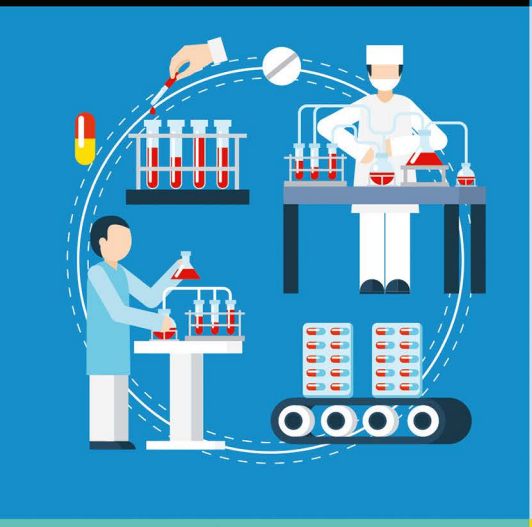
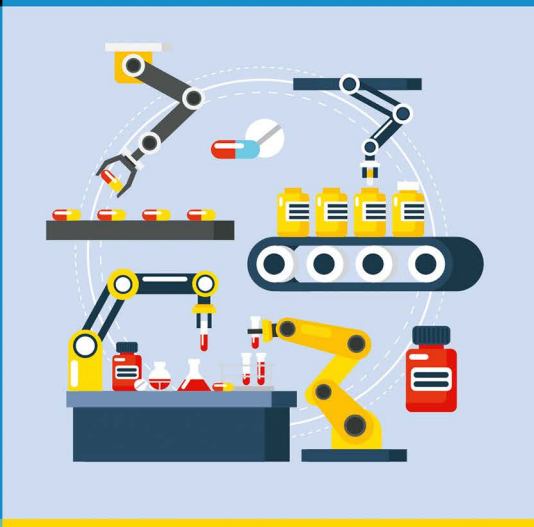
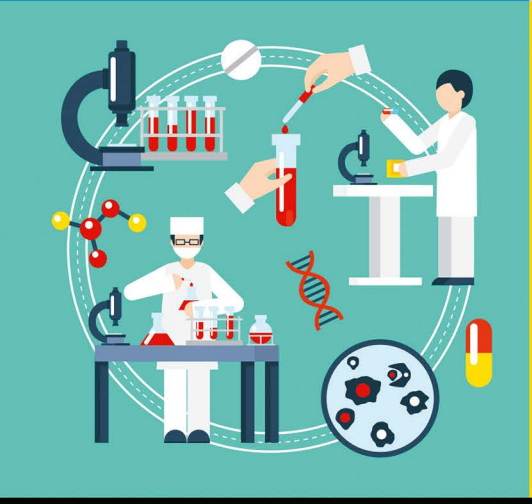
Pharmaceutical Dosage Forms and Drug Delivery

Third Edition







Ram I. Mahato and Ajit S. Narang

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Third Edition: Revised and Expanded

by

Ram I. Mahato, PhD
Department of Pharmaceutical Sciences,
University of Nebraska Medical Center
Omaha, NE

Ajit S. Narang, PhD
Small Molecule Pharmaceutical Sciences, Genentech, Inc.
One DNA Drive, South San Francisco, CA

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I dedicate this book to my wife Subhashini, my children Kalika and Vivek for their love and support; my late mother Sarswati for believing in me; and to my students and mentors who have always helped me in my quest for learning and in achieving higher goals.

Ram I. Mahato

To Tirath Singh and Gurdip Kaur, my parents, who taught me simplicity, sincerity, and hard work.

Ajit S. Narang

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Foreword

Education and practice of the pharmaceutical sciences are rapidly evolving in the modern times, not only with the new ways of doing things enabled by technological advancements of the twenty-first century—but also by the advent of new medicines and modalities of drug therapy. As much as the basic sciences and the fundamental principles of pharmaceutical sciences remain sound, there is an increasing need to integrate the education of dosage forms and drug delivery with the current research and contemporary practices in the current biopharmaceutical industry. It is here that this book—coauthored by leading scientists in both academia and industry—makes a strong impact by presenting the basic principles in a succinct manner that affords a deeper understanding of their reduction to practice.

The revised and expanded third edition of *Pharmaceutical Dosage Forms and Drug Delivery* provides greater emphasis to the multidisciplinary nature of drug discovery and development. The third edition has a new chapter on "Drug Discovery" and the authors have significantly updated and modified the chapter on "Drug Development and Regulatory Processes." These revised chapters provide not only an industry perspective of current practices in pharmaceutical sciences, they also share interdisciplinary nature of *what it takes to discover and bring a new drug to the market* by equally emphasizing the role of regulatory authorities and decision-making criteria in a stage-gate process of drug development.

Modern drug discovery is facing increasing challenges of identifying new drug targets and accessing the difficult-to-reach targets. Although early years of drug discovery focused predominantly on extracellular and cell-surface targets, recent efforts have refocused on new mechanisms of disease progression and targets that are intracellular and often also intraorganelle. These new frontiers are exemplified by the treatment of hepatitis C infection and the emergence of immuno-oncology and antibody–drug conjugates. Pharmaceutical scientists are increasingly using targeted drug-delivery strategies to address challenges inherent with evolving targets and increasingly complex nature of the therapeutic moieties. This edition includes a new chapter on "Targeted Drug Delivery" that provides a concise and in-depth overview of different strategies as applied in current practice.

A new chapter has been added on "Radiopharmaceuticals" to familiarize the students with the basic principles; their utilization is currently embedded in the current practice of diagnostic and therapeutic medicine, and the emerging paradigms of their use in new drug development. This revised edition has many more changes to improve and update several other chapters of this book.

The recent years have seen an explosive increase in the information and progress in various subdisciplines of pharmaceutical sciences as well as the basic sciences, which forms the foundation of this applied science. This up-to-date book incorporates both the basics of the underlying sciences and the changes currently underway in a balanced fashion to enable a holistic development of the next generation of students.

I am confident that this book will enable a deeper understanding of fundamental principles and a wider perspective of their practice to our next generation of students.

Happy reading!

Courtney Fletcher
University of Nebraska Medical Center

Preface

This book is designed as a textbook for teaching basic principles of pharmaceutics, dosage form design, and drug delivery to the Doctor of Pharmacy (Pharm. D.) students in the United States and Bachelor of Pharmacy (B. Pharm.) students in other countries. Although there are numerous books on the science of pharmaceutics and dosage form design, including *Martin's Physical Pharmacy* and *Pharmaceutical Sciences* by Sinko, *Physicochemical Principles of Pharmacy* by Florence and Attwood, *Pharmaceutics: The Science of Dosage form Design* by Aulton, *Theory and Practice of Contemporary Pharmaceutics* by Ghosh and Jasti, and *Pharmaceutical Sciences* by Remington, these books cover different areas of the discipline in varying depths and provide limited insight into contemporary practices and practical applications. Each of these textbooks, by themselves, does not provide *an integrated approach* to the students. This leads to the students as well as the teachers to refer many textbooks to develop an overall understanding of the basic physicochemical principles and their applications to the design and development of different pharmaceutical dosage forms. In an attempt to overcome these challenges, this book provides a unified perspective of the overall field to the students as well as instructors.

The students need to know the basic physicochemical principles, application of these principles to the design of dosage forms, and the relevance of these principles to the biopharmaceutical aspects of drugs. Another important aspect of teaching that is urgently needed in our Pharm. D. curricula is to expose students to the *latest developments* in the application of biomaterials as well as protein and nucleic acid-based pharmaceutical dosage forms and therapeutics, and various biotechnology-based developments. Various books that are currently taught to students miss these latest developments in the field of pharmaceutics and drug delivery. Exposure of students to these latest developments is critical to the successful training of future pharmacists, because these therapeutic modalities and options are likely to be clinically significant in the future. All these principles and applications need to be integrated in a single textbook, so that the student develops a better and overall understanding of the principles involved in dosage

form design and drug delivery. This book covers an in-depth discussion on what physiochemical parameters can be used for the design, development, and evaluation of biotechnological dosage forms for delivery of proteins, peptides, oligonucleotides, and genes.

What's new in the third edition of Pharmaceutical Dosage Forms and Drug Delivery? This edition is significantly revised and expanded in the content matter of each chapter—to make sure the most recent progress in the field and pharmaceutical research is captured adequately—and expanded to include additional chapters that provide contemporary practices. These new chapters include "Drug Discovery" and "Drug Development" as expanded separate chapters, "Organ Specific Drug Delivery," and "Radiopharmaceuticals."

You have an updated, contemporary, new book that can serve as a textbook for Pharm. D. students and a valuable resource for novice in the pharmaceutics and drug delivery fields.