Generic Drug Product Development: Solid Oral Dosage Forms, Second Edition (Drugs and the Pharmaceutical Sciences)

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In this era of increased pharmaceutical industry competition, success for generic drug companies is dependent on their ability to manufacture therapeutic-equivalent drug products in an economical and timely manner, while also being cognizant of patent infringement and other legal and regulatory concerns.

Generic Drug Product Development: Solid Oral Dosage Forms, Second Edition presents in-depth discussions from more than 30 noted specialists describing the development of generic drug products—from the raw materials to the development of a therapeutic-equivalent drug product to regulatory approval.

Major topics discussed include:

- Active pharmaceutical ingredients
- Experimental formulation development, including a new section on Quality by Design (QbD)
- Scale-up
- Commercial product formulation
- Quality control and bioequivalence
- Drug product performance
- ANDA regulatory process
- Post-approval changes
- Post-marketing surveillance
- Legislative and patent challenges

This second edition also contains a new chapter on the relationship between the FDA and the United States Pharmacopeia and in Chapter 4, using specific examples, the application of Quality by Design (QbD) during formulation development is examined.The book is a thorough guide to the development of solid oral generic dosage formulations. This textbook is ideal for the pharmaceutical industry, graduate programs in pharmaceutical sciences, and health professionals working in the area of generic drug development.

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