SEVENTH EDITION PHARMACEUTICAL DOSAGE FORMS AND DRUG DELIVERY SYSTEMS

Howard C. Ansel Loyd V. Allen, Jr. Nicholas G. Popovich

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Section VI. Sterile Dosage Forms and Delivery Systems

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PARENTERALS

Chapter at a Glance

Injections Parenteral Routes of Administration Intravenous Route Intramuscular Route Subcutaneous Route Intradermal Route Specialized Access Official Types of Injections Solvents and Vehicles for Injections Nonaqueous Vehicles Added Substances Methods of Sterilization Steam Sterilization **Dry-Heat Sterilization** Sterilization by Filtration Gas Sterilization Sterilization by Ionizing Radiation Validation of Sterility Pyrogens and Pyrogen Testing The Industrial Preparation of Parenteral Products Packaging, Labeling, and Storage of Injections Quality Assurance for Pharmacy-Prepared Sterile Products Available Injections Small Volume Parenterals Insulin Injection (Regular) Human Insulin

Lispro Insulin Solution Isophane Insulin Suspension (NPH Insulin) Isophane Insulin Suspension and Insulin Injection Insulin Zinc Suspension Extended Insulin Zinc Suspension Prompt Insulin Zinc Suspension Insulin Infusion Pumps Large Volume Parenterals (LVPs) Maintenance Therapy Replacement Therapy Water Requirement Electrolyte Requirement Caloric Requirements Parenteral Hyperalimentation **Enteral Nutrition** Intravenous Infusion Devices Special considerations associated with parenteral therapy Adsorption of Drugs Handling/Disposal of Chemotherapeutic Agents for Cancer Other Injectable Products—Pellets or Implants Levonorgestrel Implants Irrigation and Dialysis Solutions Irrigation Solutions Dialysis Solutions

CONSIDERED IN this chapter are important pharmaceutical dosage forms that have the common characteristic of being prepared to be sterile; that is, free from contaminating microorganisms. Among these sterile dosage forms are the various small- and large-volume injectable preparations, inigation fluids intended to bathe body wounds or surgical openings, and dialysis solutions. Biological preparations as vaccines, toxoids, and antitoxins are also among this group and discussed in Chapter 15. Sterility in these preparations is of utmost importance because they are placed in direct contact with

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