

**Second Edition** 

Joel E. Houglum Gary L. Harrelson

# PRINCIPLES OF Pharmacology for Athletic Trainers

**Second Edition** 

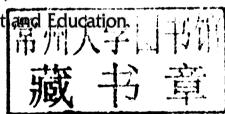
Joel E. Houglum, PhD
Assistant Dean and Professor of Pharmaceutical Sciences, Emeritus
College of Pharmacy
South Dakota State University
Brookings, South Dakota

Gary L. Harrelson, EdD, ATC

Director, Organizational Development and Education.

DCH Health System

Tuscaloosa, Alabama





# www.slackbooks.com

ISBN: 978-1-55642-901-9

Copyright © 2011 by SLACK Incorporated

Principles of Pharmacology for Athletic Trainers Second Edition includes ancillary materials specifically available for faculty use. Included are Test Bank Questions and PowerPoint slides. Please visit www.efacultylounge.com to obtain access.

All rights reserved. No part of this book may be reproduced, stored in a retrieval system or transmitted in any form or by any means, electronic, mechanical, photocopying, recording or otherwise, without written permission from the publisher, except for brief quotations embodied in critical articles and reviews.

The procedures and practices described in this book should be implemented in a manner consistent with the professional standards set for the circumstances that apply in each specific situation. Every effort has been made to confirm the accuracy of the information presented and to correctly relate generally accepted practices. The authors, editor, and publisher cannot accept responsibility for errors or exclusions or for the outcome of the material presented herein. There is no expressed or implied warranty of this book or information imparted by it. Care has been taken to ensure that drug selection and dosages are in accordance with currently accepted/recommended practice. Due to continuing research, changes in government policy and regulations, and various effects of drug reactions and interactions, it is recommended that the reader carefully review all materials and literature provided for each drug, especially those that are new or not frequently used. Any review or mention of specific companies or products is not intended as an endorsement by the author or publisher.

SLACK Incorporated uses a review process to evaluate submitted material. Prior to publication, educators or clinicians provide important feedback on the content that we publish. We welcome feedback on this work.

Published by: SLACK Incorporated

6900 Grove Road

Thorofare, NJ 08086 USA Telephone: 856-848-1000 Fax: 856-853-5991

Fax: 856-853-5991 www.slackbooks.com

Contact SLACK Incorporated for more information about other books in this field or about the availability of our books from distributors outside the United States.

Library of Congress Cataloging-in-Publication Data

Houglum, Joel E.

Principles of pharmacology for athletic trainers / Joel Houglum, Gary Harrelson. -- 2nd ed.

p.; cm.

Includes bibliographical references and index.

ISBN 978-1-55642-901-9 (alk. paper)

1. Pharmacology. 2. Athletic trainers. I. Harrelson, Gary L. II. Title.

[DNLM: 1. Sports Medicine--methods. 2. Drug Therapy--methods. 3. Pharmaceutical Preparations. 4. Pharmacology--methods. QT 261 H8384p 2011]

RM300.H68 2011

615'.1--dc22

### 2010025135

For permission to reprint material in another publication, contact SLACK Incorporated. Authorization to photocopy items for internal, personal, or academic use is granted by SLACK Incorporated provided that the appropriate fee is paid directly to Copyright Clearance Center. Prior to photocopying items, please contact the Copyright Clearance Center at 222 Rosewood Drive, Danvers, MA 01923 USA; phone: 978-750-8400; web site: www.copyright.com; email: info@copyright.com

Last digit is print number: 10 9 8 7 6 5 4 3 2 1

# **DEDICATION**

For You, Lord, are good, and ready to forgive, and abundant in mercy to all those who call upon You.—Psalm 86:5. IEH

To Brian, Keith, Mark, Mike, Rusty, and Paul.

Six guys who encourage me, hold me accountable and speak truth into my life when needed.

May all men be as blessed as I to have guys in their lives like all of you as we each yearn to allow

God to mold us daily into the image of Christ.

As iron sharpens iron, so one man sharpens another.—Proverbs 27:17 GLH

## ABOUT THE AUTHORS

Gary L. Harrelson, EdD, ATC, received his Bachelor of Science in Athletic Training, Master's of Science in Exercise Physiology, and EdD in Administration and Teaching all from the University of Southern Mississippi. He is the Director of Organizational Development and Education (ODE) for the DCH Health System in Tuscaloosa, Alabama. Since his certification as an athletic trainer in 1985, Gary has worked as an athletic trainer in multiple settings, which include high school, clinic, collegiate, and professional sports. Gary has taught in the athletic training curriculums at the University of Alabama and the University of Southern Mississippi. He was an Associate Editor for the Journal of Athletic Training and Athletic Therapy Today. Additionally, he is the coauthor of Physical Rehabilitation of the Injured Athlete now in its 3rd edition, Administrative Topics in Athletic Training: Concepts to Practice, as well as a CD-ROM on Joint Mobilization and a 8-video series on evaluation. He has authored numerous articles and made many professional presentations at the state, regional, and national levels as well as internationally.

Joel E. Houglum, PhD received a Bachelor of Science in Pharmacy from the University of Minnesota and a PhD in Pharmaceutical Biochemistry from the University of Wisconsin. He was Assistant Dean and Professor of Pharmaceutical Sciences in the College of Pharmacy at South Dakota State University where he taught courses in pharmacology and pharmaceutical biochemistry for 28 years. His other publications have been in the areas of leukotrienes, analytical chemistry, curriculum planning and evaluation, and pharmacology for athletic trainers.

## CONTRIBUTING AUTHORS

Robert P. Nickell, RPh, FACA, FAPO grew up working in his father's corner drugstore in Norwalk, California. Since that time, he has become the leading expert in the practice of sports pharmacy. Robert was the founder and CEO of SportPharm from 1995 to 2008, which represented greater than 75% of every professional sports team in the nation, as well as many colleges and universities. Robert is the first pharmacist to receive Honorary Membership in the National Athletic Trainers' Association, and the first pharmacist to officially serve on the USA Olympic Sports Medicine Team in Athens, Greece (2004). He served as the lead course instructor for the USC School of Pharmacy Pharmaceutical Compounding Lab, teaching beginning and advanced compounding from 1993 to 2005. Robert currently manages a consulting firm to physician and professional medical practices. He is the father of 5 children and lives happily with his wife Katy in Hermosa Beach, California.

Michael Powers, PhD, ATC, CSCS, EMT is an Associate Professor and the Athletic Training Department Chair and Program Director at Marist College. Dr. Powers received his Bachelor's and Master's degrees in Athletic Training from Northeastern University and the University of Florida, respectively, and went on receive his Doctoral degree in Sports Medicine from the University of Virginia. He is a certified athletic trainer through the National Athletic Trainers' Association, a certified strength and conditioning specialist through the National Strength and Conditioning Association, and a certified EMT at the intermediate level. His primary research interests include the safety and efficacy of performance-enhancing supplements and drugs. In addition to his academic duties, Dr. Powers continues to volunteer his services as an athletic trainer for events such as the Boston Marathon, state games, and the Dew Tour.

Cindy Thomas, AT-R has over 25 years of experience in collegiate athletic training, academics, and athletic administration. As an active member in the National Athletic Trainers' Association for over 27 years, Cindy completed her undergraduate degree from Longwood College and her Master's degree in Physical Education with a specialization in Athletic Training from Indiana State University. She served as NCAA Assistant Director of Sports Sciences administering the organization's drug-testing programs before joining The National Center for Drug Free Sport.

### PREFACE

A more drug-using and drug-aware society requires that athletic trainers have an appropriate understanding of pharmacology, especially related to drugs being used by the athlete. This textbook provides the basic principles of pharmacology specifically aimed at the needs of the athletic trainer. Consequently, the drug categories that are included are primarily those that may be pertinent to the treatment of athletic injuries or that may impact athletic performance. A discussion of pharmacological principles of other drug categories, as well as detailed and methodical listings of all available drugs, can be obtained from other references, examples of which are discussed at the end of the first chapter.

The athletic trainer cares for the physically active, but the employment opportunities for the athletic trainer are broader in scope than they once were; athletic trainers are now treating patients across a wide age range. No longer are athletic trainers only providing care for a young physically healthy population, but also for the aging, yet physically active, who have diseases that are being treated with physical activity as well as drug therapy. For example, an athletic trainer may be treating an older patient for a musculoskeletal injury but must be aware that the patient is also taking a  $\beta$ -blocker medication that reduces cardiac output; thus the athletic trainer may need to adjust the exercise prescription accordingly. This text addresses the diseases and drug treatment options for the physically active population treated by athletic trainers.

The challenge of writing a textbook such as this is identifying the "need to know" information for the targeted audience. Pharmacology is based in biochemistry and knowing that an athletic trainer's background in biochemistry is limited, we have attempted to present the information as best we can for the athletic trainer. We have used several strategies to help in this quest, which include the following:

- Summaries are not at the end of the chapter, but after each major topic within the chapter. This is an attempt to help manage cognitive overload and aid the reader in understanding what was just read.
- Advanced organizers are used at the beginning of each chapter in order for the reader to see what the chapter contains and get a sense of how the chapter is structured, which ultimately also helps manage cognitive overload.
- Key words are in italics and are defined in the glossary.
- · Concept maps graphically present important, yet complex, processes in a concise way.
- Textboxes (shaded) throughout the text either add additional information to the topic or help the reader to recall a key concept or process that was addressed in an earlier chapter.
- Very specific learning objectives are stated at the beginning of each chapter.

The second edition of this textbook contains three new chapters: Drugs for Treating Psychiatric Disorders, Drugs for Treating Diabetes Mellitus, and Herbal Supplements. All of the chapters have been updated in regards to content. Additionally, medications and treatment strategies have been updated in those chapters addressing specific conditions and/or pathologies. Finally, there are ancillary materials available to facilitate the teaching and learning process and these include PowerPoint slides and test questions for each chapter.

Even though this textbook provides drug information that will be useful for the athletic trainer in professional practice, caution is also warranted: the athletic trainer will not be transformed into a drug expert through a study of this textbook. The athletic trainer should have sufficient knowledge about drugs to provide basic information, to improve compliance with therapy, and to identify drug-related problems in the athlete. Just as important, however, is the ability to realize one's own limitations and to appropriately identify the need to refer the athlete. The expertise of the physician and pharmacist regarding drug information should be among the resources utilized by the athletic trainer. Frequent contact with the athlete provides the opportunity for the athletic trainer to assist the athlete with drug-related issues; this textbook will help provide the knowledge to do it.

Finally, we would like to acknowledge the first edition work of Deidre Leaver-Dunn, PhD, ATC. Many of her suggestions and improvements to the first edition have been carried on to this second edition and we thank her for them.

# CHAPTER 1: ADVANCE ORGANIZER

# **Foundational Concepts**

• What is a drug?

# **Drug Names**

# Classification of Drugs

- Nonprescription drugs
- Prescription drugs
- Scheduled drugs

# Food and Drug Administration and New Drug Development

• Drug information sources

Summary

# **C**ONTENTS

	<i>V</i>
	six
Contributing Aut	horsxi
Preface	xiii
Chapter 1	Introduction to Pharmacology1
Chapter 2	Pharmacokinetic Principles: Processes That Affect Drugs From Entry to Exit
Chapter 3	Pharmacodynamic Principles:  Mechanism of Drug Action and Therapeutic Considerations41
Chapter 4	Medication Management in Athletic Training Facilities
Chapter 5	Drugs for Treating Infections
Chapter 6	Drugs for Treating Inflammation
Chapter 7	Drugs for Treating Pain
Chapter 8	Drugs for Relaxing Skeletal Muscle
Chapter 9	Drugs for Treating Asthma
Chapter 10	Drugs for Treating Colds and Allergies
Chapter 11	Drugs for Treating Gastrointestinal Disorders211
Chapter 12	Drugs for Treating Hypertension and Heart Disease237
Chapter 13	Drugs for Treating Psychiatric Disorders
Chapter 14	Drugs for Treating Diabetes Mellitus303
Chapter 15	Herbal Supplements327
Chapter 16	Performance-Enhancing Drugs
Chapter 17	Drug Testing in Sports

### viii Contents

Glossary	421
Pharmacological Abbreviations	439
Bibliography/Suggested Readings	443
Financial Disclosures	449
Index	451

# Introduction to Pharmacology

# CHAPTER OBJECTIVES

At the end of this chapter, the reader will be able to:

- · Define what a drug is.
- Differentiate between a drug's chemical, generic, and trade names.
- Explain the difference between a generic name and a generic drug.
- List the differences between a generic-name and trade-name drug.
- List and explain the 4 ways drugs are classified.
- Explain the United States Food and Drug Administration's (FDA) role in new drug development and the recall of drugs.
- Locate drug information sources for prescription and nonprescription medication.
- Employ the use of drug information sources to locate specific drugs.

The availability and use of drugs for therapeutic purposes continues to rise. The number of prescriptions dispensed increases each year. In 2007, there were over 3.5 billion prescriptions dispensed. New drugs have been developed in the past several years to treat diabetes, gastrointestinal (GI) ulcers, infection, inflammation, mental disorders, hyperlipidemia, and asthma to name a few. In recent years, the number of drugs and therapeutic categories available without a prescription has also increased and thus the retail sales of over-the-counter (OTC) drug products continue to rise. Society, including athletes, has many more options for self-therapy, which complicates the task for athletic trainers to monitor the drugs being used by the athlete.

# FOUNDATIONAL CONCEPTS

A good starting point for foundational concepts is to define *pharmacology*. Simply put, human pharmacology is the effect of drugs on the body and the effect of the body on drugs. Drugs interact with the cells and extracellular components on a molecular level to produce beneficial and detrimental responses. At the same time, other molecular interactions between the drug and body components will determine how, when, and where the action of the drug will be terminated. Consequently, pharmacology encompasses the therapeutic responses and adverse effects of drugs as well as the absorption, metabolism, and excretion of drugs.

Subdivisions of pharmacology include pharmacokinetics and pharmacodynamics. A study of the factors that affect the time course of drug events is called pharmacokinetics. The rate at which drugs begin to take effect, the duration of the effect, and factors that impact the rate of change in concentration of drugs at the site of action are included in pharmacokinetics. These parameters impact the optimal dosage schedule and route of administration for the drug and will be discussed in Chapter 2. Pharmacodynamics is the study of the mechanism of action of drugs. Some drugs, for example, combine with an enzyme to inhibit the enzymatic process whereas others combine with receptors to either initiate or inhibit a particular effect. A more detailed discussion of pharmacodynamics is the focus of Chapter 3.

# What Is a Drug?

Asking the question, "What is a drug?" can spark a philosophical discussion. All drugs are chemicals.

Table 1-1. Different Names for Chemical Structure

Type of Name Example(s)

Chemical name 4-(dimethyl-amino)-1,4,4a,5,5a,6,11,12a-octahydro-3,5,10,12,12a-pentahydroxy-

6-methyl-1,11-dioxo-2-naphthacenecarboxamide

Generic name Doxycycline

Trade names Vibramycin

Periostat Monodox Doryx Vibra-Tabs

Arsenic trioxide is a chemical but is very toxic with no therapeutic application—is it a drug? In the realm of therapeutics, drugs are chemicals that are used to treat or prevent disease. Table sugar (sucrose) is typically not considered a drug, but what if a diabetic is experiencing the sweating, tachycardia, and jittery feeling associated with hypoglycemia and uses table sugar as treatment; is the sucrose a drug? What about vitamin supplements being used by a person in whom there is no evidence of dietary deficiency? Herbal products are chemicals, many of which have unproven claims of effectiveness in preventing or treating disease; is a chemical a drug if it has no therapeutic benefit but is used for a perceived benefit? Legal, ethical, and therapeutic issues all enter the discussion to obtain an all-encompassing definition. For the purpose of this text, a suitable definition of a drug is a chemical that has demonstrated to be effective for preventing or treating a disease.

# DRUG NAMES

Because drugs are chemicals, they each have a chemical name that specifies the chemical structure. The chemical name is often much too cumbersome for common usage and thus a shorter generic name is also assigned to each drug entity (ie, each chemical compound). For example, 4-(dimethyl-amino)-1,4,4a,5,5a,6,11,12a-octahydro-3,5,10,12,12a-pentahydroxy-6-methyl-1,11-dioxo-2-naphthacenecarboxamide is the chemical name for the generic name doxycycline. The generic name is also known as the

nonproprietary name, as the name is not the property of any company. The proprietary name, more commonly known as trade name or brand name, is selected by the company that markets the drug. There is only one generic name for each drug, but there may be more than one trade name if the drug is marketed by more than one company (Table 1-1). Doxycycline has more than 10 trade names and is also marketed under the generic name by a few other companies.

There is a difference between the generic "name" and a generic "drug." Although every drug has a generic name, not all drugs are marketed as generics. When the patent for the drug expires, companies other than the owner of the patent can market the drug, but these other companies cannot use the trade name owned by the original manufacturer. Consequently, most of these drugs are marketed by one or more companies using the generic name. These generic drugs are typically less expensive than the corresponding trade-name drug because they bring price competition to the marketplace and because the companies marketing them have not invested the initial research and development costs necessary to originally obtain FDA approval to market the drug (see next). The average retail price of a prescription for a trade-name drug in 2007 was 3.5 times the average retail price of a generic drug. Similarly, drugs with expired patents can be marketed by other companies under new trade names owned by these companies. For example, since the patent is expired for ibuprofen (generic name), this drug is now marketed by several companies under this generic name and by

Table 1-2. Contents of Selected Product Combinations

Trade Name	Contents	Classification
Darvocet-N	100 mg propoxyphene napsylate 650 mg acetaminophen	Controlled Substance C-IV
Excedrin Migraine	65 mg caffeine 250 mg acetaminophen 250 mg aspirin	OTC
Excedrin P.M.	38 mg diphenhydramine citrate 500 mg acetaminophen	OTC
Exedrine P.M.	25 mg diphenhydramine 500 mg acetaminophen	OTC
Hista-Vent DA	<ul><li>20 mg phenylephrine HCl</li><li>8 mg chlorpheniramine maleate</li><li>2.5 mg methscopolamine nitrate</li></ul>	Prescription
Nucofed Capsules	20 mg codeine phosphate 60 mg pseudoephedrine HCl	Controlled Substance C-III
Rynatuss Tablets	<ul><li>5 mg chlorpheniramine tannate</li><li>10 mg phenylephrine tannate</li><li>10 mg ephedrine tannate</li><li>60 mg carbetapentane tannate</li></ul>	Prescription
Vicodin Tablets	5 mg hydrocodone bitartrate 500 mg acetaminophen	Controlled Substance C-III

See also Tables 7-2, 7-3, and 10-2 for additional examples of products that contain multiple components.

C = category, referring to category of the controlled substance; OTC = over the counter; HCl = hydrochloride.

other companies under various trade names (ie, Advil, Medipren, Motrin, Nuprin, Rufen).

Besides cost, there are other notable differences between using a generic name versus a trade-name product. Typically, trade names are shorter and easier to pronounce than the generic name. However, because there can be multiple trade names, it is more difficult to remember all of them. Also, unlike the generic name, which refers to one chemical entity, the trade name refers to the entire product contents, which may include more than one active ingredient. For example, Vanquish is the trade name for a product that contains the drugs acetaminophen, aspirin, and caffeine. As evident in Table 1-2, there is no way of knowing from the trade name the number of drugs contained in the product.

Patents last for 20 years but it takes about 8.5 years for an experimental drug to move through the FDA approval process, leaving about 11.5 years for the marketing of the drug to be protected by the patent.

When generic or trade-name products contain the same quantities of the same drug(s), they usually do not differ significantly in the observed therapeutic response. Companies that market generic drugs must obtain FDA approval through an abbreviated new drug application (NDA) process. The abbreviated process does not require the company to repeat all of the clinical trials that were conducted by the company that first obtained FDA approval to market the drug. Rather, the approval process focuses on demonstrating

### Table 1-3. Difference Between Trade-Name and Generic-Name Drugs

Trade-Name Drug

Can have multiple trade names.

Names are shorter and easier to pronounce.

Trade name refers to the entire product, which may include more than one active ingredient.

Generic-Name Drug

Only one generic name.

Refers to one chemical entity.

Less expensive.

Not all drugs are marketed as a generic drug.

Generic drugs can be marketed by one or more companies.

Must obtain FDA approval, but through an abbreviated process.

Must be bioequivalent to the trade-name drug.

that the generic product is bioequivalent to the tradename product.

This approval can be obtained while the trade-name drug is still under patent, thus allowing the generic product to be marketed immediately after the patent expires. As more trade-name drugs go off patent, the number of generic drugs increases. Although the cost of generic drugs is significantly less than trade-name drugs, companies that market generic drugs have the potential to gain significant profits because they do not have to recoup costs associated with research, development, and a lengthy approval process. Consequently, profit margin and availability of off-patent drugs are among the driving forces that will continue to increase the number of generic drugs. Table 1-3 provides a summary of the difference between trade-name and generic-name drugs.

Bioequivalence is discussed in the next chapter. Two drug formulations are bioequivalent if the amount and rate of the drug entering the blood stream is approximately the same.

# CLASSIFICATION OF DRUGS

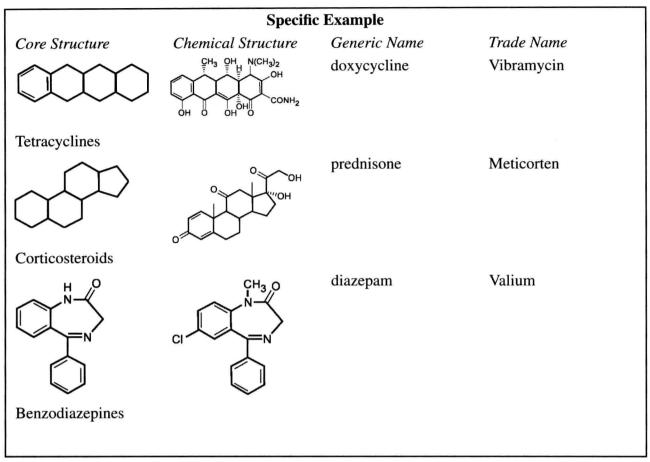
Drugs may be classified in a variety of ways. Because all drugs are chemicals, they can be grouped based on their chemistry (Figure 1-1). For example, the tetracyclines are a group of antibiotics that chemically each contain 4 rings linked together. Although each of the

individual tetracycline compounds such as doxycycline (Vibramycin), minocycline (Minocin), and oxytetracycline (Terramycin) have some unique chemical characteristics, they all have a 4-ring core structure and share the same mechanism of action. Other examples of drug categories based on chemical structure are the penicillins, cephalosporins, benzodiazepines, and corticosteroids.

Sometimes drug categories are based on the mechanism of action such as the protein synthesis inhibitors, beta ( $\beta$ )-blockers, proton pump inhibitors, H<sub>2</sub>-blockers, and  $\beta$ -adrenergic agonists. A broader means of categorizing drugs is by therapeutic effect. As shown in Table 1-4, there are generally several subcategories within the therapeutic category.

Protein synthesis inhibitor is a term used to describe the mechanism of action of several antibiotics, including the tetracyclines and macrolides, as discussed in Chapter 5. β-blockers are a group of drugs used to treat hypertension and certain heart diseases, as discussed in Chapter 12. Proton pump inhibitors and H<sub>2</sub>-blockers are groups of drugs used to treat GI disorders as discussed in Chapter 11. β-adrenergic agonists are drugs used to treat asthma and are discussed in Chapter 9.

Another means of categorizing drugs is by their legal classification. Several federal laws have created 3 classifications: OTC drugs, prescription drugs, and



**Figure 1-1.** Examples of groups of drugs based on chemical structure. The drugs in these 3 chemical categories (tetracyclines, corticosteroids, benzodiazepines) have the core chemical structure shown, but each specific drug also has additional smaller chemical groups attached at various places on the core structure.

controlled substances (Table 1-5). The federal laws that led to these classifications are summarized in Table 1-6 (see also Box 4-2 for other federal acts related to the control and distribution of drugs).

# Nonprescription Drugs

Drugs that do not require a prescription are also referred to as OTC drugs. There are an estimated 1000 active ingredients used in over 100,000 OTC products on the market. Some of these products contain a single drug as the active ingredient, whereas many others contain combinations of active ingredients. Table 1-2 lists a few OTC products and their active ingredients.

Several OTC drugs were originally available only by prescription but were later approved for use in nonprescription products, usually at a lower amount of drug per dosage unit. Motrin (400, 600, or 800 mg per tablet) and naproxen (250 or 500 mg per tablet) are prescription nonsteroidal anti-inflammatory drugs (NSAIDs) that are also available as OTC medications at a maximum of 200 mg per tablet. It is the responsibility of the FDA to approve a drug in the OTC classification. Many factors are considered including evidence that there is a relatively low frequency of toxic and other adverse effects, no need for periodic medical examination or laboratory work to monitor the effectiveness or toxicity, and demonstration of effectiveness in a significant proportion of patients at the dosage recommended on the OTC product label.

Table 1-4. Examples of Therapeutic Categories and Subcategories

Therapeutic Category	Examples of Subcategories	Chapter Reference
Analgesics	NSAIDs	7
	Opioids	
Antibiotics	Tetracyclines	.5
	Penicillins	
	Cephalosporins	
Antihypertensives	$\beta_2$ -blockers	12
	Diuretics	
	ACE inhibitors	
Anti-inflammatory drugs	NSAIDs	6
	Corticosteroids	
Asthma drugs	$\beta_2$ -agonists	9
	Corticosteroids	
	Leukotriene modifiers	

NSAIDs = nonsteroidal anti-inflammatory drugs, ACE = angiotensin-converting enzyme

Table 1-5. Classification of Drugs

Classification	Characteristics
OTC drugs	Drugs that do not require a prescription.  Usually contain a lower amount of drug per dosage unit compared with the cor-
	responding prescription drug.  Often contain multiple active ingredients in the same dosage form.
Prescription drugs	Prescription drugs generally have a greater potential for adverse effects than OTC drugs, require monitoring for interactions with other medications, should only be used for a restricted time period, or have other problems that necessitate the enhanced restrictions associated with prescription drugs.  Medical supervision is mandated through the physician writing the prescription and the pharmacist filling it.
Controlled substances	Also referred to as scheduled drugs. They have an abuse potential and thus have more restrictive requirements regarding distribution, storage, and record keeping compared with prescription drugs.  Schedule I controlled substances (or C-I drugs) have the greatest potential for abuse whereas Schedule V (C-V) drugs have the lowest abuse potential.

# **Prescription Drugs**

Compared to OTC drugs, prescription drugs generally have a greater potential for adverse effects, require monitoring for interactions with other medications,

should only be used for a restricted time period, and have other problems that necessitate the enhanced restrictions associated with prescription drugs. Medical supervision is mandated through the physician writing

Table 1-6. Federal Laws Leading to the Three Classifications of Drugs

Act	Purpose	Comment		
Federal Pure Food Act of 1906	Prohibited adulteration and misbranding of medications.	The label had to accurately reflect the strength, quality, and purity of the contents. However, the Act did not require the drug to be safe or effective.  The United States Pharmacopeia/ The National Formulary were also established by this act as the official standards for drug quality.  Drugs that meet the standard can have "USP" placed on the label after the name of the drug.		
Food, Drug, and Cosmetic Act of 1938	Required that the safety of new drugs be reviewed and approved by the FDA before the drug could be marketed for interstate commerce.	This Act was the beginning of the NDA process. However, efficacy was not addressed.		
1952 Durham-Humphrey Amendment of the 1932 Act	Differentiated between prescription and nonprescription drugs.	Drugs that were determined to be unsafe without medical super- vision required a prescription. The amendment also prohibited certain drugs, such as opioids and hypnotics, to be refilled without a new prescription.		
1962 Kefauver-Harris Amendment of the 1938 Act	Required that the effectiveness of new drugs, whether prescription or nonprescription, be reviewed and approved by the FDA prior to the drug being marketed.	Drugs marketed between 1938 and 1962 were also included in this amendment. Consequently, drugs now had to be approved as safe and effective before available to the public.		
Comprehensive Drug Abuse Prevention and Control Act of 1970	Established categories designated C-I to C-V (see Table 1-7), for drugs with an abuse potential.	Drugs in schedule C-I have the highest abuse potential and greatest restriction for use. This portion of the Act is referred to as the Controlled Substances Act and thus these drugs are also referred to as controlled substances.  The Act regulates the manufacture, distribution, and dispensing of controlled substances. The Drug Enforcement Agency (DEA), a part of the Department of Justice, was designated the responsibility of enforcing the Act.		
USP = United States Pharmacopeia				