DESCRIPTION

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 pharmaceutical scientists, regulators, and graduate students.

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Jack Zheng, PhD, is Research Advisor and Team Leader in the Pharmaceutical Sciences R&D Division of Eli Lilly and Company and Adjunct Professor at Beijing University. Dr. Zheng is the author of more than thirty articles and several book chapters. He has been invited to present his work at numerous national and international scientific meetings. He was involved in more than ten new drug product development and regulatory filing with the Food and Drug Administration.