

Siz Biznesmensizbi Anda Sizge Bul Pajdaluu Bolot

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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

developing solid oral dosage forms is intended for pharmaceutical professionals engaged in research and development of oral dosage forms it covers essential principles of physical pharmacy biopharmaceutics and industrial pharmacy as well as various aspects of state of the art techniques and approaches in pharmaceutical sciences and technologies along with examples and or case studies in product development the objective of this book is to offer updated or current knowledge and skills required for rational oral product design and development the specific goals are to provide readers with basics of modern theories of physical pharmacy biopharmaceutics and industrial pharmacy and their applications throughout the entire process of research and development of oral dosage forms tools and approaches of preformulation investigation formulation process design characterization and scale up in pharmaceutical sciences and technologies new developments challenges trends opportunities intellectual property issues and regulations in solid product development the first book ever that provides comprehensive and in depth coverage of what s required for developing high quality pharmaceutical products to meet international standards it covers a broad scope of topics that encompass the entire spectrum of solid dosage form development for the global market including the most updated science and technologies practice applications regulation intellectual property protection and new development trends with case studies in every chapter a strong team of more than 50 well established authors co authors of diverse background knowledge skills and experience from industry academia and regulatory agencies

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