Pharmaceutical Excipients Properties Functionality And Applications In Research And Industry

Innovative textile materials are used for numerous applications. Understanding the properties of such materials is imperative to ensure proper utilization. Emergent Research on Polymeric and Composite Materials is an essential reference work featuring the latest scholarly research on the synthesis, characterizations, and physico-chemical properties of textile materials. Including coverage on a range of topics such as nanomaterials, ceramics, and clays, this book is ideally designed for researchers, academicians, industries, and students seeking current research on emerging developments and applications of polymeric and composite materials.

This book deals with various unique elements in the drugdevelopment process within chemical engineering science andpharmaceutical R&D. The book is intended to be used as aprofessional reference and potentially as a text book reference inpharmaceutical engineering and pharmaceutical sciences. Many of theexperimental methods related to pharmaceutical process developmentare learned on the job. This book is intended to provide many ofthose important concepts that R&D Engineers and manufacturingEngineers should know and be familiar if they are going to besuccessful in the Pharmaceutical Industry. These include basicanalytics for quantitation of reaction components– oftenskipped in ChE Reaction Engineering and kinetics books. In additionChemical Engineering in the Pharmaceutical Industryintroduces contemporary methods of data analysis for kineticmodeling and extends these concepts into Quality by Designstrategies for regulatory filings. For the current professionals,in-silico process modeling tools that streamlineexperimental screening approaches is also new and presented here.Continuous flow processing, although mainstream for ChE, is uniquein this context given the range of scales and the complex economicsassociated with transforming existing batch-plant capacity. The book will be split into four distinct yet related parts.These parts will address the fundamentals of analytical techniquesfor engineers, thermodynamic modeling, and finally provides anappendix with common engineering tools and examples of theirapplications.

This book is aimed at raising awareness of researchers, scientists and engineers on the benefits of Principal Component Analysis (PCA) in data analysis. In this book, the reader will find the applications of PCA in fields such as taxonomy, biology, pharmacy,finance, agriculture, ecology, health and architecture.

A practical guide to Quality by Design for pharmaceutical product development Pharmaceutical Quality by Design: A Practical Approach outlines a new and proven approach to pharmaceutical product development which is now being rolled out across the pharmaceutical industry internationally. Written by experts in the field, the text explores the QbD approach to product development. This innovative approach is based on the application of product and process understanding underpinned by a systematic methodology which can enable pharmaceutical companies to ensure that quality is built into the product. Familiarity with Quality by Design is essential for scientists working in the pharmaceutical industry. The authors take a practical approach and put the focus on the industrial aspects of the new QbD approach to pharmaceutical product development and manufacturing. The text covers quality risk management tools and analysis, applications of QbD to analytical methods, regulatory aspects, quality systems and knowledge management. In addition, the book explores the development and manufacture of drug substance and product, design of experiments, the role of excipients, multivariate analysis, and include several examples of applications of QbD in actual practice. This important resource: Covers the essential information about Quality by Design (QbD)

that is at the heart of modern pharmaceutical development Puts the focus on the industrial aspects of the new QbD approach Includes several illustrative examples of applications of QbD in practice Offers advanced specialist topics that can be systematically applied to industry Pharmaceutical Quality by Design offers a guide to the principles and application of Quality by Design (QbD), the holistic approach to manufacturing that offers a complete understanding of the manufacturing processes involved, in order to yield consistent and high quality products.

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.

Pharmaceutical ExcipientsProperties, Functionality, and Applications in Research and IndustryJohn Wiley & Sons

Drug products are complex mixtures of drugs and excipients and, as such, their chemical and physical stability kinetics are complex. This book discusses the stability of these dosage forms with preformulation studies through to the studies on the final products. The book is intended for graduate students, researchers and professionals in the field of Pharmaceutics and Pharmaceutical Chemistry.

Peptide therapy has become a key strategy in innovative drug development, however, one of the potential barriers for the development of novel peptide drugs in the clinic is their deficiencies in clearly defined chemistry, manufacturing and controls (CMC) strategy from clinical development to commercialization. CMC can often become a rate-limiting step due to lack of knowledge and lack of a formal policy or guidelines on CMC for peptide-based drugs. Regulators use a risk-based approach, reviewing applications on a case-by-case basis. Peptide Therapeutics: Strategy and Tactics for Chemistry, Manufacturing, and Controls covers efficient manufacturing of peptide drug substances, a review of the process for submitting applications to the regulatory authority for drug approval, a holistic approach for quality attributes and quality control from a regulatory perspective, emerging analytical tools for the characterisation of impurities, and the assessment of stability. This book is an essential reference work for students and researchers, in both academia and industry, with an interest in learning about CMC, and facilitating development and manufacture of peptide-based drugs.

Pharmaceutical Preformulation and Formulation: A Practical Guide from Candidate Drug Selection to Commercial Dosage Form reflects the mounting pressure on pharmaceutical companies to accelerate the new drug development and launch process, as well as the shift from developing small molecules to the growth of biopharmaceuticals. The book meets the need for advanced information for drug preformulation and formulation and addresses the current trends in the continually evolving pharmaceutical industry. Topics include: Candidate drug selection Drug discovery and development Preformulation predictions and drug selections Product design to commercial dosage form Biopharmaceutical support in formulation Development The book is ideal for practitioners working in the pharmaceutical arena—including R&D

scientists, technicians, and managers—as well as for undergraduate and postgraduate courses in industrial pharmacy and pharmaceutical technology.

The Handbook of Pharmaceutical Excipients contains essential data on the physical properties of excipients, their safe use and potential toxicity.

To improve physico-chemical properties of an active pharmaceutical ingredient (API) at its preformulation stage, myriad of excipients having defined functional roles like solubility enhancement by co-solvent, micells formation and complexation, intestinal permeability enhancement through the inhibition of efflux transport mechanisms, stability-improvement using pH adjustment, cryo-and lyo-protectants, etc are incorporated into a dosage form containing the API. Although considered primarily as inactive materials, the excipient(s) may react with the API resulting in the development of a detrimental or beneficial substance within the API-loaded dosage form itself. If detrimental substances are formed, then, the issue of API-excipient incompatibility will come up and demand the reformulation of the API, which is costly and time-consuming. This book surveys a comprehensive list of published examples of API-excipient incompatibility relevant to currently or previously marketed drugs. With this coverage, this book also provides first-hand information on the multicomponent nature and complexity of the excipients to the formulation scientist.

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

This book constitutes the refereed proceedings of the 13th International Conference on Intelligent Data Engineering and Automated Learning, IDEAL 2012, held in Natal, Brazil, in August 2012. The 100 revised full papers presented were carefully reviewed and selected from more than 200 submissions for inclusion in the book and present the latest theoretical advances and real-world applications in computational intelligence.

The 7th edition of the European Pharmacopoeia was published July 15 2010 and consists of a two-volume main edition. It is complemented by non-cumulative supplements that are to be kept for the duration of the 7th Edition. Two supplements were published in 2010 and three supplements will be published in each 2011 and 2012. It contains information on all types of active substances used to prepare pharmaceutical products: various chemical substances, antibiotics, biological substances, vaccines for human or veterinary use, immunosera, radiopharmaceutical preparations, herbal drugs and homoepathic preparations. Over 1800 specific and general monographs are included.

To facilitate the development of novel drug delivery systems and biotechnology-oriented drugs, the need for new excipients to be developed and approved continues to increase. Excipient Development for Pharmaceutical, Biotechnology, and Drug Delivery Systems serves as a comprehensive source to improve understanding of excipients and forge new avenue

This new edition brings you up-to-date on the role of pharmaceutics and its future paradigms in the design of medicines. Contributions from over 30 international thought leaders cover the core disciplines of pharmaceutics and the impact of biotechnology, gene therapy, and cell therapy on current findings. Modern Pharmaceutics helps you stay current

Teaches future and current drug developers the latest innovations in drug formulation design and optimization This highly accessible, practice-oriented book examines current approaches in the development of drug formulations for preclinical and clinical studies, including the use of functional excipients to enhance solubility and stability. It covers oral, intravenous, topical, and parenteral administration routes. The book also discusses safety aspects of drugs and excipients, as well as regulatory issues relevant to formulation. Innovative Dosage Forms: Design and Development at Early Stage starts with a look at the impact of the polymorphic form of drugs on the preformulation and formulation development. It then offers readers reliable strategies for the formulation development of poorly soluble drugs. The book also studies the role of reactive impurities from the excipients on the formulation shelf life; preclinical formulation assessment of new chemical entities; and regulatory aspects for formulation design. Other chapters cover innovative formulations for special indications, including oncology injectables, delayed release and depot formulations; accessing pharmacokinetics of various dosage forms; physical characterization techniques to assess amorphous nature; novel formulations for protein oral dosage; and more. -Provides information that is essential for the drug development effort -Presents the latest advances in the field and describes in detail innovative formulations, such as nanosuspensions, micelles, and cocrystals -Describes current approaches in early pre-formulation to achieve the best in vivo results -Addresses regulatory and safety aspects, which are key considerations for pharmaceutical companies -Includes case studies from recent drug development programs to illustrate the practical challenges of preformulation design Innovative Dosage Forms: Design and Development at Early Stage provides valuable benefits to interdisciplinary drug discovery teams working in industry and academia and will appeal to medicinal chemists, pharmaceutical chemists, and pharmacologists.

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.

Integrating the basic principles and industrial practices of pharmaceutical granulation production, this book discusses technologies and demonstrates cost-effective approaches to manufacturing solid-dosage forms with content uniformity

and consistent physical properties while complying with regulatory requirements. Specialists from pharmaceutical companies, academia, and the U.S. Drug Regulatory Affairs agency address current and changing practices in industrial drug granulation production. Text, charts, figures, and photographs illustrate the pros and cons of diverse methods and technologies for accurately achieving strong bonding of particles in tablets and capsules.

Featuring methodology, applications, and up-to-date advances through the perspectives of developers, users, and regulatory personnel,Pharmaceutical Excipients provides an overview of excipients, functionalities of excipients in pharmaceutical dosage forms, case studies, and how their selection can influence pharmaceutical products manufacture. Including up-to-date advancements of their use in the field, this valuable resource for scientists, researchers, and chemical engineers compiles ten detailed chapters that encompass the overview, applications, and most current research.

Naturally occurring or manufactured through chemical and/or physical processes, particulate materials are substances consisting of individual particles which have significance to the global economy, society and environments. Due to the diversity and intrinsic nature, manufacturing, handling and processing of particulate materials still face numerous challenges. Aimed at addressing these challenges, this book contains a selection of papers discussing the state-of-the-art research in particulate materials science that were presented at the UK China Particle Technology Forum III held at Birmingham, UK in 2011. Classified into four distinct topics namely synthesis, characterisation, processing and modelling, the chapters showcase the advances in these areas including a range of advanced synthesis methods for example, spray-pyrolysis, supercritical fluid synthesis assisted with ultrasound, continuous synthesis using supercritical water, hydrothermal synthesis of nano-particulate materials and jet milling. For characterisation, various methods for characterising particulate materials at both particle and system levels are introduced and how these properties affect the behaviour of particulate materials in various processes, such as inhalation, filling, and consolidation, are discussed. In the processing section, recent advances such as capsule filling, micro-dosing, dry granulation, roll compaction, milling, and more are presented. The last section concerns mathematical and numerical modelling in particulate materials, for which the book includes both analytical methods and advanced numerical methods, such as discrete element methods (DEM), computational fluid dynamics (CFD), lattice Boltzmann methods (LBM), coupled DEM/CFD and DEM/LBM, and their applications. Particulate Materials is aimed at research communities dealing with these diverse materials, and scientists and engineers in powder handling industries, such as pharmaceutical, food, fine chemical and detergents. "

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 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 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.

With more restrictions upon animal experimentations, pharmaceutical industries are currently focusing on a new generation of experiments and technologies that are considerably more efficient and less controversial. The integration of computational and experimental strategies has led to the identification and development of promising compounds. Computer Applications in Drug Discovery and Development is a pivotal reference source that provides innovative research on the application of computers for discovering and designing new drugs in modern molecular biology and medicinal chemistry. While highlighting topics such as chemical structure databases and dataset utilization, this publication delves into the current panorama of drug discovery, where high drug failure rates are a major concern and properly designed virtual screening strategies can be a time-saving, cost-effective, and productive alternative. This book is ideally designed for chemical engineers, pharmacists, molecular biologists, students, researchers, and academicians seeking current research on the unexplored avenues and future perspectives of drug design.

There are unique challenges in the formulation, manufacture, analytical chemistry, and regulatory requirements of low-dose drugs. This book provides an overview of this specialized field and combines formulation, analytical, and regulatory aspects of low-dose development into a single reference book. It describes analytical methodologies like dissolution testing, solid state NMR, Raman microscopy, and LC-MS and presents manufacturing techniques such as granulation,

compaction, and compression. Complete with case studies and a discussion of regulatory requirements, this is a core reference for pharmaceutical scientists, regulators, and graduate students.

The book describes the properties, analytical methods and the applications of different polyvinylpyrrolidone excipients (povidone, crospovidone, copovidone etc.) for use in pharmaceutical preparations. This group of excipients is one of the most important excipients used in modern technology to produce drugs. The book is intended for all persons working in the research, development and quality control of drugs. It gives a survey of all applications in solid, liquid and semisolid dosage forms including many drug formulation examples and more than 600 references to the literature.

This book is about the chemical properties of starch. The book is a rich compendium driven by the desire to address the unmet needs of biomedical scientists to respond adequately to the controversy on the chemical properties and attendant reactivity of starch. It is a collective endeavor by a group of editors and authors with a wealth of experience and expertise on starch to aggregate the influence of qualitative and quantitative morphological, chemical, and genetic properties of starch on its functionalities, use, applications, and health benefits. The chemical properties of starch are conferred by the presence, amount and/or quality of amylose and amylopectin molecules, granule structure, and the nature and amounts of the lipid and protein molecules. The implication of this is comprehensively dealt with in this book.

Presents a detailed discussion of important solid-state properties, methods, and applications of solid-state analysis Illustrates the various phases or forms that solids can assume and discussesvarious issues related to the relative stability of solid forms and tendencies to undergo transformation Covers key methods of solid state analysis including X-ray powder diffraction, thermal analysis, microscopy, spectroscopy, and solid state NMR Reviews critical physical attributes of pharmaceutical materials, mainly related to drug substances, including particle size/surface area, hygroscopicity, mechanical properties, solubility, and physical and chemical stability Showcases the application of solid state material science in rational selection of drug solid forms, analysis of various solid forms within drug substance and the drug product, and pharmaceutical product development Introduces appropriate manufacturing and control procedures using Quality by Design, and other strategies that lead to safe and effective products with a minimum of resources and time

The global cost of health care is increasing year after year, and one of the ways governments and health care providers are looking to reduce cost is by reducing the cost of drug products. The generic industry is under tremendous pressure to remain competitive in the market place by reducing the cost of their product, with the main cost factor being the active pharmaceutical ingredient and some of the excipients used in the manufacture of the drug product. These companies are expected to follow the required guidelines set out by the international regulatory authorities and more specifically of the countries they intent to market their product in if they are planning to change the source of the material. These regulatory

guidelines are general in nature with a focus on safety and efficacy and the evaluation of an alternate source of material by pharmaceutical companies varies greatly from company to company. The evaluation is conducted mainly on the basis of chemical and physical data from the Certificate of Analysis comparing the current and alternate source to determine equivalency. Differences in process and critical processing parameters of the material can have significant impact on the behavior of the chemical, which may not be detectable through evaluation of the Certificates of Analysis. It is, therefore, critical to study properties that are not captured on the Certificate of Analysis, such as polymorphism, melting point, solubility, particle shape, packing tendencies among other aspects of the material that are important for the performance of the material in the drug product formulation and manufacturing process. The differences in these properties can have significant impact on the unit operations during the manufacturing process as well as the critical quality attributes and the stability of the drug product. The evaluation is conducted by utilizing various tools of analytical and process testing to determine the physical performance, physicochemical evaluation, chemical evaluation and functional performance evaluation for the active pharmaceutical ingredient and excipient. The evaluation of the Certificate of Analysis will also need to be more in depth, and go beyond the alternate source meeting the specifications as there can be significant differences with the results obtained even though they meet specification. It is important to identify these differences earlier in the evaluation stage and to assess the impact, if any, on the manufacturing process and the drug product prior to introducing the change. This study was conducted with active pharmaceutical ingredients selected based on the processing unit operations, such as direct compression process (metformin HCl), dry compaction (gabapentin), and hot-melt process (fenofibrate). The selection of the excipients was based on their functional properties, such as binders (copovidone NF/EP) and super disintegrant (croscarmellose Sodium NF/EP), allowing for evaluation with respect to differences in functionality if any, from the different sources. Additionally, the copovidone NF/EP is the binder in the gabapentin USP tablet formulation while the croscarmellose Sodium NF/EP is the super disintegrant in the fenofibrate EP/BP tablet formulation. An example of this challenge is that the evaluation of Certificate of Analysis for the materials supplied from two companies and two sources revealed differences in tests required for the two materials and a significant difference in some of the results obtained; however, both materials met their respective Certificate of Analysis specifications. Several tests beyond the Certificate of Analysis were performed and significant differences were also observed in many of these as well. The two sources were evaluated with respect to the compression process and the alternate source of material did show significant challenges during the tablet compression process and did not meet some of the in-process critical quality attributes test. The in-vitro performance for both sources were comparable, however, the recommendation will be not to proceed with the alternate source. There were many differences between the

sources of all the materials evaluated including differences in particle size, morphology, moisture, manufacturing process and residual solvents among others. The impact on the manufacturing unit operation varies from no impact for the fenofibrate EP/BP materials, to not meeting the critical quality attributes for metformin HCl tablets with the new source of the active pharmaceutical ingredients. This study indicates the importance of a systematic evaluation of a material from an alternate source with respect to the performance of the manufacturing process, drug product, and their critical quality attributes; understanding the impact of these changes to the material and having the ability to correlate these to potential issues with the manufacturing process and drug product critical quality attributes prior to introducing an alternate source of material is critical.

Despite advances in the development of new drugs, a drug may never reach the target organ, or it may be difficult to achieve the necessary level of drug in the body. Large doses can result in serious side effects and can harm normal, as well as diseased, cells and organs, and for this reason it is vital that controlled release and the targeting of delivery systems must evolve in parallel to drug research. Chemical Aspects of Drug Delivery Systems reflects the modern challenge to devise effective drug delivery and targeting systems, giving particular emphasis to recent innovations in the field. Delivery systems described include carbohydrate derivatives, novel nonionic surfactant vesicles and various polymers, including polyacrylates and aqueous shellac solutions, as well as hydrogels. In addition, many of the key issues, such as the understanding of biosystems and targets and the development of materials to provide the deserved carrier and excipient properties for controlled, targeted drug delivery, are considered in depth. This book will be of equal interest to undergraduate, graduate, researcher and those in the pharmaceutical industries, and it complements two previous RSC Special Publications, Encapsulation and Controlled Release and Excipients and Delivery Systems for Pharmaceutical Formulations.

Food biopolymers: Structural, functional and nutraceutical properties provides valuable coverage of all major food biopolymers from plant, animal and marine sources. The text focuses on the structural characteristics of biopolymers including starch, non-starch polysaccharides, proteins and fats. A full section is dedicated to the nutraceutical potential and applications of these polymers. Further sections provide comprehensive overviews of the development of functional food products and important data on biopolymer behavior and nutraceutical potential during processing. Researchers hoping to gain a basic understanding of the techno-functional, nutraceutical potential and applications of food biopolymers will find a singular source with this text. The first section of this work focuses on the the structure, functions, bioactivity and applications of starches. The next chapters cover non-starch polysaccharides. Further sections are dedicated to proteins, lipids and oils. A detailed overview is provided for each, followed by application procedures,

specifics on individual types, proteins and enzymes, and nutraceutical properties. This work can be used as a singular source for all relevant information on food biopolymers and their structural and functional properties, including their potential to increase food quality, improve shelf life, and reduce pollution and waste in the food industry.

Compaction of powder constituents—both active ingredient and excipients—is examined to ensure consistent and reproducible disintegration and dispersion profiles. Revised to reflect modern pharmaceutical compacting techniques, this second edition of Pharmaceutical Powder Compaction Technology guides pharmaceutical engineers, formulation scientists, and product development and quality assurance personnel through the compaction formulation process and application. This unique reference covers: The physical structure of pharmaceutical compacts Bonding phenomena that occur during powder compaction Compression mechanisms of pharmaceutical particles Theories and basic principles of powder compaction New topics include: Compaction data analysis techniques The migration of powder constituents into commercial manufacture Instrumentation for compaction Compaction functionality testing, which is likely to become a USP requirement Design space for compaction Metrics required for scalability in tablet compression Interactive compaction and preformulation database for commonly used excipients

This title focuses on the comprehension of the properties of water in foods, enriched by the approaches from polymer and materials sciences, and by the advances of analytical techniques. The International Symposium on the Properties of Water (ISOPOW) promotes the exchange of knowledge between scientists involved in the study of food materials and scientists interested in water from a more basic point of view and the dialogue between academic and industrial scientists/technologists. This comprehensive book covers the topics presented at the 10th ISOPOW held in Bangkok, Thailand in 2007, including water dynamics in various systems, the role of water in functional food and nano-structured biomaterials. Special features include: Latest findings in the properties of water in food, pharmaceutical and biological systems Coverage of the 10th International Symposium on the Properties of Water (ISOPOW) Includes water dynamics, water in foods stability, and water in micro and nano-structured food and biomaterials Reflects the vast array of research and applications of water world wide

This edited volume brings together the expertise of numerous specialists on the topic of particles – their physical, chemical, pharmacological and toxicological characteristics – when they are a component of pharmaceutical products and formulations. The book discusses in detail properties such as the composition, size, shape, surface properties and porosity of particles with respect to how they impact the formulations and products in which they are used and the effective delivery of pharmaceutical active ingredients. It considers all dosage forms of pharmaceuticals involving particles, from powders to tablets, creams to ointments, and solutions to dry-powder inhalers, also including the latest nanomedicine products. Further, it discusses examples of particle toxicity, as well as the important subject of pharmaceutical industry regulations, guidelines and legislation. The book is of interest to researchers and practitioners who work on testing and developing pharmaceutical dosage and delivery systems.

Interest in ionic liquids (ILs) has grown with its evolution now spanning three generations: (1) ILs with tunable physical properties; (2) ILs with tunable chemical properties; and (3) ILs with tunable biological properties. A growing number of biological applications using ILs are underway as a replacement solvent for synthesis, for use as a biological constituent and for preserving and enhancing the functionality of biomolecular species. Therapeutic biomolecules play a significant role in the medical field and in the research field, with many being trialed and developed for various applications; primarily as the name suggests for therapeutic uses. The storage and stability of therapeutic

biomolecules has long been an issue. It is now among common knowledge to store therapeutic biomolecules at low temperatures ranging from 4°C to -196°C, depending on the concentrations in use. Ideally the freeze thaw cycles are also limited to maintain stability and activity. It is also commonly kept on ice whilst in use in a laboratory space. Although the use of refrigeration and ice in laboratories and hospitals may not be an issue, in third world countries this is still a significant problem. The transportation and storage of such therapeutic molecules can be problematic, hence the storage, stability and activity to be maintained at room temperature is vital in sterile and non-sterile conditions.The focus of this thesis is to preserve the structure and activity of biomolecules using choline dihydrogen phosphate (CDHP) buffered ionic liquid (BIL). Choline is an essential nutrient in the human body, and hence a biocompatible IL is formed using choline as the cation. Choline is currently FDA approved for pharmaceutical excipients making it a favorable selection for a constituent of the ionic liquid.In light of current literature reports the stability of the biomolecules are important and is assessed via thermal stability, structural integrity and biological stability and activity. The storage of therapeutic biomolecules in CDHP-BIL was compared to phosphate buffered saline (PBS) a common storage buffer for biomolecular species. Studies were conducted for prolonged periods in conjunction with enzymatic degradation and characterized using a number of techniques including assays, gel electrophoresis, circular dichroism, UV-Vis spectrometry, flow cytometry and confocal microscopy. Three therapeutic biomolecules have been examined for this project:1) Small interfering ribonucleic acid (siRNA),2) Plasmid deoxyribonucliec Acid (pDNA) and3) Monoclonal antibodies (mAbs)Each chapter of this thesis is dedicated to each therapeutic biomolecule mentioned above. Chapter 2 reports the stabilization and retaining of biological activity of siRNA. Chapter 3, demonstrates that the stability of nucleic acids is not limited to siRNA, proving that CDHP-BIL can impede enzymatic degradation and the expression of pDNA can be enhanced. As a continuation of bimolecular therapeutic we moved on to proteins in Chapter 4, reporting inhibition of proteinase K when mAbs are stored in BILs. Finally this thesis envisages the future directions and challenges for the long term storage and stabilization of therapeutic biomolecules at room temperature. The simple manner of being able to store therapeutic molecules in a buffer that can enhance the properties of the biomolecules whilst prolonging its shelf life, is extraordinary. The applications of this study are far and wide once integrated in the medical field as it has the potential to be a new green bio-buffer.

In recent years, many animal-derived polymers have emerged as an attractive category of naturally derived polymers because of their advantageous physicochemical, chemical, and biological properties. The important biological properties of these natural polymers derived from animals are biocompatibility and biodegradation. These polymers are generally composed of repeated units of amino acids. Moreover, these polymers can be modified physically and/or chemically to improve their biomaterial properties. Natural Polymers for Pharmaceutical Applications, Volume 3: Animal-Derived Polymers looks at how these polymers can be exploited as pharmaceutical excipients in various pharmaceutical dosage forms, like microparticles, nanoparticles, ophthalmic preparations, gels, implants, etc. The commonly used animal-derived polymers used as pharmaceutical excipients are hyaluronic acid (hyaluronan), albumin, collagen, gelatin, chondroitin, etc.

This book highlights different natural products that are derived from the plants and microbes that have shown potential as the lead compounds against infectious diseases and cancer. Natural products represent an untapped source of strikingly diverse chemotypes with novel mechanisms of action and the potential to serve as anticancer and anti-infective agents. The book discusses a range of biotechnologically valuable bioactive compounds and secondary metabolites that have been derived from plant and microorganisms from various ecological niches. It also reviews the latest developments in the field of genomics, bioinformatics and industrial fermentation for harnessing the microbial products for commercial applications. In turn, the book’s closing section reviews important biotechnological

applications of various natural products. Combining the expertise of specialists in this field, the book’s goal is to promote the further investigation of natural sources for the development of standardized, safe and effective therapies.

A comprehensive, uniform guide to the uses, properties, and safety of pharmaceutical excipients and is an essential reference source for those involved in the development, production, control or regulation of pharmaceutical preparations. Features of this edition: Contains 210 excipient monographs; Collects together essential data of physical properties of excipients; Scanning electron photomicrographs included for many excipients; Contains information from various international sources; Also includes laboratory data determined specifically for the Handbook and personal observations; Contains information on the safe use and potential toxicity of the materials; All monographs in the Handbook are thoroughly cross-referenced and indexed so that excipients may be identified by either chemical, non-proprietary, or trade names; Written by over 120 pharmaceutical scientists expert in pharmaceutical formulation or excipient manufacture.

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.