

Sterile Pharmaceutical  
Products

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# Process Engineering Applications

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Drug Manufacturing  
Technology Series

Edited by  
Kenneth E. Avis



CRC Press  
Taylor & Francis Group

# Sterile Pharmaceutical Products Process Engineering Applications

**Anshul Verma, Pradeepika Verma, Kiran  
Kumar Pattanaik, Sanjay Kumar  
Dhurandher, Isaac Woungang**

## **Sterile Pharmaceutical Products Process Engineering Applications:**

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*Biotechnology and Biopharmaceutical Manufacturing, Processing, and Preservation* Kenneth E. Avis,Vincent L. Wu,2020-08-13 In this unique book experts describe practices applicable to the large scale processing of biotechnological products Beginning with processing and bulk storage preservation techniques the book provides strategies for improving efficiency of process campaigns of multiple products and manufacturing facilities for such processing techniques Large scale chromatography for the purification of biomolecules in

manufacturing and lyophilization of protein pharmaceuticals are discussed Includes a case study on blow fill seal processing technology and a chapter on economic and cost factors for bioprocess engineering **Sterile Drug Products** Michael J. Akers, 2016-04-19 Sterile Drug Products Formulation Packaging Manufacturing and Quality teaches the basic principles of the development and manufacture of high quality sterile dosage forms The author has 38 years of experience in the development and manufacture of sterile dosage forms including solutions suspensions ophthalmics and freeze dried products This *Guide to Microbiological Control in Pharmaceuticals and Medical Devices, Second Edition* Stephen P. Denyer, Rosamund M. Baird, 2006-12-26 Microbiological matters continue to exercise considerable influence on product quality In both the pharmaceutical and medical device industries products of greater sophistication along with evolving regulatory requirements are elevating the challenges related to maintaining microbiological integrity Updated to reflect technological and regulatory changes the *Guide to Microbiological Control in Pharmaceuticals and Medical Devices Second Edition* covers those principal aspects of microbiology that are relevant to the preformulation formulation manufacturing and license application stages involved with the production of pharmaceuticals and medical devices In recognition of the diverse disciplines involved in pharmaceutical and medical device production this work provides a brief introduction to microbiology geared towards the nonmicrobiologist Covering good manufacturing practice in the control of contamination the text explores quality control the preservation of formulations and principles of sterilization including microbiological specific considerations for biotechnological products and other medical devices It also provides additional materials on package integrity and contamination risks in clean rooms The editors have produced a companion text the *Handbook of Microbiological Quality Control in Pharmaceuticals and Medical Devices* see reverse which when paired with the *Guide* offers a complete theoretical and practical treatment of microbiological control This book provides a comprehensive distillation of information concerning methodology and regulations that would otherwise remain scattered throughout the literature It allows scientists from many fields to address potential problems in advance and implement suitable strategies at the earliest stages of development *The Encyclopedia of Bioprocess Technology* Michael C. Flickinger, Stephen W. Drew, 1999 *Tissue and Cell Processing* Deirdre Fehily, Scott A. Brubaker, John N. Kearney, Lloyd Wolfenbarger, Jr., 2012-06-11 By presenting the latest technological advances and growing national and international regulation this new book explores state of the art developments in the challenging field of tissue and cell processing It provides a guide to easier and safer practice in operational principles of preservation decontamination and sterilization Nearly half of the book is devoted completely to tissue or cell specific issues relating to processing With lists of learning points and case studies which consist of sample processing protocols descriptions of where processing went wrong sample risk assessments or validation studies the authors help you find specific information fast *Encyclopedia of Bioprocess Technology* Michael C. Flickinger, 1999

**Remington** David B. Troy, Paul Beringer, 2006 For over 100 years Remington has been the definitive textbook and

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**Advanced Network Technologies and Intelligent Computing** Anshul Verma, Pradeepika Verma, Kiran Kumar Pattanaik, Sanjay Kumar Dhurandher, Isaac Woungang, 2024-08-07

The 4 volume proceedings set CCIS 2090 2091 2092 and 2093 constitute the refereed post conference proceedings of the Third International Conference on Advanced Network Technologies and Intelligent Computing ANTIC 2023 held in Varanasi India during December 20 22 2023 The 87 full papers and 11 short papers included in this book were carefully reviewed and selected from 487 submissions The conference papers are organized in topical sections on Part I Advanced Network Technologies Part II Advanced Network Technologies Intelligent Computing Part III IV Intelligent Computing

*Chemical Engineering in the Pharmaceutical Industry* Mary T. am Ende, David J. am Ende, 2019-04-01 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

**Dosage Form Design Parameters**, 2018-07-25 Dosage Form Design Parameters Volume II examines the history and current state of the field within the pharmaceutical sciences presenting key developments Content includes drug development issues the scale up of formulations regulatory issues intellectual property solid state properties and polymorphism Written by experts in the field this volume in the Advances in Pharmaceutical Product Development and Research series deepens our understanding of dosage form design parameters Chapters delve into a particular aspect of this fundamental field covering principles methodologies and the technologies employed by pharmaceutical scientists In addition the book contains a comprehensive examination suitable for researchers and advanced students working in pharmaceuticals cosmetics biotechnology and related industries Examines the history and recent developments in drug dosage forms for pharmaceutical sciences Focuses on physicochemical aspects preformulation solid state properties and polymorphism Contains extensive references for further discovery and learning that are appropriate for advanced undergraduates graduate students and those interested in drug dosage design

**Biotechnology** Kenneth E. Avis, Carmen M. Wagner, Vincent L. Wu, 2020-04-22 Biotechnology Quality Assurance and Validation provides a practical detailed discussion of what issues Quality Assurance and Quality Control need to identify for effective control in the preparation of biotechnology products The book presents a series of topics that define some of the unique challenges facing biotechnology companies in producing biopharmaceutical products The topics selected address quality and validation issues starting with the cryopreservation of cell lines through the filling and finishing of the product It includes a validation guide a clear presentation of how to use filtration effectively a synoptic view of cleaning procedures and much more

**Pharmaceutical Technology: Concepts and applications** S. Bharath, 2013 Pharmaceutical Technology Concepts and Applications articulates on the various pharmaco technological concepts associated with industrial pharmacy The book not only focuses on providing comprehensive information on formulation development and affiliated areas but also emphasizes on their industrial applications With a plethora of examples that illustrate important concepts the book equips students of pharmacy to rise to the requirements of the industry

**Remington** Adeboye Adejare, 2020-11-03 The PCP's Bicentennial Edition Remington The Science and Practice of Pharmacy Twenty Third Edition offers a trusted completely updated source of information for education training and development of pharmacists Published for the first time with Elsevier this edition includes coverage of biologics and biosimilars as uses of those therapeutics have increased substantially since the previous edition Also discussed are formulations drug delivery including prodrugs salts polymorphism With clear detailed color illustrations fundamental information on a range of pharmaceutical science areas and information on new developments in industry pharmaceutical industry scientists especially those involved in drug discovery and development will find this edition of Remington an

essential reference Intellectual property professionals will also find this reference helpful to cite in patents and resulting litigations Additional graduate and postgraduate students in Pharmacy and Pharmaceutical Sciences will refer to this book in courses dealing with medicinal chemistry and pharmaceutics Contains a comprehensive source of principles of drug discovery and development topics especially for scientists that are new in the pharmaceutical industry such as those with trainings degrees in chemistry and engineering Provides a detailed source for formulation scientists and compounding pharmacists from produg to excipient issues Updates this excellent source with the latest information to verify facts and refresh on basics for professionals in the broadly defined pharmaceutical industry *PHARMACEUTICAL ENGINEERING*

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*24th European Symposium on Computer Aided Process Engineering* ,2014-06-20 The 24th European Symposium on Computer Aided Process Engineering creates an international forum where scientific and industrial contributions of computer aided techniques are presented with applications in process modeling and simulation process synthesis and design operation and process optimization The organizers have broadened the boundaries of Process Systems Engineering by inviting contributions at different scales of modeling and demonstrating vertical and horizontal integration Contributions range from applications at the molecular level to the strategic level of the supply chain and sustainable development They cover major classical themes at the same time exploring a new range of applications that address the production of renewable forms of energy environmental footprints and sustainable use of resources and water

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