

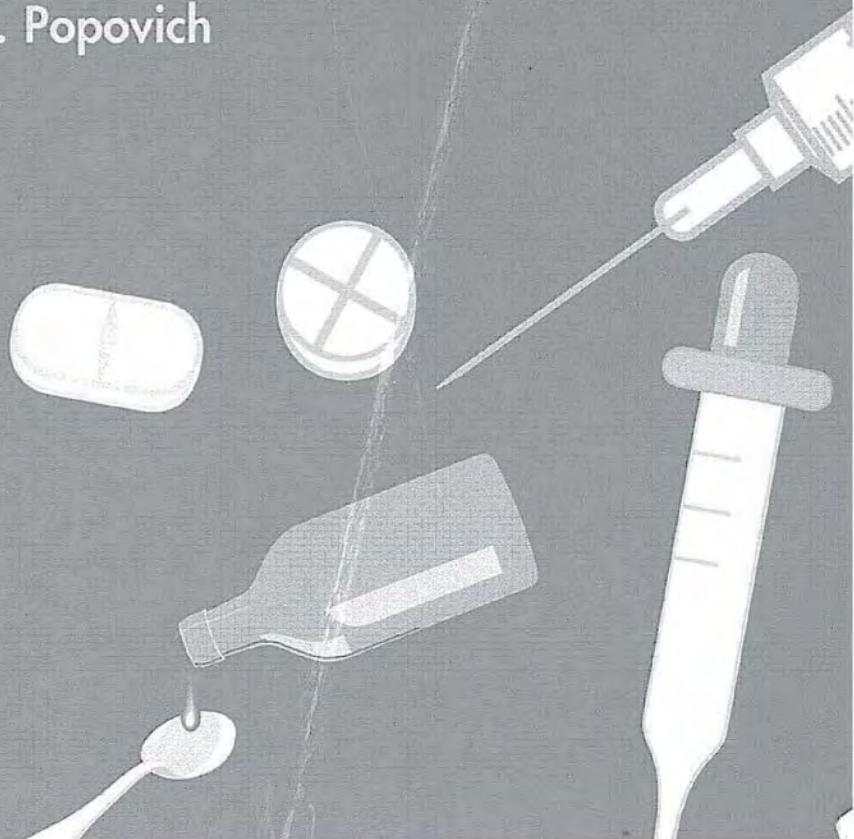
SEVENTH EDITION

PHARMACEUTICAL DOSAGE FORMS AND DRUG DELIVERY SYSTEMS

Howard C. Ansel

Loyd V. Allen, Jr.

Nicholas G. Popovich



Editor: Donna Balado
Managing Editor: Jennifer Schmidt
Marketing Manager: Christine Kushner

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351 West Camden Street
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DOSAGE FORM DESIGN: BIOPHARMACEUTIC AND PHARMACOKINETIC CONSIDERATIONS

Chapter at a Glance

General Principles of Drug

Absorption

Passive Diffusion

Specialized Transport Mechanisms

Dissolution and Drug Absorption

Surface Area

Crystal or Amorphous Drug Form

Salt Forms

Other Factors

Bioavailability and Bioequivalence

FDA Bioavailability Submission

Requirements

Blood (or Serum or Plasma) Concentration-Time Curve

Parameters for Assessment and Comparison of Bioavailability

Peak Height

Time of Peak

Area Under the Serum Concentration Time Curve

Bioequivalence of Drug Products

Routes of Drug Administration

Oral Route

Dosage Forms Applicable

Absorption

Rectal Route

Parenteral Route

Dosage Forms Applicable

Subcutaneous Injections

Intramuscular Injections

Intravenous Injections

Intradermal Injections

Epicutaneous Route

Ocular, Oral and Nasal Routes

Other Routes

Fate of Drug After Absorption

Drug Metabolism (Biotransformation)

Excretion of Drugs

Pharmacokinetic Principles

Half-Life

Concept of Clearance

Dosage Regimen Considerations

AS DISCUSSED in the previous chapter, the biologic response to a drug is the result of an interaction between the drug substance and functionally important cell receptors or enzyme systems. The response is due to an alteration in the biologic processes that were present prior to the drug's administration. The magnitude of the response is related to the concentration of the drug achieved at the site of its ac-

tion. This drug concentration depends on the dosage of the drug administered, the extent of its absorption and distribution to the site, and the rate and extent of its elimination from the body. The physical and chemical constitution of the drug substance—particularly its lipid solubility, degree of ionization, and molecular size—determines to a great extent its ability to effect its biological activity. The area of

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