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Formulation and Analytical Development for Low-Dose Oral Drug Products Jack Zheng, 2009-02-09 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 *Developing Solid Oral Dosage Forms* Yihong Qiu, Yisheng Chen, Geoff G.Z. Zhang, Lawrence Yu, Rao V. Mantri, 2016-11-08 *Developing Solid Oral Dosage Forms Pharmaceutical Theory and Practice Second Edition* illustrates how to develop high quality safe and effective pharmaceutical products by discussing the latest techniques tools and scientific advances in preformulation investigation formulation process design characterization scale up and production operations This book covers the essential principles of physical pharmacy biopharmaceutics and industrial pharmacy and their application to the research and development process of oral dosage forms Chapters have been added combined deleted and completely revised as necessary to produce a comprehensive well organized valuable reference for industry professionals and academics engaged in all aspects of the development process New and important topics include spray drying amorphous solid dispersion using hot melt extrusion modeling and simulation bioequivalence of complex modified released dosage forms biowaivers and much more Written and edited by an international team of leading experts with experience and knowledge across industry academia and regulatory settings Includes new chapters covering the pharmaceutical applications of surface phenomenon predictive biopharmaceutics and pharmacokinetics the development of formulations for drug discovery support and much more Presents new case studies throughout and a section completely devoted to regulatory aspects including global product regulation and international perspectives **Pharmaceutical Blending and Mixing** P. J. Cullen, Rodolfo J. Románach, Nicolas Abatzoglou, Chris D. Rielly, 2015-05-11 Written in four parts this book provides a dedicated and in depth reference for blending within the pharmaceutical manufacturing industry It links the science of blending with regulatory requirements associated with pharmaceutical manufacture The contributors are a combination of leading academic and industrial experts who provide an informed and industrially relevant perspective of the topic This is an essential book for the pharmaceutical manufacturing industry and related academic researchers in pharmaceutical science and chemical and mechanical engineering *Water-Insoluble Drug Formulation* Ron Liu, 2008-01-18 Scientists have attributed more than 40 percent of the failures in new drug development to poor biopharmaceutical properties particularly water insolubility Issues surrounding water insolubility can postpone or completely derail important new drug development Even much needed reformulation of currently marketed products can be significantly affected by

these challenges Water Insolubility is the Primary Culprit in over 40% of New Drug Development Failures The most comprehensive resource on the topic this second edition of Water Insoluble Drug Formulation brings together a distinguished team of experts to provide the scientific background and step by step guidance needed to deal with solubility issues in drug development Twenty three chapters systematically describe solubility properties and their impact on formulation from theory to industrial practice With detailed discussion on how these properties contribute to solubilization and dissolution the text also features six brand new chapters on water insoluble drugs exploring regulatory aspects pharmacokinetic behavior early phase formulation strategies lipid based systems for oral delivery modified release of insoluble drugs and scalable manufacturing aspects The book includes more than 15 water insoluble drug delivery systems or technologies illustrated with case studies featuring oral and parenteral applications Highlighting the most current information and data available this seminal volume reflects the significant progress that has been made in nearly all aspects of this field Development and

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