Ansel's Pharmaceutical Dosage Forms and Drug Delivery Systems

NINTH EDITION

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Preface

The purpose of this text is to introduce pharmacy students to the principles, practices, and technologies applied in the preparation of pharmaceutical dosage forms and drug delivery systems. An integrated presentation is used in this textbook to demonstrate the interrelationships between pharmaceutical and biopharmaceutical principles, product design, formulation, manufacture, compounding, and the clinical application of the various dosage forms in patient care. Regulations and standards governing the manufacturing and compounding of pharmaceuticals are also presented.

As has been the hallmark of this textbook since its first edition more than 40 years ago, each chapter is written at a level consistent with the requirements of students being introduced to this area of study. Because this textbook often is used early in the professional curriculum, it contains important introductory topics, such as the historical development of drugs and pharmacy, the role of the pharmacist in contemporary practice, standards of the United States Pharmacopeia–National Formulary, systems and techniques of pharmaceutical measurement, pharmaceutical and biopharmaceutical principles applicable to drug product development, current good manufacturing practice and current good compounding practice standards, and the regulatory process by which pharmaceuticals are approved for marketing by the federal Food and Drug Administration.

The detailed presentation of each dosage form includes physical, physicochemical, and clinical discussions. The new activities at the end of each chapter are designed to provide opportunities for creative thought and application of the content.

CONTINUING FEATURES IN THIS EDITION

The ninth edition presents another significant rewrite of some of the sections of the previous edition and many updated and new figures. We have retained the eight divisions, containing 20 chapters, based upon traditional pharmaceutical pedagogy. This allows the systematic presentation of dosage forms according to their physical form and characteristics. The "Physical Pharmacy Capsules" introduced in the sixth edition continue to emphasize important underlying pharmaceutical principles. Other features that we have retained from the eighth edition include

1. Enhanced considerations of dosage form design and formulation
2. Two case studies (one pharmaceutical and one clinical) in each of the dosage form chapters (see "Explanation of the SOAP Format for Case Studies" later in the preface)
3. An update of the current good compounding practices
4. Expanded clinical considerations in the use of the dosage forms
5. Two glossaries in the appendices, one listing the dosage forms and one listing the pharmaceutical terms

WHAT IS NEW IN THIS EDITION?

New features of this edition include

- Chapter objectives that inform students what they will master in each chapter.
- An "Applying the Principles and Concepts" section at the end of each chapter that provides faculty and students with group and individual activities for the application of the material in each chapter.
- Information related to both manufactured and compounded dosage forms, nonsterile and sterile i.e., Quality assurance for pharmacy-prepared sterile products: revised USP Chapter <797>, June 1, 2008. This is important because the contemporary practice of pharmacy requires the knowledge of both to effectively work with prescribers, patients, and other pharmacists.
- Ancillaries as described in the following section.

ADDITIONAL RESOURCES

Ansel's Pharmaceutical Dosage Forms and Drug Delivery Systems, Ninth Edition, includes additional resources for both instructors and students that are available on the book's companion Web site at thePoint.lww.com/Allen9e.

INSTRUCTORS

Approved adopting instructors will be given access to the following additional resources:

- PowerPoint slides.

STUDENTS

Students who have purchased *Ansel's Pharmaceutical Dosage Forms and Drug Delivery Systems*, Ninth Edition, have access to the following additional resources:

- A quiz bank with more than 200 questions.

In addition, purchasers of the text can access the searchable full text online by going to the *Ansel's Pharmaceutical Dosage Forms and Drug Delivery Systems*, Ninth Edition, Web site at thePoint.lww.com/Allen9e. See the inside front cover of this text for more details, including the passcode you will need to gain access to the Web site.

EXPLANATION OF THE SOAP FORMAT FOR CASE STUDIES[a]

The most commonly used documentation format for case studies is referred to by the mnemonic SOAP, which stands for *S*ubjective information, *O*bjective information, *A*ssessment, and *P*lan.

Before a SOAP note is begun, the following must be clearly defined:

- What are the patient's most important problems that must be addressed and/or resolved *now*?
- What is the evidence that each problem exists?
- What are the therapeutic goals and options for each problem?

The answer to each of these questions forms the content of the assessment section of the SOAP note. Therefore, the assessment is written mentally before the actual SOAP note is begun. After the problems are defined, subjective and objective information needed to justify why those problems exist should be written down.

The first paragraph begins with "**S:**" and contains subjective information, which is obtained from the patient interview. Examples of subjective information include patient—provided information about disease symptoms, over-the-counter medications, drug allergy descriptions, and compliance.

The second paragraph begins with "**O:**" and contains objective information obtained by physically examining the patient, reviewing laboratory data, checking prescription records for doses and refill patterns, locating medication costs from a printed or online formulary, and so on. Some information can be either subjective or objective, depending on how it is obtained. The most important thing to remember when composing the subjective and objective portions of notes is that *only information pertaining directly to the assessment should be included*.

The third paragraph begins with "**A:**" and contains the pharmacist's assessment of the patient's medical and pharmacologic problem or problems. If the subjective and objective paragraphs are written well, the problem should be obvious to the reader. Other types of information included in the assessment paragraph are the therapeutic goals and a brief discussion of the therapeutic alternatives.

The fourth paragraph begins with either "**P:**" or "**R:**" and details either a plan (P) or a recommendation (R), whichever is more appropriate for the situation. The plan should include individualized

[a]Adapted with permission from O'Sullivan TA, Wittkowsky AK. Clinical drug monitoring. In: Stein S, ed. Boh's Pharmacy Practice Manual: A Guide to the Clinical Experience. 3rd Ed. Baltimore: Lippincott Williams & Wilkins, 2010; 483.

instructions (drug by generic name, dose, route, frequency, and, when applicable, duration of therapy). The exact dose and frequency should be identified.

Also, the monitoring plan must be detailed, including specifically what should be measured (e.g., laboratory test, symptom), who should measure it (patient, caregiver, pharmacist), when and how frequently the measurement should be performed, and at what point changing therapy should be considered. A backup plan for use in the event of therapeutic failure should also be noted here. Finally, instructions for the proper use of prescribed medication or medications should be included to enhance the therapeutic outcome.

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I acknowledge with grateful appreciation the major contributions and foresight of Howard C. Ansel, the originator of this textbook, whose guidance and hard work over the years have significantly contributed to the education of tens of thousands of pharmacists worldwide. Deep appreciation is given to Nicholas G. Popovich for his extensive contribution to this textbook on clinical pharmacy and pharmacy practice and for his unique ability to present the integrated approach used in this book. Together, we extend our gratitude to the students and academic colleagues who have shared their thoughts with us on this revision; we hope that we have been successful in responding to their thoughtful suggestions. We also acknowledge with appreciation our colleagues in industry who have generously provided scientific and technical information and updated the figures and photos for our use.

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New to this edition are the individual and group exercises. A number of former doctoral students at the Purdue University School of Pharmacy and the University of Illinois at Chicago, College of Pharmacy helped conceive them, and we sincerely appreciate their contributions to this book. Those who helped create these exercises were Vyto Damasius, PharmD; Elizabeth Choing, PharmD; Janet Lee, PharmD; Eric Haas, PharmD; Nicole Vanderhei, PharmD; Jenna Demy, PharmD; Laura Labbe, PharmD; Kelly Gregory, PharmD; Keith Gaetano, PharmD; Sean Musil, PharmD; Robert Beckett, PharmD; Donna Prole, PharmD; Crystal Chang, PharmD; Jankhana Bhagwakar, PharmD; Ashwini Pai, PharmD; Shital Patel, PharmD; Arti Phatak, PharmD; Anthony Tardi, PharmD; Erin O'Neill, PharmD; Calea Driscoll, PharmD; Edward Song, PharmD; Phyllis Lin, PharmD; John Lee, PharmD; Lulu Jin, PharmD; and Suhail Alhreish, PharmD.

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Loyd V. Allen, Jr.

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