Active Pharmaceutical Ingredients Development Manufacturing And Regulation Second Edition Drugs And The Pharmaceutical Sciences

A guide to the development and manufacturing of pharmaceutical products written for professionals in the industry, revised second edition The revised and updated second edition of Chemical Engineering in the Pharmaceutical Industry is a practical book that highlights chemistry and chemical engineering. The book’s regulatory quality strategies target the development and manufacturing of pharmaceutically active ingredients of pharmaceutical products. The expanded second edition contains revised content with many new case studies and additional example calculations that are of interest to chemical engineers. The 2nd Edition is divided into two separate books: 1) Active Pharmaceutical Ingredients (API’s) and 2) Drug Product Design, Development and Modeling. The active pharmaceutical ingredients book puts the focus on the chemistry, chemical engineering, and unit operations specific to development and manufacturing of the active ingredients of the pharmaceutical product. The drug substance operations section includes information on chemical reactions, mixing, distillations, extractions, crystallizations, filtration, drying, and wet and dry milling. In addition, the book includes many applications of process modeling and modern software tools that are geared toward batch-scale and continuous drug substance pharmaceutical operations. This updated second edition:

• Contains 30 new chapters or revised chapters specific to API, covering topics including:
manufacturing quality by design, computational approaches, continuous manufacturing, crystallization and final form, process safety • Expanded topics of scale-up, continuous processing, applications of thermodynamics and thermodynamic modeling, filtration and drying • Presents updated and expanded example calculations • Includes contributions from noted experts in the field Written for pharmaceutical engineers, chemical engineers, undergraduate and graduate students, and professionals in the field of pharmaceutical sciences and manufacturing, the second edition of Chemical Engineering in the Pharmaceutical Industry focuses on the development and chemical engineering as well as operations specific to the design, formulation, and manufacture of drug substance and products.

Now updated - the authoritative reference on one of the most exciting and challenging areas of the modern chemical industry This highly readable and informative reference continues to take a comprehensive, in-depth view of the products, markets, and technology of the fine chemicals industry and business. Dr. Peter Pollak, one of the foremost authorities in the field, provides an insider's unique perspective on fine chemicals from both a technological and a commercial viewpoint, covering all recent developments. He provides ample facts and figures including sixty-three tables, thirty figures, and nineteen photo inserts - making this a well-illustrated and documented text. This reference is divided into three parts: Part One: The Industry discusses the types of fine chemical companies, the range of products and services, the role of research and development, the underlying technologies, and the challenges facing management Part Two: The Business explores the key markets for fine chemicals - such as the pharmaceutical, agrochemical, and animal health industries - and the relevant marketing strategies, as well as the ins and outs of pricing, distribution channels, intellectual property rights, account
management, and promotion Part Three: Outlook examines trends such as globalization and outsourcing, forecasts future growth and development by industry segment, and discusses prerequisites for success in the field. This new edition features both updated and new information on the offer/demand balance for fine chemicals and the escalating impact of emerging companies in Asia, particularly from China and India. It describes the inversion of the mergers and acquisitions scenario from a seller's to a buyer's market, the broadening of the fine chemical business model, and the expanding role of biotechnology, as well as the impact of increased outsourcing of chemical manufacturing and the growing consumption of pharmaceuticals and agrochemicals by the life science industry. Also included are numerous molecular structures, engineering diagrams, and tables to facilitate understanding. For a thorough understanding of the technology, the business, and the future of the fine chemicals industry, this book's insight is unprecedented. It is ideally suited for those in the industry - including employees, suppliers, customers, investors, and consulting companies - as well as academic and other research organizations, students and educators, public officials, media representatives, and anyone else who wants to understand the intricacies of the industry. Fine Chemicals has been recognized as Outstanding Academic Title 2012 (Choice, v.50, no. 05, January 2013).

The Active Pharmaceutical Ingredients (API) is functional ingredients of a drug that acts against diseases. In other words, the active ingredient(s) in a drug or medicine are the substances that produce intended pharmacologic effects which might be positive or negative. The quality and safety of the drugs depends on API and new chemical entity development entirely depends on it. Most of the pharmaceutical industries buy API from other manufacturing
units. Therefore, it becomes mandatory to check quality of APIs and other raw materials. In the present study, assessment of the level of APIs in local drugs and microbial quality of water used in Pakistani pharmaceutics were studied. The present study found that twelve (n=12) drugs being analyzed for their APIs concentration were within acceptable level. These drugs include mefenamic acid, pyrethral pamoate, lignocaine hydrochlorid, ephedrine hydrochloride, cimetidine, aspirin, metronidazole, salbutamol, sulphamethoxazole, trimethoprim, benzyl benzoate and dexamethasone. The obtained results were statistical different for different drugs (P 0.05). However, no significant differences were found within drugs groups.

When a biological drug patent expires, alternative biosimilar products are developed. The development of biosimilar products is complicated and involves numerous considerations and steps. The assessment of biosimilarity and interchangeability is also complicated and difficult. Biosimilar Drug Product Development presents current issues for the development of biosimilars and gives detailed reviews of its various stages and contributing factors as well as relevant regulatory pathways and pre- and post-approval issues.

Designed to provide a comprehensive, step-by-step approach to organic process research and development in the pharmaceutical, fine chemical, and agricultural chemical industries, this book describes the steps taken, following synthesis and evaluation, to bring key compounds to market in a cost-effective manner. It describes hands-on, step-by-step, approaches to solving process development problems, including route, reagent, and solvent selection; optimising catalytic reactions; chiral syntheses; and "green chemistry." Second Edition highlights:

- Reflects the current thinking in chemical process R&D for small molecules
- Retains similar structure and orientation to the first edition
- Contains approx. 85% new material
- Primarily
new examples (work-up and prospective considerations for pilot plant and manufacturing scale-up) • Some new/expanded topics (e.g. green chemistry, genotoxins, enzymatic processes) • Replaces the first edition, although the first edition contains useful older examples that readers may refer to Provides insights into generating rugged, practical, cost-effective processes for the chemical preparation of "small molecules" Breaks down process optimization into route, reagent and solvent selection, development of reaction conditions, workup, crystallizations and more Presents guidelines for implementing and troubleshooting processes
This revised publication serves as a handy and current reference for professionals engaged in planning, designing, building, validating and maintaining modern cGMP pharmaceutical manufacturing facilities in the U.S. and internationally. The new edition expands on facility planning, with a focus on the ever-growing need to modify existing legacy facilities, and on current trends in pharmaceutical manufacturing which include strategies for sustainability and LEED building ratings. All chapters have been re-examined with a fresh outlook on current good design practices.
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. Presents the most effective catalytic reactions in use today, with a special focus on process intensification, sustainability, waste reduction, and innovative methods This book demonstrates the importance of efficient catalytic transformations for producing pharmaceutically active molecules. It presents the key catalytic reactions and the most efficient catalytic processes, including their significant advantages over compared previous methods. It also places a strong
emphasis on asymmetric catalytic reactions, process intensification (PI), sustainability and waste mitigation, continuous manufacturing processes as enshrined by continuous flow catalysis, and supported catalysis. Active Pharmaceutical Ingredients in Synthesis: Catalytic Processes in Research and Development offers chapters covering: Catalysis and Prerequisites for the Modern Pharmaceutical Industry Landscape; Catalytic Process Design - The Industrial Perspective; Hydrogenation, Hydroformylation and Other Reductions; Oxidation; Catalytic Addition Reactions; Catalytic Cross-Coupling Reactions; Catalytic Metathesis Reactions; Catalytic Cycloaddition Reactions: Coming Full-Circle; Catalytic Cyclopropanation Reactions; Catalytic C-H insertion Reactions; Phase Transfer Catalysis; and Biocatalysis. Provides the reader with an updated clear view of the current state of the challenging field of catalysis for API production -Focuses on the application of catalytic methods for the synthesis of known APIs -Presents every key reaction, including Diels-Alder, CH Insertions, Metal-catalytic coupling-reactions, and many more -Includes recent patent literature for completeness Covering a topic of great interest for synthetic chemists and R&D researchers in the pharmaceutical industry, Active Pharmaceutical Ingredients in Synthesis: Catalytic Processes in Research and Development is a must-read for every synthetic chemist working with APIs. Spanning chemical, cosmetic and manufacturing industries, this book is aimed at: chemists, clinicians, ecotoxicologists, operation managers, pharmaceutical process managers, quality assurance officers, technicians and toxicologists. The assessment of bioequivalence is an important process whereby the bioavailability of a generic drug product is compared with its brand-name
counterpart. Generic pharmaceutical products must be approved as therapeutic equivalents to the brand name alternative in order to be interchangeable. The demonstration of bioequivalence is an important component of therapeutic equivalence. Bioequivalence studies are very expensive, time consuming and always have the possibility of failure. The objective of this textbook is to describe some of those specific bioequivalence issues which need to be considered for the design and conduct of bioequivalence studies. By exploring scientific, legal, and international regulatory challenges, Generic Drug Development, discusses the use of alternative approaches to the measurement of plasma drug concentrations for the demonstration of bioequivalence, and covers bioequivalence procedures for drug products that are not easily assessed - based upon the physical and chemical properties of the active drug and the nature of the drug product.

With global harmonization of regulatory requirements and quality standards and national and global business consolidations ongoing at a fast pace, pharmaceutical manufacturers, suppliers, contractors, and distributors are impacted by continual change. Offering a wide assortment of policy and guidance document references and interpretations, this Sixth Edition is significantly expanded to reflect the increase of information and changing practices in CGMP
regulation and pharmaceutical manufacturing and control practices worldwide. An essential companion for every pharmaceutical professional, this guide is updated and expanded by a team of industry experts, each member with extensive experience in industry or academic settings.

A guide to the latest industry principles for optimizing the production of solid state active pharmaceutical ingredients Solid State Development and Processing of Pharmaceutical Molecules is an authoritative guide that covers the entire pharmaceutical value chain. The authors—noted experts on the topic—examine the importance of the solid state form of chemical and biological drugs and review the development, production, quality control, formulation, and stability of medicines. The book explores the most recent trends in the digitization and automation of the pharmaceutical production processes that reflect the need for consistent high quality. It also includes information on relevant regulatory and intellectual property considerations. This resource is aimed at professionals in the pharmaceutical industry and offers an in-depth examination of the commercially relevant issues facing developers, producers and distributors of drug substances.

This important book: Provides a guide for the effective development of solid drug forms Compares different characterization methods for solid state APIs Offers a resource for understanding efficient production methods for solid state forms of
chemical and biological drugs. Includes information on automation, process control, and machine learning as an integral part of the development and production workflows. Covers in detail the regulatory and quality control aspects of drug development. Written for medicinal chemists, pharmaceutical industry professionals, pharma engineers, solid state chemists, chemical engineers, Solid State Development and Processing of Pharmaceutical Molecules reviews information on the solid state of active pharmaceutical ingredients for their efficient development and production.

Focusing on the three most critical components that successfully bring an API to market-process development, manufacturing, and governmental regulation and approval-this reference serves as a step-by-step guide to the planning and clear understanding of the bulk manufacturing of APIs. This guide offers current and timely discussions of the process development cycle, design engineering, the approval process, quality control and assurance, and validation, as well as plant manufacturing activities including materials management, maintenance, and safety.

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.

Written by a researcher with experience designing, establishing, and validating biological manufacturing facilities worldwide, this is the first comprehensive
introduction to disposable systems for biological drug manufacturing. It reviews the current state of the industry; tackles questions about safety, costs, regulations, and waste disposal; and guides readers to choose disposable components that meet their needs. This practical manual covers disposable containers, mixing systems, bioreactors, connectors and transfers, controls and sensors, downstream processing systems, filling and finishing systems, and filters. The author also shares his predictions for the future, calling disposable bioprocessing technology a "game changer."

To successfully bring an Active Pharmaceutical Ingredient (API) to market, many steps must be followed to ensure compliance with governmental regulations. Active Pharmaceutical Ingredients is an unparalleled guide to the development, manufacturing, and regulation of the preparation and use of APIs globally. Topics include: Safety, efficacy, and envi

Covering the whole area of process chemistry in the pharmaceutical industry, this monograph provides the essential knowledge on the basic chemistry needed for future development and key industrial techniques, as well as morphology, engineering and regulatory compliances. Application-oriented and well structured, the authors include recent examples of excellent industrial production of active pharmaceutical ingredients.
The loss of candidate drugs (CD) due to poor physiological properties or incompatibilities with patients (more commonly referred to as attrition) in the pharmaceutical research and development (R&D) process limits throughput, hinders productivity and results in large overhead costs. Much of the attrition in the pharmaceutical industry is due to poor physiological properties. As a result, these properties need to be identified as early as possible in the R&D process. The initial step in screening for these properties is identifying (1) all the stable forms of a CD and (2) the conditions resulting in nucleation of these solid forms. Highly complex robotic systems have been developed to increase screening efficiency. These robotic systems enable researchers to work on a scale infeasible by hand; however, the number of conditions screened is still limited by the volumes required (~100 μl per well), thus the amount of material required, and the limited number of wells per device. Using a microfluidic approach allows for earlier screening due to the reduced volumes required. The development of a microfluidic platform to screen for crystallization conditions of CDs is presented. The chip using as little as 50 nl per well on a 96 well chip. The reduced volume and improved control over fluid handling in our microfluidic platforms allow for more extensive screening before production has been scaled up. The microfluidic platform studied in this thesis utilizes Free Interface Diffusion, Temperature
control and Evaporation to control the supersaturation of CDs and therefore induce nucleation. Operation and potential has been demonstrated with Acetaminophen screens on-chip. Successful chip operation is demonstrated in all three modes using a common Active Pharmaceutical Ingredient (API), acetaminophen. Additionally, the chips have been modified to accommodate analysis by Raman spectroscopy for crystal and polymorph identification. Incompatibility of PDMS with a wide range of organic solvents has limited the analysis on-chip. To overcome this challenge, more resistant microfluidic platforms are needed for example using glass instead of PDMS as the main material for chip fabrication. We are in the process of developing a glass-based microfluidic platform to reduce the amount of absorbent material.

Thoroughly updated and expanded, this new Third Edition provides the latest information on dosage, forms, film defects, and polymer characterization. Written by renowned leaders in the field, Aqueous Polymeric Coatings for Pharmaceutical Dosage Forms is easily the most comprehensive book available on the market today. New to the Third Edition: the interaction of drugs with functional polymers the influence of processing parameters on coating quality the stabilization of polymeric film coats plasticizers and their applications in pharmaceutical coatings adhesion of polymeric films to solid substrates basic
properties of latex and pseudolatex colloidal dispersions Key topics included:
polymer interactions with drugs and excipients physical aging of polymeric films a
complete overview and in-depth analysis of recent advances in the field, which
includes information on the latest equipment used to apply polymers to a
pharmaceutical system illustrated examples explaining the appropriate steps to
be taken in order to solve formulation, processing, and stability problems to
achieve an optimized dosage form
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.
Using clear and practical examples, Polymorphism of Pharmaceutical Solids,
Second Edition presents a comprehensive examination of polymorphic behavior
in pharmaceutical development that is ideal for pharmaceutical development
scientists and graduate students in pharmaceutical science. This edition focuses
on pharmaceutical aspects of polymorphism a
Process Understanding is the underpinning knowledge that allows the manufacture of chemical entities to be carried out routinely, robustly and to the required standard of quality. This area has gained in importance over the last few years, particularly due to the recent impetus from the USA`s Food and Drug Administration. This book covers the multidisciplinary aspects required for successful process design, safety, modeling, scale-up, PAT, pilot plant implementation, plant design as well the rapidly expanding area of outsourcing. In discussing what process understanding means to different disciplines and sectors throughout a product`s life cycle, this handbook and ready reference reveals the factors important to the development and manufacture of chemicals. The book focuses on the fundamental scientific understanding necessary for a smoother technical transfer between the disciplines, leading to more effective and efficient process development and manufacturing. A range of case studies are used to exemplify and illustrate the main issues raised. As a result, readers will appreciate that process understanding can deliver a real competitive advantage within the pharmaceuticals and fine chemicals industry. This book serves as an aid to meeting the stringent regulations required by the relevant authorities through demonstrable understanding of the underlying science. The suspension dosage form has long been used for poorly soluble active ingre-
ents for various therapeutic indications. Development of stable suspensions over the shelf life of the drug product continues to be a challenge on many fronts. A good understanding of the fundamentals of disperse systems is essential in the development of a suitable pharmaceutical suspension. The development of a suspension dosage form follows a very complicated path. The selection of the proper excipients (surfactants, viscosity imparting agents etc.) is important. The particle size distribution in the finished drug product dosage form is a critical parameter that significantly impacts the bioavailability and pharmacokinetics of the product. Appropriate analytical methodologies and instruments (chromatographs, viscometers, particle size analyzers, etc.) must be utilized to properly characterize the suspension formulation. The development process continues with a successful scale-up of the manufacturing process. Regulatory agencies around the world require clinical trials to establish the safety and efficacy of the drug product. All of this development work should culminate into a regulatory filing in accordance with the regulatory guidelines. Pharmaceutical Suspensions, From Formulation Development to Manufacturing, in its organization, follows the development approach used widely in the pharmaceutical industry. The primary focus of this book is on the classical disperse system – poorly soluble active pharmaceutical ingredients suspended in a suitable vehicle.
Quality assurance and good laboratory practices are becoming essential knowledge for professionals in all sorts of industries. This includes internal and external audit procedures for compliance with the requirements of good clinical, laboratory and manufacturing practices. Spanning chemical, cosmetic and manufacturing industries, Good Clinical, Laboratory and Manufacturing Practices: Techniques for the QA professional is aimed at: chemists, clinicians, ecotoxicologists, operation managers, pharmaceutical process managers, quality assurance officers, technicians and toxicologists. In addition sections on harmonisation of quality systems will be of value to safety, health and environment advisors. This comprehensive and high level reference will be an indispensable guide to research laboratories in academia and industry. Additional training material is also included.

During the last two decades, the pharmaceutical industry has been under pressure to reduce development costs and the time needed to bring drugs to market in order to maximize return on investment and bring treatments to patients sooner. To meet these ends, pharmaceutical scientists working in the differing areas of pharmacy, pharmaceutics, and phar...
modeling tools and concepts. It gives you the "what, why, and how" of using JMP® Pro for building and applying analytic models. This book is designed for business analysts, managers, and practitioners who may not have a solid statistical background, but need to be able to readily apply analytic methods to solve business problems. In addition, this book will greatly benefit faculty members who teach any of the following subjects at the lower to upper graduate level: predictive modeling, data mining, and business analytics. Novice to advanced users in business statistics, business analytics, and predictive modeling will find that it provides a peek inside the black box of algorithms and the methods used. Topics include: regression, logistic regression, classification and regression trees, neural networks, model cross-validation, model comparison and selection, and data reduction techniques. Full of rich examples, Building Better Models with JMP Pro is an applied book on business analytics and modeling that introduces a simple methodology for managing and executing analytics projects. No prior experience with JMP is needed. Make more informed decisions from your data using this newest JMP book.

Preclinical Drug Development, Second Edition discusses the broad and complicated realm of preclinical drug development. Topics range from assessment of pharmacology and toxicology to industry trends and regulatory
expectations to requirements that support clinical trials. Highlights of the Second Edition include: Pharmacokinetics
Modeling and simulation.

This textbook is written as a unified approach to various topics, ranging from drug discovery to manufacturing, techniques and technology, regulation and marketing. The key theme of the book is pharmaceuticals - what every student of pharmaceutical sciences should know: from the active pharmaceutical ingredients to the preparation of various dosage forms along with the relevant chemistry, this book makes pharmaceuticals relevant to undergraduate students of pharmacy and pharmaceutical sciences. This book explains how a particular drug was discovered and then converted from lab-scale to manufacturing scale, to the market. It explains the motivation for drug discovery, the reaction chemistry involved, experimental difficulties, various dosage forms and the reasoning behind them, mechanism of action, quality assurance and role of regulatory agencies. After having a course based on this book, the student will be able to understand: 1) the career prospects in the pharmaceutical industry, 2) the need for interdisciplinary teamwork in science, 3) the techniques and technology involved in making pharmaceuticals starting from bulk drugs, and 4) different dosage forms and critical factors in the development of pharmaceutical formulations in relation to the principles of chemistry. A few blockbuster drugs
including atorvastatin, sildanefil, ranitidine, ciprofloxacin, amoxicillin, and the longest serving drugs such as aspirin and paracetamol are discussed in detail. Finally, the book also covers the important current pharmaceutical issues like quality control, safety, counterfeiting and abuse of drugs, and future prospects for pharmaceutical industry. Unified approach explaining drug discovery, bulk drug manufacturing, formulation of dosage forms, with pharmacological and therapeutic actions Manufacturing processes of representative active pharmaceutical ingredients and their chemistry plus formulation of dosage forms presented in this book are based on actual industrial processes Covers many aspects relevant to students of the pharmaceutical sciences or newly employed pharmaceutical researchers/employees. It contains summary information about regulatory agencies of different countries Dietary Supplement GMP is a one-stop "how-to" road map to the final dietary supplement GMP regulations recently issued by the FDA covering the manufacture, packaging, and holding of dietary supplement products. The recent regulations, outlining broad goals, intentionally avoid specifics to allow for future technological advances—leaving implementation to the discretion of each firm. Given this latitude and flexibility, this new resource is an essential source of workable and practical suggestions on ways the industry can best meet the
goals. Based on broad experience with GMP compliance techniques worked out over the years in the food, drug, and medical device industries, it is a must-have guide for all DS companies, especially the many smaller firms for whom this is new territory. Dietary Supplement GMP provides: a practical guide in easy to understand language to help navigate through the requirements for systems covering process and quality control suggestions and practical recommendations on "how-to" achieve full compliance explanation of the FDA’s role regarding inspection, enforcement, recall/seizure of products and prosecution Dietary Supplement Good Manufacturing Practices (GMP) covers: Personnel Plants and Grounds Equipment and Utensils Sanitation of Buildings and Equipment Quality Assurance and Laboratory Operations The Quality Control Unit Production and Process Controls
The first edition of Pharmaceutical Extrusion Technology, published in 2003, was deemed the seminal book on pharmaceutical extrusion. Now it is expanded and improved, just like the usage of extrusion has expanded, improved and evolved into an accepted manufacturing technology to continuously mix active pharmaceutical ingredients with excipients for a myriad of traditional and novel dosage forms. Pharmaceutical Extrusion Technology, Second Edition reflects how this has spawned numerous research activities, in addition to hardware and
Crystallization is a widely used purification and separation technique in the pharmaceutical industry. More than 90% of the active pharmaceutical ingredients are produced in the crystalline form. The quality of the crystalline
product greatly affects the downstream processing and bioavailability of the drug. The Food and Drug Administration (FDA) initiated in 2004 the use and implementation of process analytical technology (PAT) in the pharmaceutical development and production and encourages the pharmaceutical industry to adopt quality by design (QBD) approaches. The prime objective of this initiative has been to optimize the drug development and manufacturing process by reducing cost, improving product quality and reducing the number of failed batches. The work presented in this thesis focuses on expanding the use of two PAT tools, namely attenuated total reflection ultra violet/visible spectroscopy (ATR-UV/Vis spectroscopy) and focused beam reflectance measurement (FBRM). ATR-UV/Vis spectroscopy and FRBM are mostly used for process monitoring. The aim here was to develop sophisticated control approaches using these in situ tools for enhancing the product quality. Chemometrics is an integral part of PAT, and can provide valuable information about the system. This tool has also been used in this study for calibration model development and monitoring the cooling and antisolvent crystallization processes for single and multicomponent crystallisations. The development of an accurate and robust calibration model is necessary for qualitative and quantitative analysis of a system using spectroscopy. A systematic methodology was therefore presented
for the selection of a suitable calibration model for ATR-UV/Vis spectroscopy. The developed model was then used as part of supersaturation control approach (SSC). SSC uses information from ATR-UV/Vis spectroscopy in a feedback control loop to keep the system at desired supersaturation. The developed approach resulted in the production of crystals of uniform size and can represent the bases for a model-free direct design approach for crystallization systems.

Active Pharmaceutical Ingredients Development, Manufacturing, and Regulation, Second Edition

Presenting authoritative and engaging articles on all aspects of drug development, dosage, manufacturing, and regulation, this Third Edition enables the pharmaceutical specialist and novice alike to keep abreast of developments in this rapidly evolving and highly competitive field. A dependable reference tool and constant companion for years to come.

Outlining the steps for developing fixed dose combination (FDC) drugs, this book gives a systematic approach to the full scope of FDCs – concept, design, formulation, and commercialization. • Includes case studies to illustrate best practices and challenges • Deals with a growing part of the pharmaceutical industry, as FDCs are ideal for targeting many chronic illnesses and for reducing the number of medications an increasingly-aging population needs to take • Ensures consistency in the delivery of FDC medication, which can be pivotal in increasing patient compliance and quality of
life • Collects dispersed knowledge – from patents in addition to scientific and clinical literature – so researchers can access a single source reference • Covers regulatory guidelines from around the world and looks ahead at developing areas of personalized medicine for FDCs

A guide to the development and manufacturing of pharmaceutical products written for professionals in the industry, revised second edition The revised and updated second edition of Chemical Engineering in the Pharmaceutical Industry is a practical book that highlights chemistry and chemical engineering. The book's regulatory quality strategies target the development and manufacturing of pharmaceutically active ingredients of pharmaceutical products. The expanded second edition contains revised content with many new case studies and additional example calculations that are of interest to chemical engineers. The 2nd Edition is divided into two separate books: 1) Active Pharmaceutical Ingredients (API's) and 2) Drug Product Design, Development and Modeling. The active pharmaceutical ingredients book puts the focus on the chemistry, chemical engineering, and unit operations specific to development and manufacturing of the active ingredients of the pharmaceutical product. The drug substance operations section includes information on chemical reactions, mixing, distillations, extractions, crystallizations, filtration, drying, and wet and dry milling. In addition, the book includes many applications of process modeling and modern software tools that are geared toward batch-scale and continuous drug substance pharmaceutical operations. This
updated second edition: • Contains 30 new chapters or revised chapters specific to API, covering topics including: manufacturing quality by design, computational approaches, continuous manufacturing, crystallization and final form, process safety • Expanded topics of scale-up, continuous processing, applications of thermodynamics and thermodynamic modeling, filtration and drying • Presents updated and expanded example calculations • Includes contributions from noted experts in the field

Written for pharmaceutical engineers, chemical engineers, undergraduate and graduate students, and professionals in the field of pharmaceutical sciences and manufacturing, the second edition of Chemical Engineering in the Pharmaceutical Industry focuses on the development and chemical engineering as well as operations specific to the design, formulation, and manufacture of drug substance and products.

The development of manufacturing tablets in a continuous way has been possible greatly to the fabrication of polymer based thin-films. It is estimated that the pharmaceutical industry loses as much as a 25% on revenues based on the currently employed batch manufacturing method. Here we studied a continuous way of manufacturing tablets based on API-based polymer formulations that are cast and subsequently rolled into a tablet. Selections of two active pharmaceutical ingredients (SPP-100 and Acetaminophen) were studied into how well it forms mechanical robust, chemical and physical compatible HPMC polymer based films. As well, HPMC polymer based films with no drug loading were compared to measure out the dispersion of the
Physiochemical studies were performed by DSC, XRD, FT-IR, and SEM. Moisture content was measured out by Karl Fischer Titration and mechanical properties such as tensile strength were measured for all API/HPMC and placebo films. It was found that the mechanical and physiochemical properties of SPP-100/HPMC films were regarded as the most promising thin film tablet candidate and it is further being tested for other mechanical properties such as bonding, friction, and compression.