Annex 9 Guidelines On Packaging For Pharmaceutical Products

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WHO Expert Committee on Specifications for Pharmaceutical Preparations World Health Organization
This book is the 4th in a series of Acute Care books written with the aim to address the NEEDS of health care providers when handling the acutely ill patients. Globally it has become apparent that the study of pharmacology and subsequent clinical training has not always adequately equipped young doctors with the ability to administer drugs to their patients safely and confidently, particularly in the critically ill patient. Compounding this issue is the lack of resource material related to these pharmacological concepts contained in one book that can help health care providers to understand and manage drug therapy in the acute situation. In spite of progressively newer and more developed protocols, guidelines, algorithms and many other books addressing the technical aspects of what needs to be done, most health care providers still find it difficult to grasp the basic pharmacological knowledge and rationally deliver the CARE that is required in the acute phase of patient management. The editors/authors have therefore aimed for a book that highlights topics and pharmacological issues pertinent to management of patients in their hour of need. This is a multi-author book but the style has been guided by 3 editors. The editors have used a different perspective – that of normalizing abnormal physiological processes with pharmacological agents – to address the GAPS in a bedside to bench approach. The details are pared down but important principles/concepts are emphasized.
GRAB YOUR DREAM JOB IN PHARMA: INTERVIEW QUESTIONS & ANSWERS Springer
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.
Access to NCD medicines: emergent issues during the COVID-19 pandemic and key structural factors John Wiley & Sons
The coronavirus disease (COVID-19) pandemic exacerbated pre-existing inequalities in the treatment and care of non-communicable diseases (NCD). The report examines the effect of the COVID-19 pandemic on access to NCD medicines, and the policies and strategies implemented by countries and health systems to anticipate and mitigate stresses across NCD medicine supply chains. The full range of upstream and downstream impacts are investigated, including: manufacturing; procurement, importation and last mile delivery; patient-level effects through affordability and availability; and the effects on NCD medicine availability by category of disease. The report culminates in recommended actions and interventions for key stakeholders in the NCD pharmaceutical supply chain, including governments, regulatory authorities, manufacturers and the private sector; as well as directions for future research for improving access and supply chain access resilience.
Air Navigation Law Open Book Publishers
The International Pharmacopoeia contains a collection of recommended methods for analysis and quality specifications for pharmaceutical substances, excipients and products. This new edition consolidates the texts of the five separate volumes of the third edition and includes new monographs for antiretroviral substances (didanosine, indinavir sulfate, nelfinavir mesilate, nevirapine, ritonavir, saquinovir, and saquinovir mesilate) adopted by the WHO Expert Committee on Specifications for Pharmaceutical Preparations in October 2004. It includes some additions and amendments to the general notices of the Pharmacopoeia, as well as some changes to its layout and format. Volume one contains monographs for pharmaceutical substances A to O and the General Notices; and volume two contains monographs for pharmaceutical substances P to Z, together with those for dosage forms and radiopharmaceutical preparations, the methods of analysis and reagents.
Oversight of the Consumer Product Safety Commission Routledge
The Expert Committee on Specifications for Pharmaceutical Preparations works towards clear, independent and practical standards and guidelines for the quality assurance of medicines and provision of global regulatory tools. The Expert Committee develops standards through worldwide consultation and an international consensus-building process. The following new guidance texts were adopted and recommended for use: WHO good manufacturing practices for excipients used in pharmaceutical products (revision); IAEA/WHO good manufacturing practices for in-house cold kits for radiopharmaceutical preparations (new); WHO good practices for pharmaceutical quality control laboratories (revision); WHO/UNFPA female condom generic specification (new); WHO Biowaiver List: proposal to waive in vivo bioequivalence requirements for WHO Model List of Essential Medicines immediate-release (updated), solid oral dosage forms; WHO guideline on Biopharmaceutics Classification System-based biowaivers (revision); and Multisource (generic) pharmaceutical products: guidelines on registration requirements to establish interchangeability (republished). All of the above are included in this report and recommended for implementation.
Handbook of Stability Testing in Pharmaceutical Development World Health Organization
Pharmaceutical packaging requires a greater knowledge of materials and a greater intensity of testing than most other packed products, not to mention a sound knowledge of pharmaceutical products and an understanding of regulatory requirements. Structured to meet the needs of the global market, this volume provides an assessment of a wide range of issues. It covers the entire supply chain from conversion of raw materials into packaging materials and then assembled into product packs. Integrating information from many drug delivery systems, the author discusses testing and evaluation and emphasizes traceability and the need to for additional safeguards.
Good Manufacturing Practice (GMP) Guidelines Smithers Rapra
Pharmaceutics: the science of medicine design explores the different forms that medicines can take, and demonstrates how being able to select the best form - be it a tablet, injectable liquid, or an inhaled gas - requires an understanding of how chemicals behave in different physical states.
Guidelines for the international packaging and shipping of vaccines John Wiley & Sons
The Expert Committee on Specifications for Pharmaceutical Preparations works towards clear, independent and practical standards and guidelines for the quality assurance of medicines. Standards are developed by the Committee through worldwide consultation and an international consensus-building process. The following new guidelines were adopted and recommended for use, in addition to 20 monographs and general texts for inclusion in The International Pharmacopoeia and 11 new International Chemical Reference Substances. The International Pharmacopoeia - updating mechanism for the section on radiopharmaceuticals; WHO good manufacturing practices for pharmaceutical products: main principles; Model quality assurance system for procurement agencies; Assessment tool based on the model quality assurance system for procurement agencies: aide-memoire for inspection; Guidelines on submission of documentation for prequalification of finished pharmaceutical products approved by stringent regulatory authorities; and Guidelines on submission of documentation for a multisource (generic) finished pharmaceutical product: quality part.
Pharmaceutical Packaging Technology Pharmalogika
This title combines all of the human and veterinary Regulations, Directives and guidance for medicinal products used by the pharmaceutical industry as their main source when manufacturing and distributing medicinal products in the

European Union.

WHO Expert Committee on Specifications for Pharmaceutical Preparations Sanjivan Saini

This book covers the chemistry, physics, materials science, engineering, and therapeutic aspects of many different types of packaging materials, emphasizing throughout the applicability of various aspects of packaging science and technology. It also provides a simultaneous discussion of interrelated fields, and addresses the universal issues within these fields' application areas. Intended as a technical reference and as a study aid, it is relevant to anyone who studies or uses packaging or packaging materials. Packaging Technology and Engineering: Pharmaceutical, Medical and Food Applications begins with an overview of the history of the topic. It then offers chapters on the methods of obtaining raw materials, the chemistry of polymeric and non-polymeric packaging materials, physico-chemical quality parameters, and the manufacturing of packaging. Other topics look at: additives, use, suppliers, safety and environmental concerns, regulation, anti-fraud activities, new trends, and the future of packaging technology. The book also features numerous problems and worked solutions to aid student comprehension. Covers packaging and packaging materials, their properties and technologies Addresses the chemical engineering, physics, and chemistry of packaging materials, and the individual requirements for food, pharmaceutical, and medical device packaging Includes current issues such as environmental concerns and sustainability, recycling and after-use, anti-counterfeiting technology, and packaging regulations and guidelines Packaging Technology and Engineering: Pharmaceutical, Medical and Food Applications will appeal to all packaging technologists, scientists, and engineers in industry, and in regulatory agencies. It is also an excellent book for advanced students studying packaging courses, within pharmacy, pharmaceutical sciences, chemical sciences, biomedical sciences, medical sciences, engineering, product design and technology, and food science/technology.

Pharmaceutical Manufacturing Handbook John Wiley & Sons

These guidelines form a comprehensive overview of Failure Mode and Effects Analysis (FMEA) and examines why FMEA has become a powerful and respected analytical technique for effectively managing and reducing risks. Readers learn how to use FMEA throughout the life cycles of their product to improve customer satisfaction and assure safety and regulatory compliance. They will obtain sound advice on selecting a study team, setting up and conducting a study, and analyzing the results. Other topics include Failure Mode, Effects, and Criticality Analysis, Risk Management Planning, Advanced Quality Planning, Product Quality Control Plans, and Dynamic Control Plans.

Pharmaceutics TSO

With its coverage of Food and Drug Administration regulations, international regulations, good manufacturing practices, and process analytical technology, this handbook offers complete coverage of the regulations and quality control issues that govern pharmaceutical manufacturing. In addition, the book discusses quality assurance and validation, drug stability, and contamination control, all key aspects of pharmaceutical manufacturing that are heavily influenced by regulatory guidelines. The team of expert authors offer you advice based on their own firsthand experience in all phases of pharmaceutical manufacturing.

Pharmacological Basis of Acute Care WHO Technical Report

"Packaging" by Sanjivan Saini is a comprehensive book that provides an overview of various aspects of packaging. It covers a wide range of topics related to packaging, including special packaging, safety precautions, exportable goods packaging, dangerous goods packaging, packaging for cold products, freezing products, dairy products, and packaging for hot products. Additionally, the book delves into the cost involved in packaging, its components, and various other relevant subjects. Here is a brief overview of the main units covered in the book: 1. Packaging: This unit likely introduces the fundamentals of packaging, including its purpose, importance, and various applications across industries. It may cover topics such as packaging materials, design, and functions. 2. Special Packaging: The section on special packaging explores specific packaging requirements for products with unique characteristics or needs, such as medical devices, fragile items, or hazardous substances. 3. Safety Precautions: Safety is paramount in packaging. This unit likely discusses safety measures and guidelines for packaging, including how to handle hazardous materials safely and ensure compliance with regulations. 4. Exportable Goods Packaging: Exporting goods requires careful packaging to withstand the rigors of transportation. This unit would cover the packaging considerations for goods destined for international markets. 5. Dangerous Goods Packaging: This unit delves into the packaging requirements for dangerous goods, including hazardous chemicals, radioactive materials, and other substances that require specialized containment. 6. Packaging for Cold Products, Freezing Products, Dairy Products: These sections likely focus on packaging solutions for perishable goods, such as food items that need refrigeration or freezing to maintain their quality and safety. 7. Packaging for Hot Products: In contrast to the previous unit, this section would cover packaging designed to handle products that require high temperature resistance, such as hot food items or industrial materials. 8. Cost Involved, Component of Cost Involved: This unit would explore the economic aspects of packaging, including the various costs associated with packaging materials, design, production, and transportation. The book "Packaging" by Sanjivan Saini is likely to be a valuable resource for students, professionals, and anyone interested in gaining a comprehensive understanding of the diverse aspects of packaging. It covers a wide range of topics, providing practical insights into designing effective and safe packaging solutions for different types of products and industries.

Child-resistant Packaging Oxford University Press

Packaging, Packages, Childproof equipment, Drug containers, Safety devices, Type testing, Performance testing

The International Pharmacopoeia Stationery Office/Tso

A QUICK INTERVIEW REVISION BOOK Grab Your Dream Job in Pharma Interview Questions & Answers for: Drug Regulatory Affairs Scientific Research Writing Research and Development Pharma QA/ QC/ Production Pharmacovigilance Clinical Research Clinical Data Management Pharmaceutical Marketing List of companies in India & QR Codes 100+ Pharma Business ideas Overview: This comprehensive questionnaire with answers, written by industry experts, educators, and professionals, is designed to bridge the gap between HR and candidates by offering common interview questions specific to pharmacovigilance. Thus, it enhances jobseeker's preparation and confidence. The author aims to revolutionize the healthcare and, pharmaceutical and research industries by equipping professionals with the knowledge and skills they need to ace their interviews & jobs. As the pharmaceutical and healthcare industry continues to evolve and expand, there is a growing demand for professionals with specialized knowledge and skills in such areas. We have gone the extra mile to develop specialized tools and support in this book, such as career guidance exclusively for job seekers. Our vision is to empower job seekers and professionals like you to take charge of their careers by providing them with the necessary market knowledge. Key Features: ü A trusted companion for job seekers with authentic data and references. ü Pharmacovigilance Technical Interview Q & A: Everything a Candidate Needs in One Place. ü Updated with Current Affairs. 100+ New Pharma Business Ideas. ü Useful for Pharmacy , Medicine and other healthcare sectors competitive exams. ü Learn Technical Skills to get hired.

Packaging - Child-resistant packaging - Requirements and testing procedures for non-reclosable packages for non-pharmaceutical products John Wiley & Sons

Providing a truly global overview of legislation in all major countries, this practical volume contains the information vital for manufactures of food contact materials and food producers, facilitating a comparison of the requirements and making mutual requirements easier to identify. It covers not only plastics but also other food contact materials, such as paper, board, coatings, ceramics, cork, rubber, and textiles.

International instruments on the use of antimicrobials across the human, animal and plant sectors World Health Organization

The GMP Compendium for Medical Products is a valuable resource for manufacturers, regulators, and other stakeholders involved in producing and distributing medical products. It covers various topics, from quality management systems to personnel hygiene, equipment validation, and complaint handling. The guidance provided is based on the latest scientific and technical knowledge and considers the evolving regulatory landscape and the challenges faced by the industry.

Pharmaceutical Microbiological Quality Assurance and Control World Health Organization

This book provides detailed and comprehensible information about Quality Control (QC) in the industry. Different viewpoints are explained in relation to food companies, packaging producers and technical experts, including regulatory aspects. One of the most important steps is the comprehension of QC failures in relation to the 'food product' (food/packaging). The book also presents a detailed selection of proposals about new testing methods. On the basis of regulatory obligations in the EU about the technological suitability of food packaging materials, a list of 'performance-oriented' guidelines is proposed. Food sectors are mentioned in relation to products, related packaging materials, known failures and existing quality control procedures. This volume serves as a practical guide on food packaging and QC methods and a quick reference to food operators, official safety inspectors, public health institutions, Certification bodies, students and researchers from the academia and the industry.

Dosage Forms, Formulation Developments and Regulations World Health Organization

This book provides insight into the world of pharmaceutical quality systems and the key elements that must be in place to change the business and organizational dynamics from task-oriented procedure-based cultures to truly integrated quality business systems that are self-detecting and correcting. Chapter flow has been changed to adopt a quality systems organization approach, and supporting chapters have been updated based on current hot topics including the impact of the worldwide supply chain complexity and current regulatory trends.

Packaging Technology and Engineering Springer Science & Business Media

International shipping of vaccines is the first leg of the complex journey that vaccines undertake to reach the end users in a country. Particular challenges include the size and weight of packages, implementation of quality control checks at reception, ensuring environmental sustainability, and maintaining required temperatures during the journey. Although there are many possibilities of transport e.g. sea freight and terrestrial transportation, air freight currently remains the most widely used means of transport for vaccines. In recognition of this fact, these guidelines apply predominantly to the air freighting of vaccines. Transportation of vaccines from the manufacturing facility to the airport facility require the use of ground transportation, and reference is also made to the qualification of refrigerated road vehicles as well. The objective of these guidelines is to provide technical guidance to help ensure the quality of vaccines during all stages of the international air transportation process. These guidelines are applicable to all persons and institutions involved in international air shipment of vaccines from the premises of the product manufacturer to the recipient country. This includes all parties involved in shipment, vaccine manufacturers, logistics service providers (LSPs), freight forwarders, carriers and their employees. The relevant sections of these guidelines should also be considered for implementation by UN procurement agencies and other international procurement organizations, countries, donor agencies and certifying bodies.

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