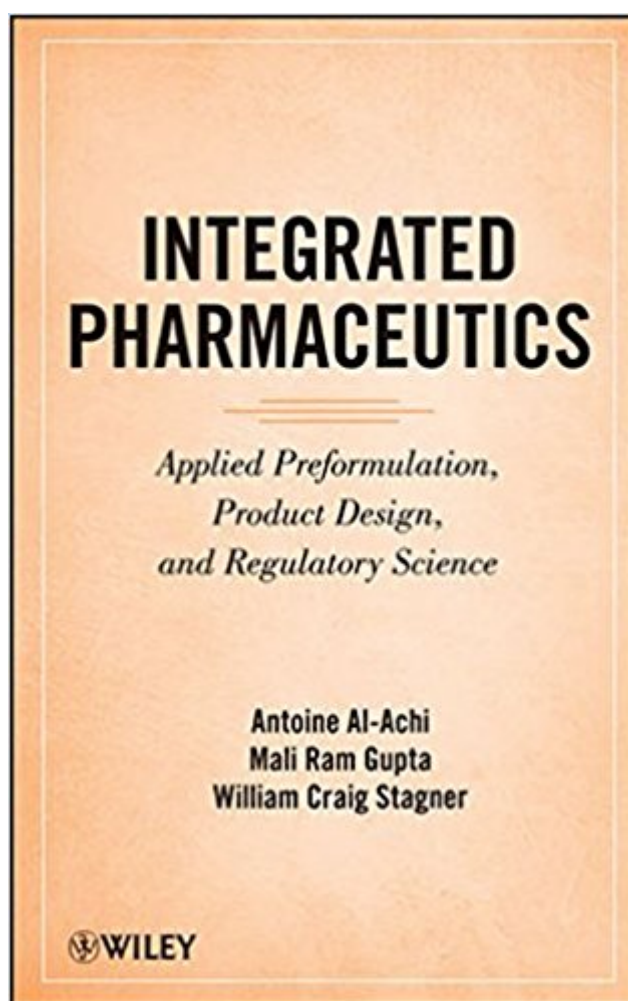


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# Integrated Pharmaceuticals: Applied Preformulation, Product Design, And Regulatory Science



## Synopsis

Focusing on the application of physical pharmacy, drug design, and drug regulations as they relate to produce effective dosage forms for drug delivery, *Integrated Pharmaceutics* provides a comprehensive picture of pharmaceutical product design, describing the science and art behind the concepts of dosage form development. Combining physical pharmacy, product design, and regulatory affairs issues in a single book, the authors address topics governing drug regulations of United States, European, and Japanese agencies and detail new regulatory guidelines, including quality by design, design space analysis, and blend sample uniformity.

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## Customer Reviews

An examination of all aspects of the science and art of dosage form development Integrating physical pharmacy, drug design, and drug regulation, this book examines all the key elements needed to produce effective dosage forms for drug delivery. It begins by setting a solid foundation of physical pharmacy principles such as drug stability estimation, rheology, and interfacial properties. Next, the authors explain how to incorporate these principles into product design. Lastly, the book integrates harmonized pharmaceutical development regulatory guidelines and requirements with the science and technology of pharmaceutical product design in the United States, European Union, and Japan. *Integrated Pharmaceutics* offers a comprehensive portrait of pharmaceutical product design, fully describing the science and art of dosage form development. Readers will find clear and thorough coverage of: Fundamental physical pharmacy principles and their role in drug product

design Regulatory science section covering drug regulation, pharmacy compounding practices, manufacturing validation, and quality systems and controls Recent regulatory guidelines for quality by design, design space analysis, process analytical technology, polymorphism characterization, blend sample uniformity, stability protocols, and biopharmaceutical classification systems Each chapter includes a glossary defining key terms and a list of references leading to the primary literature in the field. Many of the chapters also feature case studies, reference appendices, and practical problems, enabling readers to apply the principles set forth in the book to solve common problems in drug product design. With its comprehensive, multidisciplinary approach, Integrated Pharmaceutics is recommended for graduate-level courses in pharmacy, the pharmaceutical sciences, pharmaceutics, physical pharmacy, drug formulation and design, and biomedicine. The book will also enable professionals in the pharmaceutical industry to apply an effective integrated approach to drug product design.

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Very resourceful

There are a lot of distilled information and wise advices. This book should be a good reference for manufacturing and RD scientists.

Being a professor of pharmaceutics in a pharmacy school, I am delighted to own a copy of "Integrated Pharmaceutics" book! It is becoming a "to-go" reference for most of my lecture material, and I am glad to provide a review of this book. I would like to acknowledge the authors for writing such a comprehensive book which serves as a great resource for anyone in the field of

Pharmaceutics. This book is a unique compilation of current topics taught to undergraduate as well as graduate students. "Integrated Pharmaceutics" offers various topics from physical pharmacy, biostatistics, pharmaceutical dosage forms and regulatory science. The book provides practical problem solving exercises, case studies and various references, which are helpful for the reader. I hope this review serves to be helpful for my peers who are looking for a resource with such unique yet comprehensive compilation of topics.

This book is an excellent comprehensive reference or study guide for those in pharmaceutical industry or student of pharmaceutics. The contents are organized so well and inclusive, it extensively covers the basics of preformulation, product design ( formulation) and regulatory science, which is an extremely important part of the pharmaceutical industry. A Great book !

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