Solution A	
Sedium chloride	160.0 g
Potassium chloride	4.0 g
Calcium chloride, antipéroui	2.0 g
Magnesium chioride, anhydrous	1.0 g
Disodium hydrogen phosphate dodecabydrate	0.10 g
Water for injections R	to 1000 m/L
Solution B	
Solution A	50:0 mut.
Altrogene sulfate	0.5 mg
Sodium hydrogen carbonate	1.0 g
Glucose monohydrate	0.5 g
Water for importions R	no 1000 mil.

Solution B should be freshly prepared and used within 24 h.



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2.6.11. DEPRESSOR SUBSTANCES

Carry out the test on a cat weighing not less than 2 kg and anaesthetised with chloralose or with a barbiturate that allows the maintenance of uniform blood pressure. Protect the animal from loss of body heat and maintain it so that the rectal temperature remains within physiological limits. Introduce a cannula into the trachea. Insert a cannula filled with a heparinised 9 g/L solution of sodium chloride into the common carotid artery and connect it to a device capable of giving a continuous record of the blood pressure. Insert into the femoral vein another cannula, filled with a heparinised 9 g/L solution of sodium chloride, through which can be injected the solutions of histamine and of the substance to be examined. Determine the sensitivity of the animal tohistamine by injecting intravenously at regular intervals, doses of histamine solution R corresponding to 0.1 µg and 0.15 µg of histamine base per kilogram of body mass. Repeat the lower dose at least 3 times. Administer the second and subsequent injections not less than 1 min after the blood pressure has returned to the level it was at immediately before the previous injection. The animal is used for the test only if a readily discernible decrease in blood pressure that is constant for the lower dose is obtained and if the higher dose causes greater responses. Dissolve the substance to be examined in sufficient of a 9 g/L solution of sodium chloride or other prescribed solvent, to give the prescribed concentration. Inject intravenously per kilogram of body mass 1.0 mL of histamine solution R, followed by 2 successive injections of the prescribed amount of the solution to be examined and, finally, 1.0 ml, of histamine solution R. The second, third and fourth injections are given not less than I min after the blood pressure has returned to the level it was at immediately before the preceding injection. Repeat this series of injections twice and conclude the test by giving 1.5 mL of histamine solution R per kilogram of body mass.

If the response to 1.5 ml, of histamine solution R per kilogram of body mass is not greater than that to 1.0 ml, the test is invalid. The substance to be examined fails the test if the mean of the series of responses to the substance is greater than the mean of the responses to 1.0 ml, of histamine solution R per kilogram of body mass or if any one dose of the substance causes a greater depressor response than the concluding dose

of the histamine solution. The test animal must not be used in another test for depressor substances if the second criterion applies or if the response to the high dose of histamine given after the administration of the substance to be examined is less than the mean response to the low doses of histamine previously injected.



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2.6.12. MICROBIOLOGICAL EXAMINATION OF NON-STERILE PRODUCTS: MICROBIAL ENUMERATION TESTS:::

1. INTRODUCTION

The tests described hereafter will allow quantitative enumeration of mesophilic bacteria and fungi that may grow under aerobic conditions.

The tests are designed primarily to determine whether a substance or preparation complies with an established specification for microbiological quality. When used for such purposes follow the instructions given below, including the number of samples to be taken, and interpret the results as stated below.

The methods are not applicable to products containing viable micro-organisms as active ingredients.

Alternative microbiological procedures, including automated methods, may be used, provided that their equivalence to the Pharmacopoeia method has been demonstrated.

2. GENERAL PROCEDURES

Carry out the determination under conditions designed to avoid extrinsic microbial contamination of the product to be examined. The precautions taken to avoid contamination must be such that they do not affect any micro-organisms that are to be revealed in the test.

If the product to be examined has antimicrobial activity, this is insofar as possible removed or neutralised. If inactivators are used for this purpose, their efficacy and their absence of toxicity for micro-organisms must be demonstrated.

If surface-active substances are used for sample preparation, their absence of toxicity for micro-organisms and their compatibility with inactivators used most be demonstrated.

3. ENUMERATION METHODS

Use the membrane filtration method or the plate-count methods, as prescribed. The most-probable-number (MPN) method is generally the least accurate method for microbial counts, however, for certain product groups with a very low bioburden, it may be the most appropriate method.

The choice of method is based on factors such as the nature of the product and the required limit of micro-organisms. The chosen method must allow testing of a sufficient sample size to judge compliance with the specification. The suitability of the method chosen must be established.

4. GROWTH PROMOTION TEST, SUITABILITY OF THE COUNTING METHOD AND NEGATIVE CONTROLS

4-1. GENERAL CONSIDERATIONS

The ability of the test to detect micro-organisms in the presence of product to be tested must be established. Suitability must be confirmed if a change in testing performance, or the product, which may affect the outcome of the test is introduced.

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<u>6 12 Microbiological Examination Of Non Sterile</u>

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6 12 Microbiological Examination Of Non Sterile:

Pharmaceutical Microbiological Quality Assurance and Control David Roesti, Marcel Goverde, 2020-01-02 Relying on practical examples from the authors experience this book provides a thorough and modern approach to controlling and monitoring microbial contaminations during the manufacturing of non sterile pharmaceuticals Offers a comprehensive guidance for non sterile pharmaceuticals microbiological QA QC Presents the latest developments in both regulatory expectations and technical advancements Provides guidance on statistical tools for risk assessment and trending of microbiological data Describes strategy and practical examples from the authors experience in globalized pharmaceutical ICH Quality Guidelines Andrew Teasdale, David Elder, Raymond W. Nims, 2017-09-29 companies and expert networks Examining the implications and practical implementation of multi disciplinary International Conference on Harmonization ICH topics this book gives an integrated view of how the guidelines inform drug development strategic planning and decision making Addresses a consistent need for interpretation training and implementation examples of ICH guidelines via case studies Offers a primary reference point for practitioners addressing the dual challenge of interpretation and practical implementation of ICH guidelines Uses case studies to help readers understand and apply ICH guidelines Provides valuable insights into guidelines development with chapters by authors involved in generating or with experience implementing the guidelines Includes coverage of stability testing analytical method validation impurities biotechnology drugs and products and good manufacturing practice GMP Specification of Drug Substances and Products Christopher M. Riley, K. Lien Nguyen, 2024-09-22 Specification of Drug Substances and Drug Products is a fully comprehensive reference on Specification Setting for Pharmaceuticals There have been several recent developments in the ICH Guidelines which were not captured in previous editions notably the new guideline on Development of Analytical Procedure and the revisions to the validation quidelines and the specification guidelines. This edition contains chapters discussing the unique requirements for the universal critical quality attributes as well as the specific tests required to characterize and control different types of products ranging in complexity from small molecules in immediate release oral dosage forms to complex products such as drug antibody conjugates and mRNA based products This substantially expanded revision of the 2nd edition will serve as practical comprehensive reference for scientists managers educators and consultants involved in the development and regulation of pharmaceutical products Presents critical assessment potential impact and application of the recent revisions to ICH guidelines on method validation Q2 as well as the latest guideline on Analytical Method Development Q14 and the special regional requirements in non ICH regions Addresses comprehensive treatment of the development and validation of analytical methodologies used in the analysis control and specification of a variety of different types of dosage forms ranging from traditional oral solid dosage forms to proteins nRNA based drugs vaccines and gene therapy This book will also address drug device combination products such as digital drug delivery systems transdermal systems and inhalation products

Presents detailed treatment of latest statistical approaches including new approaches to the treatment of validation data method specification setting and shelf life prediction based on stability data *European Pharmacopoeia*, 2013

Practical Handbook of Microbiology Emanuel Goldman, Lorrence H Green, 2015-06-04 The Practical Handbook of Microbiology presents basic knowledge about working with microorganisms in a clear and concise form It also provides in depth information on important aspects of the field from classical microbiology to genomics in one easily accessible volume Practical Handbook of Microbiology This new edition retains the easy to use format of previous editions with a lo Lorrence H Green, Emanuel Goldman, 2021-05-04 Practical Handbook of Microbiology 4th edition provides basic clear and concise knowledge and practical information about working with microorganisms Useful to anyone interested in microbes the book is intended to especially benefit four groups trained microbiologists working within one specific area of microbiology people with training in other disciplines and use microorganisms as a tool or chemical reagent business people evaluating investments in microbiology focused companies and an emerging group people in occupations and trades that might have limited training in microbiology but who require specific practical information Key Features Provides a comprehensive compendium of basic information on microorganisms from classical microbiology to genomics Includes coverage of disease causing bacteria bacterial viruses phage and the use of phage for treating diseases and added coverage of extremophiles Features comprehensive coverage of antimicrobial agents including chapters on anti fungals and anti virals Covers the Microbiome gene editing with CRISPR Parasites Fungi and Animal Viruses Adds numerous chapters especially intended for professionals such as healthcare and industrial professionals environmental scientists and ecologists teachers and businesspeople Includes comprehensive survey table of Clinical Commercial and Research Model bacteria The Open Access version of this book available at http www taylorfrancis com has been made available under a Creative Commons Attribution Non Commercial No Derivatives 4 0 license Chapter 21 Archaea of this book is freely available as a downloadable Open Access PDF under a Creative Commons Attribution Non Commercial No Derivatives 4 0 license available at http www taylorfrancis com See Emanuel Goldman s Open Access article Lamarck redux and other false arguments against SARS CoV 2 vaccination https www embopress org doi full 10 15252 embr 202254675 European Pharmacopoeia Consejo de Europa. Dirección para la Calidad en los Medicamentos, 2013 Essentials of Tissue and Cells Banking George Galea, Marc Turner, Sharon Zahra, 2021-07-02 It has been 10 years since the first edition of Essentials of Tissue Banking has been published There is still relatively little published on the technical and scientific principles on routine tissue and cell banking based on scientific principles The 1st edition was very successful and after a 10 year gap there is a need of an update and an expansion of the book s remit The format of the book follows that of the previous edition split into 5 sections Management of donors and the banking of common tissues and cells Principles of storage and processing of tissues and cells Ensuring the safety of the products by testing the donor the tissues and the environment supported by a quality system and an IT

infrastructure all working within the constraints of current regulatory and ethical environments This edition however provides a significant update Many the chapters have been completely rewritten by different experts Like the 1st edition they were given a free hand in the way they wrote their chapter with a guideline that they had to be concise clear and up to date The authors were also asked to provide the scientific and technical basis that provides the rationale of the processes they describe Also the scope of the book has been somewhat extended In view of the fact that many cellular therapies are now routinely practiced 2 new chapters have been added one on the banking of haematopoietic stem cells and one on human embryonic stem cells They have been deliberately chosen to illustrate the extreme spectrum of cellular therapies from one of the simplest to one of the most complex The intention of the book has remained the same to cover and update banking of current practices in essential tissue and cell banking It is therefore hoped that by keeping the book as concise and up to date **Plasma Assisted Decontamination of** as possible it will find a place on the shelves of many tissue establishments Biological and Chemical Agents Selcuk Güceri, Alexander Fridman, 2011-10-12 Plasma decontamination is a rapidly expanding area of modern science and engineering An increasing number of engineers are using plasma methods for decontamination of chemical and biological agents Plasma decontamination is effectively applied today to clean and sterilize different surfaces high volume air and water streams industrial exhausts and even living tissue of animals and humans This book provides a fundamental introduction to virtually all aspects of modern plasma decontamination as well as the most recent technological achievements in the area The book is segmented into four specific sections of modern plasma decontamination 1 plasma bio decontamination including disinfection and sterilization of surfaces water and air streams 2 plasma decontamination of chemical agents including cleaning of air water and industrial exhaust gases from different pollutants and especially volatile organic compounds VOC 3 plasma treatment of living tissue including different subjects of plasma medicine from skin sterilization to tissue engineering 4 major electric discharges applied for the plasma assisted decontamination of chemical and biological agents Drug Safety Evaluation Shayne Cox Gad, 2016-11-18 This practical guide presents a road map for safety assessment as an integral part of the development of new drugs and therapeutics Helps readers solve scientific technical and regulatory issues in preclinical safety assessment and early clinical drug development Explains scientific and philosophical bases for evaluation of specific concerns including local tissue tolerance target organ toxicity and carcinogenicity developmental toxicity immunogenicity and immunotoxicity Covers the development of new small and large molecules generics 505 b 2 route NDAs and biosimilars Revises material to reflect new drug products small synthetic large proteins and cells and tissues harmonized global and national regulations and new technologies for safety evaluation Adds almost 20% new and thoroughly updates existing content from the last edition Pharmaceutics [GPAT] -Books [Study Notes] 7 in 1 Books with 2500+ Question Answer As Per Updated Syllabus DIWAKAR EDUCATION HUB,2022-04-01 Pharmaceutics GPAT Books Study Notes 7 Books with 2500 Question Answer As Per Updated Syllabus

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Textbook of Quality Assurance Akansha Shakya,2022-04-21 This Quality Assurance book intended for Pharmacy students especially Third year students of Bachelor of Pharmacy This book is also beneficial for professionals engaged in Quality Assurance Department We have tried to emphasize on the basics of Quality Assurance Thus complexity of the matter has been avoided with a view that complete course content has to be completed by the student in limited time period This book present a concise and effective reference to the topics with an approach to make it interesting and convenient to remember the complicated Quality Assurance terms *NASA Standard Procedures for the Microbiological Examination of* Space Hardware United States. National Aeronautics and Space Administration,1968 Pharmaceutical Analysis for Small *Molecules* Behnam Davani, 2017-08-01 A comprehensive introduction for scientists engaged in new drug development analysis and approvals Each year the pharmaceutical industry worldwide recruits thousands of recent science graduates especially chemistry analytical chemistry pharmacy and pharmaceutical majors into its ranks However because of their limited background in pharmaceutical analysis most of those new recruits find making the transition from academia to industry very difficult Designed to assist both recent graduates as well as experienced chemists or scientists with limited regulatory compendial or pharmaceutical analysis background make that transition Pharmaceutical Analysis for Small Molecules is a concise yet comprehensive introduction to the drug development process and analysis of chemically synthesized small molecule drugs It features contributions by distinguished experts in the field including editor and author Dr Behnam Davani an analytical chemist with decades of technical management and teaching experience in compendial regulatory and industry This book provides an introduction to pharmaceutical analysis for small molecules non biologics using commonly used techniques for drug characterization and performance tests The driving force for industry to perform pharmaceutical analyses is submission of such data and supporting documents to regulatory bodies for drug approval in order to market their products In addition related required supporting studies including good laboratory documentation practices including analytical instrument qualification are highlighted in this book Topics covered include Drug Approval Process and Regulatory Requirements private standards Pharmacopeias and Compendial Approval Process public standards Common methods in pharmaceutical analysis typically compendial Common Calculations for assays and impurities and other

specific tests Analytical Method Validation Verification Transfer Specifications including how to handle out of specification OOS and out of trend OOT Impurities including organic inorganic residual solvents and elemental impurities Good Documentation Practices for regulatory environment Management of Analytical Laboratories Analytical Instrument Qualifications including IQ OQ PQ and VQ Due to global nature of pharmaceutical industry other topics on both regulatory ICH and Compendial harmonization are also highlighted Pharmaceutical Analysis for Small Molecules is a valuable working resource for scientists directly or indirectly involved with the drug development process including analytical chemists pharmaceutical scientists pharmacists and quality control quality assurance professionals It also is an excellent text reference for graduate students in analytical chemistry pharmacy pharmaceutical and regulatory sciences **Textbook of Pharmaceutics - E-Book** Sanjay Kumar Jain, Vandana Soni, 2011-08-23 This adaptation of Bentley's Textbook of Pharmaceutics follows the same goals as those of the previous edition albeit in a new look The content of the old edition has been updated and expanded and several new chapters viz Complexations Stability Testing as per ICH Guidelines Parenteral Formulations New Drug Delivery Systems and Pilot Plant Manufacturing have been included with an intention to make the book more informative for the modern pharmacists The book has six sections Section I deals with the physicochemical principles Two new chapters Complexations and ICH Guidelines for Stability Testing have been added to make it more informative Section II conveys the information regarding pharmaceutical unit operations and processes Section III describes the area of pharmaceutical practice Extensive recent updates have been included in many chapters of this section Two new chapters Parenteral Formulations and New Drug Delivery Systems have been added Section IV contains radioactivity principles and applications Section V deals with microbiology and animal products Section VI contains the formulation and packaging aspects of pharmaceuticals Pilot Plant Manufacturing concepts are added as a new chapter which may be beneficial to readers to understand the art of designing of a plant from the pilot plant model Integrated **Pharmaceutics** Antoine Al-Achi, Mali Ram Gupta, William Craig Stagner, 2022-09-21 This work is an examination of all aspects of the science in developing effective dosage form for drug delivery Pharmaceutics refers to the subfield of pharmaceutical sciences that develops drug delivery products or devices to optimize the drug s performance once administered This multidisciplinary field draws on physical chemistry organic chemistry and biophysics to generate and refine these crucial elements of medical care Moreover incorporating such disparate dimensions of drug product design as material properties and legal regulation bridges the gap between effective chemicals and viable medical treatments Integrated Pharmaceutics provides a comprehensive introduction to the creation and manufacture of effective dosage forms for drug delivery It presents its subject following the principles of physical pharmacy product design and drug regulations This tripartite structure allows readers to move from theory to practice beginning from a firm foundation of physical pharmacy principles including drug solubility and stability estimation rheology and interfacial properties From there it

proceeds to discussions of drug product design and of harmonizing pharmaceutical design with the regulatory regimens and technological standards of the United States European Union and Japan Readers of the second edition of Integrated Pharmaceutics will also find A glossary defining key terms extensive informative appendices and a list of references leading to the primary literature in the field for each chapter Earlier chapters are expanded with additional new chapters including one entitled Biotechnology Products Supplementary instructor guide with questions and solutions available online for registered professors Updated regulatory guidelines including quality by design design space analysis process analytical technology polymorphism characterization blend sample uniformity and stability protocols Integrated Pharmaceutics is a useful textbook for graduate students in pharmaceutical sciences drug formulation and design and biomedical engineering In addition professionals in the pharmaceutical industry including regulatory bodies will find it a helpful reference guide

Pharmaceutical Stability & Stability Testing Prof. Abdrhman Mahmoud Gamil, 2025-09-19 Being foreword by Professor Abubakr O Nur University of Khartoum this book combines the theoretical background of dosage form degradation and stability problems together with practical procedures to perform various types of stability studies It describes the probable physical changes the chemical kinetics of degradation reactions that may take place and the microbiological spoilage It considers the influence of different factors on the stability of pharmaceuticals and their impact on the shelf life with emphasis on the effect of temperature taking in account the concept of the mean kinetic temperature and its calculation The international regulatory guidelines together with the dosage form requirements and specifications and how to estimate or predict the shelf life with practical examples This book is a valuable guide to students where they can found model question and answers researchers and professionals of industrial pharmacy

Cumulated Index Medicus, 1994

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