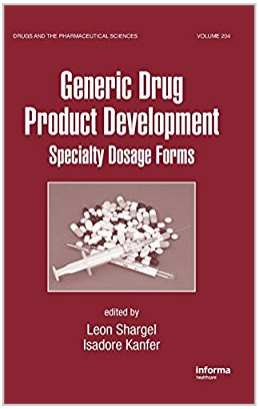

Generic Drug Product Development: Specialty Dosage Forms (Drugs and the Pharmaceutical Sciences) (Volume 1)

By Leon Shargel, Isadore Kanfer

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Generic Drug Product Development: Specialty Dosage Forms explores the issues related to providing evidence of pharmaceutical equivalence and bioequivalence for specialty drug products. It describes various scientific approaches and regulatory requirements for manufacturers who need to demonstrate the therapeutic equivalence of generic specialty drug products to brand name alternatives.

The contributors discuss measurement of drug product quality and performance, as well as the regulatory and scientific requirements of topical, nasal and inhalation, and transdermal drug delivery products, along with generic biologics and modified release parenteral drug products.

The book is essential reading for specialists and researchers in pharmaceutical drug development, regulation, manufacturing, and others in the pharmaceutical sciences.

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Editorial Review

Review

"This is a must for pharmaceutical researchers who are involved in developing generic specialty products with proven bioequivalence."
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About the Author

LEON SHARGEL is Manager, Applied Biopharmaceutics, LLC, Raleigh, North Carolina, USA. Dr. Shargel is also Affiliate Associate Professor, School of Pharmacy, Virginia Commonwealth University, Richmond, Virginia, and Adjunct Associate Professor, School of Pharmacy, University of Maryland, Baltimore, Maryland, USA. He received his B.S. in Pharmacy from the University of Maryland, Baltimore, MD and his Ph.D. in Pharmacology from the George Washington University Medical Center, Washington D.C., USA. Dr. Shargel is a registered pharmacist and has written over 150 papers, chapters and several major textbooks within the subject of pharmaceutical science. He is also co-editor of Informa Healthcare's Generic Drug Product Development: Bioequivalence Issues, Generic Drug Product Development: International Regulatory Requirements for Bioequivalence, and Generic Drug Product Development: Specialty Drug Products. Dr. Shargel currently serves on the USP Biopharmaceutics Expert Committee and is actively involved in teaching and consulting activities.

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