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(1117) MICROBIOLOGICAL BEST LABORATORY PRACTICES

INTRODUCTION

Good laboratory practices in a microbiology laboratory consist of activities that depend on several principles: aseptic technique, control of media, control of test strains, operation and control of equipment, diligent recording and evaluation of data, and training of the laboratory staff. Because of the inherent risk of variability in microbiology data, reliability and reproducibility are dependent on the use of ac-

cepted methods and adherence to good laboratory practices.

MEDIA PREPARATION AND QUALITY CONTROL

Media Preparation

Culture media are the basis for most microbiological tests. Safeguarding the quality of the media is therefore critical to the success of the microbiology laboratory. Media preparation, proper storage, and quality control testing can ensure a consistent supply of high-quality media.

It is important to choose the correct media or components in making media based on the use of accepted sources or references for formulas. The manufacturer's formula and instructions for preparation routinely accompany dehydrated media and ready-made media. Because different media types may have different preparation requirements (e.g., heating, additives, and pH adjustment), it is important to follow these instructions to ensure preparation of acceptable media quality. A certificate of analysis describing expiration dating and recommended storage conditions accompanies ready-made media, as well as the quality control organisms used in growth-promotion and selectivity testing of that media.

Water is the universal diluent for microbiological media. Purified Water is most often used for media preparation, but in certain cases the use of deionized or distilled water may be appropriate. Water of lesser quality should not be used for microbiological media preparation. The volume of the water used should be recorded.

Consistent preparation of media requires accurate weighing of dehydrated media or media constituents. A calibrated balance with the appropriate weight range for the ingredients should be used (See *Weighing on an Analytical Balance* (1251)). Clean weighing containers and tools (such as spatulas) should be used to prevent foreign substances from entering the formulation. The weight of the components should be recorded.

Dehydrated media should be thoroughly dissolved in water before dispensing and sterilization. If heating is necessary to help dissolve the media, care should be taken not to overheat media, because all culture media, to a greater or lesser extent, are heat-sensitive. Equipment used in the preparation of media should be appropriate to allow for controlled heating, constant agitation, and mixing of the media. Darkening of media (Maillard-type reaction or nonenzymatic browning) is a general indication of overheating. When adding required supplements to media, adequate mixing of the medium after adding the supplement should be performed.

Preparation of media in poorly cleaned glassware can allow inhibitory substances to enter the media. Inhibitory substances can come from detergent residue after cleaning glassware or from prior materials used in the glassware. Be sure that the cleaning process removes debris and foreign matter, and that the detergent is thoroughly rinsed out with Purified Water. See *Cleaning Glass Apparatus* (1051) for additional guidance.

Sterilization of media should be performed within the parameters provided by the manufacturer or validated by the user. Commercially prepared media should provide documentation of the sterilization method used. Autoclaving by moist heat is the preferred sterilization technique, except in instances when boiling is required in order to avoid deterioration of heat-labile components of the media. Sterilization by filtration may also be appropriate for some formulations.

The effects of the sterilization method and conditions on the media should be validated by sterility and growth-promotion testing of the media. In addition, if sterilized by moist heat, the autoclave cycle should be validated to en-

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Christian Drosten



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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 companies and expert networks

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 guidelines 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 mRNA 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

The Pharmacy Technician, 7e Perspective Press, 2020-01-15 Endorsed by the American Pharmacists Association APhA The Pharmacy Technician 7e is a valuable tool for pharmacy technician students This applied accessible book is a practical text for understanding the principles career concepts and pharmacy skills needed to be a successful pharmacy technician It offers clear concise information to help students learn the material and pass the national certification exams the Pharmacy Technician Certification Exam PTCE and the Exam for Certification of Pharmacy Technicians ExCPT This book was designed to be accompanied by The Pharmacy Technician Workbook Certification Review 7e to help prepare for the certification exams This textbook aligns with the Fifth

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Acoustics of Layered Media II Leonid M. Brekhovskikh, Oleg A. Godin, 2013-04-17 This is the sequel to our book *Acoustics of Layered Media I* Plane and Quasi Plane Waves Springer Ser Wave Phenom Vol 5 Taken together these two monographs present a systematic exposition of the theory of sound propagation in inhomogeneous media which starts from first principles and includes recent results More advanced topics are considered in this second volume Although the theory of wave beams and fields of localized sources is more sophisticated than the theory of quasi plane waves it embraces a much wider range of interesting problems that are also important for applications We exploit the results of *Acoustics of Layered Media I* as long as it is expedient to consider sound fields as a superposition of plane or quasi plane waves However the knowledgeable reader will view this book as self contained Similar topics have been treated in the book by L M Brekhovskikh *Waves in Layered Media* the English version of the second edition of which was published by Academic Press in 1980 Since *Waves in Layered Media* became very popular we have tried here to retain its spirit However the majority of this text is devoted to new material which reflects the significant progress of the theory during recent years In particular acoustic fields in a moving fluid are considered and much attention is paid to sound propagation in range dependent environments which is currently on the leading edge of research activities

Liquid Crystal - Applications And Uses (Volume 1) Birendra

Bahadur, 1990-09-15 This book reviews comprehensively the technological scientific artistic and medical applications of liquid crystals It starts with the basics of liquid crystals and covers electro optical thermo optical colour polymeric lyotropic and scientific applications of liquid crystalline materials It discusses the fabrication and operational principles of a full range of liquid crystal displays including dynamic scattering twisted nematic supertwisted nematic dichroic smectic A ferroelectric polymer dispersed light valve active matrix etc in detail It also covers the emerging applications of liquid crystals such as optical computing nonlinear optics decorative and visual arts The detailed chapters on classification theory chemical structure physical properties and surface alignment of liquid crystals facilitate the basic understanding of the science behind LCDs and other uses of liquid crystals The chapters on liquid crystal polymers and lyotropic liquid crystals give deep insight into these areas The potential uses and applications are also described in detail

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Polymer Science: A Comprehensive Reference ,2012-12-05 The progress in polymer science is revealed in the chapters of Polymer Science A Comprehensive Reference Ten Volume Set In Volume 1 this is reflected in the improved understanding of the properties of polymers in solution in bulk and in confined situations such as in thin films Volume 2 addresses new characterization techniques such as high resolution optical microscopy scanning probe microscopy and other procedures for surface and interface characterization Volume 3 presents the great progress achieved in precise synthetic polymerization techniques for vinyl monomers to control macromolecular architecture the development of metallocene and post metallocene catalysis for olefin polymerization new ionic polymerization procedures and atom transfer radical polymerization nitroxide mediated polymerization and reversible addition fragmentation chain transfer systems as the most often used controlled living radical polymerization methods Volume 4 is devoted to kinetics mechanisms and applications of ring opening polymerization of heterocyclic monomers and cycloolefins ROMP as well as to various less common polymerization techniques Polycondensation and non chain polymerizations including dendrimer synthesis and various click procedures are covered in Volume 5 Volume 6 focuses on several aspects of controlled macromolecular architectures and soft nano objects including hybrids and bioconjugates Many of the achievements would have not been possible without new characterization techniques like AFM that allowed direct imaging of single molecules and nano objects with a precision available only recently An entirely new aspect in polymer science is based on the combination of bottom up methods such as polymer synthesis and molecularly programmed self assembly with top down structuring such as lithography and surface templating as presented in Volume 7 It encompasses polymer and nanoparticle assembly in bulk and under confined conditions or influenced by an external field including thin films inorganic organic hybrids or nanofibers Volume 8 expands these concepts focusing on applications in advanced technologies e g in electronic industry and centers on combination with top down approach and functional properties like conductivity Another type of functionality that is of rapidly increasing importance in polymer science is introduced in volume 9 It deals with various aspects of polymers in biology and medicine including the response of living cells and tissue to the contact with biofunctional particles and surfaces The last volume is devoted to the scope and potential provided by environmentally benign and green polymers as well as energy related polymers They discuss new technologies needed for a sustainable economy in our world of limited resources Provides broad and in depth coverage of all aspects of polymer science from synthesis polymerization properties and characterization methods and techniques to nanostructures sustainability and energy and biomedical uses of polymers Provides a definitive source for those entering or researching in this area by integrating the multidisciplinary aspects of the science into one unique up to date reference work Electronic version has complete cross referencing and multi media components Volume editors are world experts in their

field including a Nobel Prize winner Chemical Industries ,1949 Some vols include Buyers guide The Serials Directory ,1986 *Theory of Stability of Colloids and Thin Films* B.V. Derjaguin,1989-06-30 Contents of this monograph include an examination of the state of the art and also a comprehensive review of the extended process continuing for some 50 years through which this branch of science came into being and continued to grow Topics include equilibrium and disjoining pressure of thin in **Surfaces and Interiors of Planets and Satellites** Audouin Dollfus,1970 **Modern Synthetic Rubbers** Harry Barron,1949 **Proceedings** Society of Chemical Industry (Great Britain). Chemical Engineering Group,1950 *Who's who in America* ,1962

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