

1. Record Nr.	UNINA9910792350103321
Titolo	Generic drug product development : specialty dosage forms / / edited by Leon Shargel, Isadore Kanfer
Pubbl/distr/stampa	New York : , : Informa Healthcare USA, , 2010
ISBN	0-429-13292-1 1-282-56098-0 9786612560989 1-4200-2003-X
Descrizione fisica	1 online resource (292 p.)
Collana	Drugs and the pharmaceutical sciences ; ; 204
Altri autori (Persone)	ShargelLeon <1941-> KanferIsadore
Disciplina	615.19
Soggetti	Generic drugs Drug development Drugs - Dosage forms Drugs - Therapeutic equivalency
Lingua di pubblicazione	Inglese
Formato	Materiale a stampa
Livello bibliografico	Monografia
Note generali	Description based upon print version of record.
Nota di bibliografia	Includes bibliographical references and index.
Nota di contenuto	Front Cover; Preface; Contents; Chapter 1. Introduction; Chapter 2. Nonsystemically Absorbed Oral Drug Products; Chapter 3. Topical Drug Products - Development, Manufacture, and Regulatory Issues; Chapter 4. Assessment of Topical Dosage Forms Intended for Local or Regional Activity; Chapter 5. Rectal Dosage Forms and Suppositories; Chapter 6. Nasal and Inhalation Drug Products; Chapter 7. Locally Acting Nasal and inhalation Drug Products: Regulatory and Bioequivalence Perspective; Chapter 8. Transdermal Dosage Forms Chapter 9. Pharmaceutical Development of Modified-Release Parenteral Dosage Forms Using Bioequivalence (BE), Quality by Design (QBD), and In Vitro In Vitro Correlation (IVIVC) Principles Chapter 10. Biosimilar Drug Products - Manufacture and Quality ; Index; Color Insert ; Back Cover
Sommario/riassunto	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

---