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Altri autori (Persone)	ZhengJack
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Nota di contenuto	An overview / Jack Y. Zheng -- Challenges and strategies in formulation development of oral solid low-dose drug products / Jack Y. Zheng -- Particle size of drug substance and product content uniformity: theoretical considerations / Kevin C. Johnson -- Development of low-dose formulations using fluidized bed granulation / J. Joe Zhou, and Ralph Lipp -- Development of low-dose solid oral formulations using wet granulation / Ahmad Almaya -- Challenges in development and scale-up of low dose drug products by dry granulation: a case study / Mary T. Am Ende ... [et al.] -- Development of low-dose solid oral tablets using direct compression / Jack Y. Zheng and Robert L. Ternik -- Reduction of particle size of drug substance for low-dose drug products / Christopher L. Burcham ... [et al.] -- Function, quality, and regulations of pharmaceutical excipients for oral solid dosage forms / Jack Y. Zheng -- Analytical method development: challenges and solutions for low-dose oral dosage forms / Beverly Nickerson ... [et al.] -- In vitro dissolution testing and method development / Vivian A. Gray, Jack Y. Zheng, and

Norman N. Sesi -- Analysis of physical transformation of API during manufacture and storage / Gregory A. Stephenson -- Physical characterization tests for drug substances used in low-dose formulations / Ronald G. Lacocca -- An excipient library approach to analytical development for low-dose, solid oral dosage form drug products / Qing Chang ... [et al.] -- Cleaning verification for highly potent compounds / Brian W. Pack -- Containment challenges and strategies for potent compounds in the pharmaceutical industry / Victoria Cathcart, Sarah Jones, Beverly Nickerson -- Sample handling and containment in analytical testing laboratories / David Pattavina, Nancy Sage, Beverly Nickerson -- Regulatory considerations in the development of low-dose solid oral drug products / Ravi S. Harapanhalli.

Sommario/riassunto

There are unique challenges in the formulation, manufacture, analytical chemistry, and regulatory requirements of low-dose drugs. This book provides an overview of this specialized field and combines formulation, analytical, and regulatory aspects of low-dose development into a single reference book. It describes analytical methodologies like dissolution testing, solid state NMR, Raman microscopy, and LC-MS and presents manufacturing techniques such as granulation, compaction, and compression. Complete with case studies and a discussion of regulatory requirements, this is a core reference for