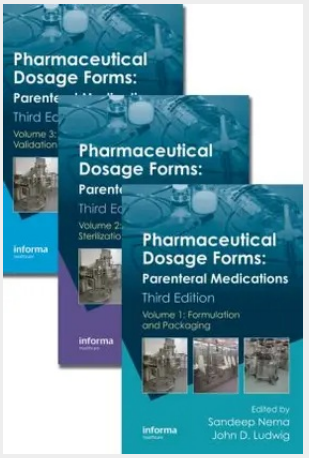
Nema / Ludwig

Pharmaceutical Dosage Forms: Parenteral Medications, Third Edition. 3 Volume Set



Pharmaceutical Dosage Forms: Parenteral Medications explores the administration of medications through other than the enteral route. First published in 1984 (as two volumes) and then last revised in 1993, this three-volume set presents the plethora of changes in the science and considerable advances in the technology associated with these products and routes of administration. Volume 1 (Formulation and Packaging) presents a historical perspective of injectable drug therapy. It discusses common routes of administration and biopharmaceutics of NCEs and NBEs. It examines the preformulation and formulation of small and large molecules, including ophthalmic dosage forms. The book also presents a range of parenteral primary packaging options —including glass and plastic containers and elastomeric closures—and discusses container-closure integrity. This edition includes chapters on solubility and solubilization, formulation of depot delivery systems, and biophysical/biochemical characterization of proteins. Volume 2 (Facility Design, Sterilization and Processing) explores aseptic facility design, environmental monitoring, and cleanroom operations. It discusses pharmaceutical water systems and quality attributes of sterile dosage forms, including particulate matter, endotoxin, and sterility testing. The book contains a detailed discussion on the processing of parenteral drug products (SVPs and LVPs) as well as widely used sterilization technologies such as steam, gas/chemical, radiation, filtration, and dry heat. It also examines lyophilization. Volume 3 (Regulations, Validation and the Future) provides an in-depth discussion of regulatory requirements, quality assurance, risk assessment and mitigation, and extractables/leachables. It explores parenteral administrations devices, injection site pain assessment, parenteral product specifications, and stability testing. It also discusses and the future of parenteral product manufacturing and siRNA delivery systems. The book covers recent developments in the areas of visual inspection, quality by design (QbD), process analytical technology (PAT) and rapid microbiological methods (RMM), as well as validation of drug product manufacturing process. Each individual volume is also available separately.

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