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Design and Manufacture of Pharmaceutical Tablets Academic Press **Design and Manufacture of Pharmaceutical Tablets offers real world solutions and outcomes of formulation and processing challenges of pharmaceutical tablets. This book includes numerous practical examples related to actual formulations that have been validated and marketed and covers important data in the areas of stability, dissolution, bioavailibity and processing. It provides important background and theoretical information on design and manufacturing and includes a full section dedicated to design experimental methodology and statistics. In addition, this book offers a a general discussion of excipients used in proper tablet design along with practical examples related to excipients. Drug development scientists in industry and academia, as well as students in the pharmaceutical sciences will greatly benefit from the practical knowledge and case examples provided throughout this book. Incorporates important mathematical models and computational applications Includes unique content on central composite design and augmented simplex lattice Provides background on important design principles with emphasis on quality-based design (QBD) of pharmaceutical dosage forms Pharmaceutics: The Design and Formulation of Medicines** American Medical Publishers **Pharmaceutical drugs are chemical compounds that are used for treating, preventing, curing or diagnosing a disease. These can be classified into groups of related drugs which have similar chemical structures, mechanism of action and target disease. Drug design is the**

process by which new medications are invented on the basis of a biological target. Usually these are complementary in shape and charge to a biomolecular target. A drug therefore binds to it and acts to activate or inhibit the function of the biomolecule thus conferring a therapeutic benefit to the patient. Drug design can be computer-aided or structure-based. Formulation involves the preparation of a drug such that it is stable and acceptable to a patient. The drug is mostly formulated into a tablet or capsule form. The field involved with the design and formulation of medicines is known as pharmaceutics. This book provides comprehensive insights into the field of pharmaceutics. It discusses the fundamentals as well as modern approaches in the design and formulation of medicines. It aims to equip students and experts with the advanced topics and upcoming concepts in this field. Pharmaceutical Capsules Pharmaceutical Press **Updated and expanded second edition covers all aspects of capsule technology, including history, standards, methods and equipment used in manufacture, filling, printing, weighing, cleaning and inspecting of both hard and soft capsules. FASTtrack Pharmaceutics Dosage Form and Design, 2nd edition** Pharmaceutical Press **FASTtrack Pharmaceutics – Dosage Form and Design focuses on what you really need to know in order to pass your pharmacy exams. It provides concise, bulleted information, key points, tips and an all-important self-assessment section, including MCQs. Pharmaceutical Dosage Forms - Tablets** CRC Press **The ultimate goal of drug product development is to design a system that maximizes the therapeutic potential of the drug substance and facilitates its access to patients. Pharmaceutical Dosage Forms: Tablets, Third Edition is a comprehensive resource of the design, formulation, manufacture, and evaluation of the tablet dosage form, an Pharmaceutical Dosage Forms Capsules** CRC Press **Pharmaceutical Dosage Forms: Capsules covers the development, composition, and manufacture of capsules. Despite the important role that capsules play in drug delivery and product development, few comprehensive texts on the science and technology of capsules have been available for the research and academic environments. This text addresses this gap, discussing how capsules provide unique capabilities and options for dosage form design and formulation. Pharmaceutical Formulation The Science and Technology of Dosage Forms** Royal Society of Chemistry **Formulation is a key step in the drug design process, where the active drug is combined with other substances that maximise the therapeutic potential, safety and stability of the final medicinal product. Modern formulation science deals with biologics as well as small molecules. Regulatory and quality demands, in addition to advances in processing technologies, result in growing challenges as well as possibilities for the field. Pharmaceutical Formulation provides an up to date source of information for all who wish to understand the principles and practice of formulation in the drug industry. The book provides an understanding of the links between formulation theory and the practicalities of processing in a commercial environment, giving researchers the knowledge to produce effective pharmaceutical products that can be approved and manufactured. The first chapters introduce**

readers to different dosage forms, including oral liquid products, topical products and solid dosage forms such as tablets and capsules. Subsequent chapters cover pharmaceutical coatings, controlled release drug delivery and dosage forms designed specifically for paediatric and geriatric patients. The final chapter provides an introduction to the vital role intellectual property plays in drug development. Covering modern processing methods and recent changes in the regulatory and quality demands of the industry, Pharmaceutical Formulation is an essential, up to date resource for students and researchers working in academia and in the pharmaceutical industry. Specialised Pharmaceutical Formulation Royal Society of Chemistry **Specialised Pharmaceutical Formulation is an essential, up to date resource and will equip readers with the ability to effectively and reliably produce products intended for less common and novel routes of administration which can be approved, manufactured and made available to administer to patients. Practical Pharmaceutics An International Guideline for the Preparation, Care and Use of Medicinal Products** Springer **This book contains essential knowledge on the preparation, control, logistics, dispensing and use of medicines. It features chapters written by experienced pharmacists working in hospitals and academia throughout Europe, complete with practical examples as well as information on current EU-legislation. From prescription to production, from usage instructions to procurement and the impact of medicines on the environment, the book provides step-by-step coverage that will help a wide range of readers. It offers product knowledge for all pharmacists working directly with patients and it will enable them to make the appropriate medicine available, to store medicines properly, to adapt medicines if necessary and to dispense medicines with the appropriate information to inform patients and caregivers about product care and how to maintain their quality. This basic knowledge will also be of help to industrial pharmacists to remind and focus them on the application of the medicines manufactured. The basic and practical knowledge on the design, preparation and quality management of medicines can directly be applied by the pharmacists whose main duty is production in community and hospital pharmacies and industries. Undergraduate as well as graduate pharmacy students will find knowledge and backgrounds in a fully coherent way and fully supported with examples. Oral Controlled Release Formulation Design and Drug Delivery Theory to Practice** John Wiley & Sons **This book describes the theories, applications, and challenges for different oral controlled release formulations. This book differs from most in its focus on oral controlled release formulation design and process development. It also covers the related areas like preformulation, biopharmaceutics, in vitro-in vivo correlations (IVIVC), quality by design (QbD), and regulatory issues. Advanced Drug Formulation Design to Optimize Therapeutic Outcomes** CRC Press **This title demonstrates how advanced formulation designs and delivery technologies can be used to improve drug efficacy and treatment outcomes in particular therapeutic categories or disease states. It discusses nanoparticle systems for cancer treatments, and also**

presents cutting edge immono-regulation agents for transplantation and the local targ Basic Physical Pharmacy Jones & Bartlett Publishers **Basic Physical Pharmacy provides a thorough yet accessible overview of the principles of physical pharmacy and their application in drug formulation and administration. This definitive guide to physical pharmacy covers all types of pharmaceuticals, from traditional forms and dosages to nanotechnology-based novel dosage design. Authored by two nationally recognized pharmaceutical scientists and active pharmacy faculty, Basic Physical Pharmacy is clearly organized into four sections: Physical Pharmacy in Solutions; Solid Dosage Forms; Polyphasic Systems; and Drug Delivery and Novel Drug Delivery Systems. Students can build upon their chemistry education to learn the physicochemical properties of drugs and their therapeutic effects on the body. With a highly accessible approach, Basic Physical Pharmacy will help students comprehend and apply the principles of physical pharmacy in clinical practice. Covers major drug products and delivery systems Features current trends in pharmaceutical research and development, including nanotechnology-based dosage design Includes many examples of useful equations and formulation methods Contains over 200 illustrations, photos, and tables Topics Include: Solutions Ionization of Drugs in Solutions Buffers and Buffered Solutions Drug Solubility Diffusion and Dissolution Distribution Phenomena Complexation and Protein Binding Interfacial Phenomena Rheology Colloids Suspensions and Emulsions Semisolid Dosage Forms Dermatologicals Suppositories Powders Capsules Tablets Aerosols Sterile Dosage Forms Ophthalmic Formulations Radiopharmaceuticals Modified Release Drug Delivery Systems Biotechnology Products Drug Product Stability Each new print textbook includes an access code for the online Companion Website. Ebooks do not include access to the Companion Website. Access to the Companion Website may also be purchased separately under the RESOURCES tab, FOR STUDENTS. Student Companion Website includes: Cross Words, Flash Cards, Interactive Glossary, Matching Questions Instructor Resources Answers to End of Chapter Questions Image Bank Power Point Presentations Test Bank Topics Include: Solutions Ionization of Drugs in Solutions Buffers and Buffered Solutions Drug Solubility Diffusion and Dissolution Distribution Phenomena Complexation and Protein Binding Interfacial Phenomena Rheology Colloids Suspensions and Emulsions Semisolid Dosage Forms Dermatologicals Suppositories Powders Capsules Tablets Aerosols Sterile Dosage Forms Ophthalmic Formulations Radiopharmaceuticals Modified Release Drug Delivery Systems Biotechnol Fundamentals of Early Clinical Drug Development From Synthesis Design to Formulation** John Wiley & Sons **An informative look at the intricacies of today's drug development process Once a discovery organization has identified a potential new drug candidate, it is the daunting task of synthetic organic chemists to identify the chemical process suitable for preparation of this compound in a highly regulated environment. Only through a multi-layered chemical process that takes into account such factors as safety, environmental considerations, freedom to operate and**

cost-effectiveness can researchers begin to refine the drug in terms of quality and yield. This book covers both recent advances in the design and synthesis of new drugs, as well as the myriad other issues facing a new drug candidate as it moves through the development process. Utilizing recent case studies, the authors provide valuable insights into the complexities of the process, from designing new synthetic methodologies and applying new automated techniques for finding optimal reaction conditions to selecting the final drug form and formulation. Both novice and active researchers will appreciate the inclusion of chapters on such diverse topics as: * Cross-coupling methods * Asymmetric synthesis * Automation * Chemical Engineering * Application of radioisotopes * Final form selection * Formulations * Intellectual property A wealth of real-world examples and contributions from leading process scientists, engineers, and related professionals make this book a valuable addition to the scientific literature. Novel Formulation Strategies for the Fabrication of Lyophilised Orally Disintegrating Tablets Orally disintegrating tablets (ODTs), also known as fast-disintegrating, fast-melt or fast-dissolving tablets, are a relatively novel dosage technology that involves the rapid disintegration or dissolution of the dosage form into a solution or suspension in the mouth without the need for water. The solution containing the active ingredients is swallowed, and the active ingredients are then absorbed through the gastrointestinal epithelium to reach the target and produce the desired effect. Formulation of ODTs was originally developed to address swallowing difficulties of conventional solid oral dosage forms (tablets and capsules) experienced by wide range of patient population, especially children and elderly. The current work investigates the formulation and development of ODTs prepared by freeze drying. Initial studies focused on formulation parameters that influence the manufacturing process and performance of lyophilised tablets based on excipients used in commercial products (gelatin and saccharides). The second phase of the work was followed up by comprehensive studies to address the essential need to create saccharide free ODTs using naturally accruing amino acids individually or in combinations. Furthermore, a factorial design study was carried out to investigate the feasibility of delivering multiparticulate systems of challenging drugs using a novel formulation that exploited the electrostatic associative interaction between gelatin and carrageenan. Finally, studies aimed to replace gelatin with ethically and morally accepted components to the end users were performed and the selected binder was used in factorial design studies to investigate and optimise ODT formulations that incorporated drugs with varies physicochemical properties. Our results show that formulation of elegant lyophilised ODTs with instant disintegration and adequate mechanical strength requires carful optimisation of gelatin concentration and bloom strength in addition to saccharide type and concentration. Successful formulation of saccharides free lyophilised ODTs requires amino acids that crystallise in the frozen state or display relatively high Tg', interact and integrate completely with the binder and, also, display short

wetting time with the disintegrating medium. The use of an optimised mixture of gelatin, carrageenan and alanine was able to create viscous solutions to suspend multiparticulate systems and at the same time provide tablets with short disintegration times and adequate mechanical properties. On the other hand, gum arabic showed an outstanding potential for use as a binder in the formulation of lyophilised ODTs. Compared to gelatin formulations, the use of gum arabic simplified the formulation stages, shortened the freeze drying cycles and produced tablets with superior performance in terms of the disintegration time and mechanical strength. Furthermore, formulation of lyophilised ODTs based on gum arabic showed capability to deliver diverse range of drugs with advantages over commercial products. Pharmaceutical Formulation Design Recent Practices BoD – Books on Demand **Pharmaceutical formulations have evolved from simple and traditional systems to more modern and complex novel dosage forms. Formulation development is a tedious process and requires an enormous amount of effort from many different people. Developing a stable novel dosage form and further targeting it to the desired site inside the body has always been a challenge. The purpose of this book is to bring together scholarly articles that highlight recent developments and trends in pharmaceutical formulation science. Each article has been written by authors specializing in the subject area and hailing from top institutions around the world. The book has been written in a systematic and lucid style explaining all basic concepts and fundamentals in a very simple way. This book aims to serve the need of all individuals involved at any level in the pharmaceutical dosage form development. I sincerely hope that the book will be liked by inquisitive students and learned colleagues. Aulton's Pharmaceutics E-Book The Design and Manufacture of Medicines** Elsevier Health Sciences **The essential pharmaceutics textbook One of the world’s best-known texts on pharmaceutics, Aulton's Pharmaceutics offers a complete course in one book for students in all years of undergraduate pharmacy and pharmaceutical sciences degrees. Thoroughly revised, updated and extended by experts in their fields and edited by Professors Kevin Taylor and Michael Aulton, this new edition includes the science of formulation, pharmaceutical manufacturing and drug delivery. All aspects of pharmaceutics are covered in a clear and readily accessible way and extensively illustrated throughout, providing an essential companion to the entire pharmaceutics curriculum from day one until the end of the course. Fully updated throughout, with the addition of new chapters, to reflect advances in formulation and drug delivery science, pharmaceutical manufacturing and medicines regulation Designed and written for newcomers to the design and manufacture of dosage forms Relevant pharmaceutical science covered throughout Includes the science of formulation and drug delivery Reflects current practices and future applications of formulation and drug delivery science to small drug molecules, biotechnology products and nanomedicines Key points boxes throughout Over 400 online multiple choice questions Integrated Pharmaceutics Applied Preformulation, Product**

Design, and Regulatory Science John Wiley & Sons **Focusing on the application of physical pharmacy, drug design, and drug regulations as they relate to produce effective dosage forms for drug delivery, Integrated Pharmaceutics provides a comprehensive picture of pharmaceutical product design, describing the science and art behind the concepts of dosage form development. Combining physical pharmacy, product design, and regulatory affairs issues in a single book, the authors address topics governing drug regulations of United States, European, and Japanese agencies and detail new regulatory guidelines, including quality by design, design space analysis, and blend sample uniformity. Integrated Pharmaceutics Applied Preformulation, Product Design, and Regulatory Science** John Wiley & Sons **Focusing on the application of physical pharmacy, drug design, and drug regulations as they relate to produce effective dosage forms for drug delivery, Integrated Pharmaceutics provides a comprehensive picture of pharmaceutical product design, describing the science and art behind the concepts of dosage form development. Combining physical pharmacy, product design, and regulatory affairs issues in a single book, the authors address topics governing drug regulations of United States, European, and Japanese agencies and detail new regulatory guidelines, including quality by design, design space analysis, and blend sample uniformity. Design of Mini-tablets-filled-capsule System of Montelukast Based on Film Coating by Combination of Hydrophilic and Hydrophobic Polymers** LAP Lambert Academic Publishing **Over the past two decades there has been a growing appreciation on the importance of circadian rhythms on GIT physiology and on disease states, together with the realization of the significance of time-of-day of drug administration on resultant pharmacodynamic and pharmacokinetic parameters. The significance of these day-night variation has not been overlooked from the drug delivery perspective and pharmaceutical scientist has displayed considerable intenuity in the development of time delayed drug delivery system to address emerging chronotherapeutic formulation. In the present study, attempt was made to develop a novel multifunctional coated mini-tablets-in-capsule system device containg immediate-release and sustain-release coated mini-tablets. The aim was to specifically target the nocturnal peak symptoms of asthma. This book will also be very much useful for those research scholars who are willing to do their research projects in mini-tablets as well as coating technology. Nitroglycerin Sustained Release Tablet. Formulation Design and Evaluation** GRIN Verlag **Master's Thesis from the year 2010 in the subject Medicine - Pharmacology, University of Dhaka (M. Pharm, in Pharmaceutical Technology), language: English, abstract: The aim of the present studies was to develop and characterize 2.6 mg sustained release matrix tablets of Nitroglycerin. Tablets were prepared by direct compression method. Methocel K15M CR and Methocel K100LV CR polymers were used as rate retarding agents in nine formulations (F-1 to F-9). The granules were evaluated for angle of repose, loose bulk density, tapped bulk density, Carr’s index, Hausner ratio, moisture content, total porosity and assay. The tablets were**

subjected to diameter, thickness, assay, uniformity of content, assay after 1Month at 40°C+75%RH, hardness, friability, and in vitro dissolution studies. The granules showed satisfactory flow properties, compressibility, and drug content. All the tablet formulations showed acceptable pharmacotechnical properties and complied with pharmacopoeial specifications for tested parameters. The in vitro dissolution study was carried out for 8 hour using USP-2009 Apparatus-I (Rotating basket method) in distilled water as the dissolution medium. The release mechanisms were explored and explained by Zero order, First order, Higuchi, Korsmeyer-Peppas and Hixson-Crowell equations. Nine formulations were prepared by using three variable ratio of two polymers; Methocel K15M CR (25%, 20% and 15%) and Methocel K100LV CR (15%, 10% and 5%) where all the formulations (F-1 to F-9) contained 0.5% colloidal silicon dioxide and 1% magnesium stearate. Among these nine formulations, six formulations; F-2 (Methocel K15M CR: Methocel K100LV CR = 25% : 10%), F-3 (Methocel K15M CR : Methocel K100LV CR = 25% : 5%), F-4 (Methocel K15M CR : Methocel K100LV CR = 20% : 15%) F-5 (Methocel K15M CR: Methocel K100LV CR = 20% : 10%), F-6 (Methocel K15M CR : Methocel K100LV CR = 20% : 5%) and F-7 (Methocel K15M CR : Methocel K100LV CR = 15% : 15%) met the official specification of release profile. It was also found that the type and the amount of polymers significantly affect the time required for 50% (T50% or MDT) of drug release, release rate constant and diffusion exponent. Higher the MDT value indicates a higher drug retaining capacity of the polymers and vice-versa. Kinetic modeling of in vitro dissolution profiles revealed the drug release mechanism of all proposed formulations followed anomalous type or non-Fickian transport (n>0.43 and n Excipient Applications in Formulation Design and Drug Delivery Springer **In recent years, emerging trends in the design and development of drug products have indicated ever greater need for integrated characterization of excipients and in-depth understanding of their roles in drug delivery applications. This book presents a concise summary of relevant scientific and mechanistic information that can aid the use of excipients in formulation design and drug delivery applications. Each chapter is contributed by chosen experts in their respective fields, which affords truly in-depth perspective into a spectrum of excipient-focused topics. This book captures current subjects of interest – with the most up to date research updates – in the field of pharmaceutical excipients. This includes areas of interest to the biopharmaceutical industry users, students, educators, excipient manufacturers, and regulatory bodies alike. Formulating Poorly Water Soluble Drugs** Springer Science & Business Media **This volume is intended to provide the reader with a breadth of understanding regarding the many challenges faced with the formulation of poorly water-soluble drugs as well as in-depth knowledge in the critical areas of development with these compounds. Further, this book is designed to provide practical guidance for overcoming formulation challenges toward the end goal of improving drug therapies with poorly water-soluble drugs. Enhancing solubility via formulation**

intervention is a unique opportunity in which formulation scientists can enable drug therapies by creating viable medicines from seemingly undeliverable molecules. With the ever increasing number of poorly water-soluble compounds entering development, the role of the formulation scientist is growing in importance. Also, knowledge of the advanced analytical, formulation, and process technologies as well as specific regulatory considerations related to the formulation of these compounds is increasing in value. Ideally, this book will serve as a useful tool in the education of current and future generations of scientists, and in this context contribute toward providing patients with new and better medicines. How to Design and Implement Powder-to-Tablet Continuous Manufacturing Systems Academic Press **How to Design and Implement Powder-to-Tablet Continuous Manufacturing Systems provides a comprehensive overview on the considerations necessary for the design of continuous pharmaceutical manufacturing processes. The book covers both the theory and design of continuous processing of associated unit operations, along with their characterization and control. In addition, it discusses practical insights and strategies that the editor and chapter authors have learned. Chapters cover Process Analytical Technology (PAT) tools and the application of PAT data to enable distributed process control. With numerous case studies throughout, this valuable guide is ideal for those engaged in, or learning about, continuous processing in pharmaceutical manufacturing. Discusses the development of strategy blueprints in the design of continuous processes Shows how to create process flowsheet models from individual unit operation models Includes a chapter on characterization methods for materials, the use of statistical methods to analyze material property data, and the use of material databases Covers the evolving regulatory expectations for continuous manufacturing Provides readers with ways to more effectively navigate these expectations Pharmaceutical Manufacturing Handbook Production and Processes** John Wiley & Sons **This handbook features contributions from a team of expert authors representing the many disciplines within science, engineering, and technology that are involved in pharmaceutical manufacturing. They provide the information and tools you need to design, implement, operate, and troubleshoot a pharmaceutical manufacturing system. The editor, with more than thirty years' experience working with pharmaceutical and biotechnology companies, carefully reviewed all the chapters to ensure that each one is thorough, accurate, and clear. Pharmaceutical Formulation The Science and Technology of Dosage Forms** Royal Society of Chemistry **Formulation is a key step in the drug design process, where the active drug is combined with other substances that maximise the therapeutic potential, safety and stability of the final medicinal product. Modern formulation science deals with biologics as well as small molecules. Regulatory and quality demands, in addition to advances in processing technologies, result in growing challenges as well as possibilities for the field. Pharmaceutical Formulation provides an up to date source of information for all who wish to understand the principles**

and practice of formulation in the drug industry. The book provides an understanding of the links between formulation theory and the practicalities of processing in a commercial environment, giving researchers the knowledge to produce effective pharmaceutical products that can be approved and manufactured. The first chapters introduce readers to different dosage forms, including oral liquid products, topical products and solid dosage forms such as tablets and capsules. Subsequent chapters cover pharmaceutical coatings, controlled release drug delivery and dosage forms designed specifically for paediatric and geriatric patients. The final chapter provides an introduction to the vital role intellectual property plays in drug development. Covering modern processing methods and recent changes in the regulatory and quality demands of the industry, Pharmaceutical Formulation is an essential, up to date resource for students and researchers working in academia and in the pharmaceutical industry. Oral Formulation Roadmap from Early Drug Discovery to Development John Wiley & Sons **Detailing formulation approaches by stage of discovery to early development, this book gives a “playbook” of practical and efficient strategies to formulate drug candidates with the least chance of failing in clinical development. • Comes from contributing authors with experience developing formulations on the frontlines of the pharmaceutical industry • Focuses on pre (or non-) clinical and early stage development, the phases where most compounds are used in drug research • Features case studies to illustrate practical challenges and solutions in formulation selection • Covers regulatory filing, drug metabolism and physical and chemical properties, toxicology formulation, biopharmaceutics classification system (BCS), screening approaches, early stage clinical formulation development, and outsourcing Oral Drug Delivery for Modified Release Formulations** John Wiley & Sons **ORAL DRUG DELIVERY FOR MODIFIED RELEASE FORMULATIONS Provides pharmaceutical development scientists with a detailed reference guide for the development of MR formulations Oral Drug Delivery for Modified Release Formulations is an up-to-date review of the key aspects of oral absorption from modified-release (MR) dosage forms. This edited volume provides in-depth coverage of the physiological factors that influence drug release and of the design and evaluation of MR formulations. Divided into three sections, the book begins by describing the gastrointestinal tract (GIT) and detailing the conditions and absorption processes occurring in the GIT that determine a formulation’s oral bioavailability. The second section explores the design of modified release formulations, covering early drug substance testing, the biopharmaceutics classification system, an array of formulation technologies that can be used for MR dosage forms, and more. The final section focuses on in vitro, in silico, and in vivo evaluation and regulatory considerations for MR formulations. Topics include biorelevant dissolution testing, preclinical evaluation, and physiologically-based pharmacokinetic modelling (PBPK) of in vivo behaviour. Featuring contributions from leading researchers with expertise in the different aspects of MR formulations, this volume: Provides authoritative coverage of**

physiology, physicochemical determinants, and in-vitro in-vivo correlation (IVIVC) Explains the different types of MR formulations and defines the key terms used in the field Discusses the present status of MR technologies and identifies current gaps in research Includes a summary of regulatory guidelines from both the US and the EU Shares industrial experiences and perspectives on the evaluation of MR dosage formulations Oral Drug Delivery for Modified Release Formulations is an invaluable reference and guide for researchers, industrial scientists, and graduate students in general areas of drug delivery including pharmaceutics, pharmaceutical sciences, biomedical engineering, polymer and materials science, and chemical and biochemical engineering. Promoting Safety of Medicines for Children World Health Organization **Monitoring the safety of medicine use in children is of paramount importance since, during the clinical development of medicines, only limited data on this aspect are generated through clinical trials. Use of medicines outside the specifications described in the license (e.g. in terms of formulation, indications, contraindications or age) constitutes off-label and off-license use and these are a major area of concern. These guidelines are intended to improve awareness of medicine safety issues among everyone who has an interest in the safety of medicines in children and to provide guidance on effective systems for monitoring medicine safety in the pediatric populations. This book will be of interest to all health care professionals, medicine regulatory authorities, pharmacovigilance centers, academia, the pharmaceutical industry and policy-makers. Systems for monitoring medicine safety are described in Annex 1. Pharmacovigilance methods and some examples of recent information on adverse reactions to marketed medicines are discussed in Annex 2.--Publisher's description. Chemical Engineering in the Pharmaceutical Industry Drug Product Design, Development, and Modeling** John Wiley & Sons **A guide to the important chemical engineering concepts for the development of new drugs, revised second edition The revised and updated second edition of Chemical Engineering in the Pharmaceutical Industry offers a guide to the experimental and computational methods related to drug product design and development. The second edition has been greatly expanded and covers a range of topics related to formulation design and process development of drug products. The authors review basic analytics for quantitation of drug product quality attributes, such as potency, purity, content uniformity, and dissolution, that are addressed with consideration of the applied statistics, process analytical technology, and process control. The 2nd Edition is divided into two separate books: 1) Active Pharmaceutical Ingredients (API's) and 2) Drug Product Design, Development and Modeling. The contributors explore technology transfer and scale-up of batch processes that are exemplified experimentally and computationally. Written for engineers working in the field, the book examines in-silico process modeling tools that streamline experimental screening approaches. In addition, the authors discuss the emerging field of continuous drug product manufacturing. This revised second edition: Contains 21 new or revised**

chapters, including chapters on quality by design, computational approaches for drug product modeling, process design with PAT and process control, engineering challenges and solutions Covers chemistry and engineering activities related to dosage form design, and process development, and scale-up Offers analytical methods and applied statistics that highlight drug product quality attributes as design features Presents updated and new example calculations and associated solutions Includes contributions from leading experts in the field Written for pharmaceutical engineers, chemical engineers, undergraduate and graduation students, and professionals in the field of pharmaceutical sciences and manufacturing, Chemical Engineering in the Pharmaceutical Industry, Second Edition contains information designed to be of use from the engineer's perspective and spans information from solid to semi-solid to lyophilized drug products. Aulton's Pharmaceutics The Design and Manufacture of Medicines Elsevier Health Sciences **Pharmaceutics is one of the most diverse subject areas in all of pharmaceutical science. In brief, it is concerned with the scientific and technological aspects of the design and manufacture of dosage forms or medicines. An understanding of pharmaceutics is therefore vital for all pharmacists and those pharmaceutical scientists who are involved with converting a drug or a potential drug into a medicine that can be delivered safely, effectively and conveniently to the patient. Now in its fourth edition, this best-selling textbook in pharmaceutics has been brought completely up to date to reflect the rapid advances in delivery methodologies by eye and injection, advances in drug formulations and delivery methods for special groups (such as children and the elderly), nanomedicine, and pharmacognosy. At the same time the editors have striven to maintain the accessibility of the text for students of pharmacy, preserving the balance between being a suitably pitched introductory text and a clear reflection of the state of the art. provides a logical, comprehensive account of drug design and manufacture includes the science of formulation and drug delivery designed and written for newcomers to the design of dosage forms New to this edition New editor: Kevin Taylor, Professor of Clinical Pharmaceutics, School of Pharmacy, University of London. Twenty-two new contributors. Six new chapters covering parenteral and ocular delivery; design and administration of medicines for the children and elderly; the latest in plant medicines; nanotechnology and nanomedicines, and the delivery of biopharmaceuticals. Thoroughly revised and updated throughout. Engineering Drug Delivery Systems** Woodhead Publishing **Engineering Drug Delivery Systems is an essential resource on a variety of biomaterials engineering approaches for creating drug delivery systems that have market and therapeutic potential. The book comprehensively discusses recent advances in the fields of biomaterials and biomedical sciences in relation to drug delivery. Chapters provide a detailed introduction to various engineering approaches in designing drug delivery systems, delve into the engineering of body functions, cover the selection, design and evaluation of biomaterials, and discuss the engineering of colloids as drug carriers. The**

book's final chapters address the engineering of implantable drug delivery systems and advances in drug delivery technology. This book is an invaluable resource for drug delivery, materials scientists and bioengineers within the pharmaceutical industry. Examines the properties and synthesis of biomaterials for successful drug delivery Discusses the important connection between drug delivery and tissue engineering Includes techniques and approaches applicable to a wide range of users Reviews innovative technologies in drug delivery systems such as 3-D printed devices for drug delivery Time and Site Specific "Tablets in Capsule" System for Nocturnal Asthma Current Advances in Drug Delivery Through Fast Dissolving/Disintegrating Dosage Forms Bentham Science Publishers **Fast Dissolving/Disintegrating Dosage Forms (FDDFs) have been commercially available since the late 1990s. FDDFs were initially available as orodispersible tablets, and later, as orodipsersible films for treating specific populations (pediatrics, geriatrics, and psychiatric patients). Granules, pellets and mini tablets are among latest additions to these dosage forms, which are still in the development pipeline. As drug delivery systems, FDDFs enable quicker onset of action, immediate drug delivery, and sometimes offer bioavailability benefits due to buccal/sublingual absorption. With time, FDDF have evolved to deliver drugs in a sustained and controlled manner. Their current market and application is increasing in demands with advances in age adapted dosage forms for different patients and changing regulatory requirements that warrant mandatory assessments of new drugs and drug products before commercial availability. This book presents detailed information about FDDFs from their inception to recent developments. Readers will learn about the technical details of various FDDF manufacturing methods, formulation aspects, evaluation and methods to conduct clinical studies. The authors also give examples of marketed fast disintegrating/dissolving drug products in US, Europe, Japan, and India. This reference is ideal for pharmacology students at all levels seeking information about this specific form of drug delivery and formulation. Developing Solid Oral Dosage Forms Pharmaceutical Theory and Practice** Academic Press **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 3D Printing of Pharmaceuticals Springer **3D printing is forecast to revolutionise the pharmaceutical sector, changing the face of medicine development, manufacture and use. Potential applications range from pre-clinical drug development and dosage form design through to the fabrication of functionalised implants and regenerative medicine. Within clinical pharmacy practice, printing technologies may finally lead to the concept of personalised medicines becoming a reality. This volume aims to be the definitive resource for anyone thinking of developing or using 3D printing technologies in the pharmaceutical sector, with a strong focus on the translation of printing technologies to a clinical setting. This text brings together leading experts to provide extensive information on an array of 3D printing techniques, reviewing the current printing technologies in the pharmaceutical manufacturing supply chain, in particular, highlighting the state-of-the-art applications in medicine and discussing modern drug product manufacture from a regulatory perspective. This book is a highly valuable resource for a range of demographics, including academic researchers and the pharmaceutical industry, providing a comprehensive inventory detailing the current and future applications of 3D printing in pharmaceuticals. Abdul W. Basit is Professor of Pharmaceutics at the UCL School of Pharmacy, University College London. Abdul’s research sits at the interface between pharmaceutical science and gastroenterology, forging links between basic science and clinical outcomes. He leads a large and multidisciplinary research group, and the goal of his work is to further the understanding of gastrointestinal physiology by fundamental research. So far, this knowledge has been translated into the design of new technologies and improved disease treatments, many of which are currently in late-stage clinical trials. He has published over 350 papers, book chapters and abstracts and delivered more than 250 invited research presentations. Abdul is also a serial entrepreneur and has filed 25 patents and founded 3 pharmaceutical companies (Kuecept, Intract Pharma, FabRx). Abdul is a frequent speaker at international conferences, serves as a consultant to many pharmaceutical companies and is on the advisory boards of scientific journals, healthcare organisations and charitable bodies. He is the European Editor of the International Journal of Pharmaceutics. Abdul was the recipient of the Young Investigator Award in Pharmaceutics and Pharmaceutical Technology from the American Association of Pharmaceutical**

Scientists (AAPS) and is the only non-North American scientist to receive this award. He was also the recipient of the Academy of Pharmaceutical Sciences (APS) award. Simon Gaisford holds a Chair in Pharmaceutics and is Head of the Department of Pharmaceutics at the UCL School of Pharmacy, University College London. He has published 110 papers, 8 book chapters and 4 authored books. His research is focused on novel technologies for manufacturing medicines, particularly using ink-jet printing and 3D printing, and he is an expert in the physico-chemical characterisation of compounds and formulations with thermal methods and calorimetry. Aulton's Pharmaceutics E-Book The Design and Manufacture of Medicines Elsevier Health Sciences **From a review of the previous edition: 'For all the pharmacy students out there part of your pharmacy degree will be to study formulation design and pharmaceutics. This is the holy grail of pharmaceutical technology books. The text reads well and introduces difficult concepts in a more easy-to-understand way, it is definitely worth the money to help you get through the module, if you're doing a research project in pharmaceutical design then this would also be an excellent buy...This is essential for passing exams and developing professional competence.' This is the best known text on pharmaceutics. Its strength lies mainly in being a complete course in one book. Reviewers consistently praise its comprehensiveness and its extremely high quality-quality content. Pharmaceutics is one of the most diverse subject areas in pharmaceutical science and an understanding of it is vital for all pharmacists and scientists involved in converting drugs to medicines that can be safely delivered to a patient. The editorial and author team deliver a tour de force of accessibility, coverage and currency in this new edition of a world-class textbook. Relevant chemistry covered throughout Reflects current and future use of biotechnology products throughout Covers ongoing changes in our understanding of biopharmaceutics, certain areas of drug delivery and the significance of the solid state Includes the science of formulation and drug delivery Designed and written for newcomers to the design of dosage forms Key points boxes throughout Summaries at the end of each chapter Fully updated throughout, with particular focus on delivery of biopharmaceuticals, nanotechnology and nanomedicines, parenteral and ocular drug delivery mechanisms. Now comes with online access on StudentConsult. Formulation Development of Bilayer Tablets of Carvedilol Phosphate** LAP Lambert Academic Publishing **The aim of the current investigation is to design oral once daily bi layer tablets of carvedilol phosphate, which release the drug for 24 hours and match with marketed extended release capsule. The basic objective was to develop a generic version of anti hypertensive tablets in line with the innovator. A generic version of Tablets was developed that is safe, efficacious and bio equivalent to the reference product.The tablets were prepared by the direct compression method using hydrophilic and hydrophobic polymers in different combinations. Anti hypertensive tablets formulated by direct compression showed comparable result with innovator. The techniques employed were practically simple and commercial exploited.**

Formulating Poorly Water Soluble Drugs Springer **The objective of this volume is to consolidate within a single text the most current knowledge, practical methods, and regulatory considerations pertaining to formulations development with poorly water-soluble molecules. A pharmaceutical scientist's approach toward solubility enhancement of a poorly water-soluble molecule typically includes detailed characterization of the compound's physiochemical properties, solid-state modifications, advanced formulation design, non-conventional process technologies, advanced analytical characterization, and specialized product performance analysis techniques. The scientist must also be aware of the unique regulatory considerations pertaining to the non-conventional approaches often utilized for poorly water-soluble drugs. One faced with the challenge of developing a drug product from a poorly soluble compound must possess at minimum a working knowledge of each of the abovementioned facets and detailed knowledge of most. In light of the magnitude of the growing solubility problem to drug development, this is a significant burden especially when considering that knowledge in most of these areas is relatively new and continues to develop Water-Insoluble Drug Formulation** CRC Press **Properties and Formulation: From Theory to Real-World Application 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 the much-needed reformulation of currently marketed products can be significantly affected by these challenges. More recently it was reported that the percentage increased to 90% for the candidates of new chemical entities in the discovery stage and 75% for compounds under development. In the most comprehensive resource on the topic, this third 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 the detailed discussion on solubility theories, solubility prediction models, the aspects of preformulation, biopharmaceutics, pharmacokinetics, regulatory, and discovery support of water-insoluble drugs to various techniques used in developing delivery systems for water-insoluble drugs. This book includes more than 15 water-insoluble drug delivery systems or technologies, illustrated with case studies and 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. The aim of this book is to provide a handy reference for pharmaceutical scientists in the handling of formulation issues related to water-insoluble drugs. In addition, this book may be useful to pharmacy and chemistry undergraduate students and pharmaceutical and biopharmaceutical graduate students to enhance their knowledge in the techniques of drug solubilization and dissolution enhancement. Biopharmaceutics Applications in Drug Development** Springer Science & Business Media **The**

highly experienced authors here present readers with step-wise, detail-conscious information to develop quality pharmaceuticals. The book is made up of carefully crafted sections introducing key concepts and advances in the areas of dissolution, BA/BE, BCS, IVIC, and product quality. It provides a specific focus on the integration of regulatory considerations and includes case histories highlighting the biopharmaceutics strategies adopted in development of successful drugs.