

Test Report

No. XXXXXXXXXX

Date: XXXXXXXXXX

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(01) Microbial Limit Test [U.S. Pharmacopoeia (USP) <61>]

Test Method: U.S. Pharmacopoeia (USP) <61>

Sample	Test Item	Test Result cfu/g	Rating
001	Total Aerobic Microbial Count	6.4 x 10 ³	NC
	Total Combined Yeasts & Molds Count	3.4 x 10 ²	
	Total Viable Count	6.8 x 10 ³	
- "<" means less than; - "cfu/ml(g)" means "colony forming unit per millilitre" - NC means no comment			

(02) Microbial Enumeration Test - Test for Specific [U.S. Pharmacopoeia (USP) <62>]

Test Method: U.S. Pharmacopoeia (USP) <62>

Sample	Test Item	Test Result	Requirement	Rating
001	E.Coli	Not detected/g	Not detected/g	FAIL
	Salmonella	Not detected /10g	Not detected /10g	
	Pseudomonas Aeruginosa	Not detected /g	Not detected /g	
	Staphylococcus Aureus	Not detected /g	Not detected /g	
	Bile-Tolerant Gram-Negative Bacteria	Not detected /g	Not detected /g	
	Clostridia	Detected/g	Not detected /g	
	Candida Albicans	Not detected /g	Not detected /g	
- "Not detected /g(ml)" means Not detected per gram (millilitre) - "Detected/g(ml)" means Detected per gram (millilitre)				

(03) California Technical Bulletin 117-2013 Section 3: Resilient Filling Material

Test Method: California Technical Bulletin 117-2013 section 3

Tested Item(s): Resilient Filling Material

Initial test result:

Specimen #	Open Flaming	Smoldering time > 45 min.	Char length/ in.	Rating
1	No	yes	/	FAIL
2	No	yes	/	FAIL
3	No	No	0.9	PASS
4	No	No	0.8	PASS
5	No	yes	/	FAIL
6	No	yes	/	FAIL

Usp 3chapter 61

Celso Gomes, Michel Rautureau



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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

Microbial Limit and Bioburden Tests Lucia Clontz, 2008-10-14 In recent years the field of pharmaceutical microbiology has experienced numerous technological advances accompanied by the publication of new and harmonized compendial methods It is therefore imperative for those who are responsible for monitoring the microbial quality of pharmaceutical biopharmaceutical products to keep abreast of the latest c

Specification of Drug Substances and Products Christopher M. Riley, Thomas W. Rosanske, George L. Reid, 2020-07-23 Specification of Drug Substances and Products Development and Validation of Analytical Methods Second Edition presents a comprehensive and critical analysis of the requirements and approaches to setting specifications for new pharmaceutical products with an emphasis on phase appropriate development validation of analytical methods and their application in practice This thoroughly revised second edition covers topics not covered or not substantially covered in the first edition including method development and validation in the clinical phase method transfer process analytical technology analytical life cycle management special challenges with generic drugs genotoxic impurities topical products nasal sprays and inhalation products and biotechnology products The book s authors have been carefully selected as former members of the ICH Expert Working Groups charged with developing the ICH guidelines and or subject matter experts in the industry academia and in government laboratories Presents a critical assessment of the application of ICH guidelines on method validation and specification setting Written by subject matter experts involved in the development and application of the guidelines Provides a comprehensive treatment of the analytical methodologies used in the analysis control and specification of new drug substances and products Covers the latest statistical approaches including analytical quality by design in the development of specifications method validation and shelf life prediction

Integrated Pharmaceutics Antoine Al-Achi, Mali Ram Gupta, William Craig Stagner, 2013-01-22 Focusing on the application of physical pharmacy drug design and drug regulations as they relate to produce effective dosage forms for drug delivery Integrated Pharmaceutics provides a comprehensive picture of pharmaceutical product design describing the science and art behind the concepts of dosage form development Combining physical pharmacy product design and regulatory affairs issues in a single book the authors address topics governing drug regulations of United States European and Japanese agencies and detail new regulatory guidelines including

quality by design design space analysis and blend sample uniformity **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 Compounding Sterile Preparations Ryan Forrey, Lindsey Amerine, Angela W. Yaniv, 2023-11-13 The latest edition of Compounding Sterile Preparations by Ryan A Forrey Lindsey B Amerine and Angela W Yaniv reflects the latest advancements in the field providing you with an indispensable resource to navigate the complex landscape of sterile compounding New in this Edition Updated Standards All chapters have undergone extensive revisions to align with the most recent literature and the revised USP standards USP Chapter Now includes information on radiopharmaceutical compounding in USP Chapter Expanded Knowledge Base Two brand new chapters covering Allergenic Extracts and Corrective and Preventative Action CAPA Plans

Minerals latu sensu and Human Health Celso Gomes, Michel Rautureau, 2021-05-18 This volume provides a comprehensive academic review of both positive and negative effects of minerals on human health and quality of life The book adopts the concept of mineral latu sensu mineral l s which encompasses a broad spectrum of natural inorganic solid and crystalline of natural and inorganic chemical elements metals and metalloids of modified natural minerals of biominerals and of syntetic minerals all products that branch across the disciplines of earth soil environmental materials nutrition and health sciences Using this broad framework the authors are able to provide a multidisciplinary assessment on many types of minerals which can be essential beneficial and hazardous to human health covering applications in medical geology medical hydrology or balneotherapy pharmacology chemistry nutrition and biophysics The book performs historical analyses of the uses of minerals for therapeutic and cosmetic purposes to better understand current trends and developments in mineral research and human health The book will be of interest to students public health officials environmental agencies and researchers from various disciplines as well as scientific societies and organizations focusing on medical geology health resort medicine crenotherapy hydrotherapy and climatotherapy and on pharmaceutical cosmetic and biomedical applications

Generic Drug Product Development Leon Shargel, Isadore Kanfer, 2016-04-19 Generic Drug Product Development Specialty Dosage Forms explores the issues related to providing evidence of pharmaceutical equivalence and bioequivalence for specialty drug products It describes various scientific approaches and regulatory requirements for manufacturers who need to demonstrate the therapeutic equivalence of generic specialty dru *Pharmaceutical Microbiology* Michael Rieth, 2025-05-19 All in one guide to monitoring and maintaining microbiological safety in the manufacturing of

pharmaceuticals diagnostics and cosmetics Addressing the full spectrum of microbiological quality control and quality assurance in pharmaceutical production Pharmaceutical Microbiology covers methods and technologies required by regulatory authorities throughout the world with all methods and protocols rated in terms of their compliance with current 2023 EU legislation Written by the former head of biological quality assurance for one of Europe s biggest pharmaceutical and diagnostics companies Pharmaceutical Microbiology covers sample topics including General conditions for the operation of microbiological laboratories calibration and qualification of devices and type culture maintenance Industrial hygiene ambient monitoring quality control process validation microbiological water examination and rapid microbiological methods Automation in the microbiology laboratory quality assurance identification of microorganisms cleaning sterilization decontamination and disposal and contract testing Pharmacopoeial and non pharmacopoeial methods for the identification and quantification of microorganisms including cell culture and selected animal tests Pharmaceutical Microbiology is an essential practice oriented all in one reference for engineers researchers and professionals involved in setting up and running a microbiological quality control unit in the pharmaceuticals diagnostics and cosmetics industries Microbial Contamination Control in the Pharmaceutical Industry Luis Jimenez,2004-08-30 This authoritative reference presents an up to date review of the testing methods emerging technologies and analytical systems and procedures used to prevent the microbial contamination of pharmaceutical processes products and environments It identifies new tools for sample analysis and evaluation and the impact of these advancements on the co Manual for Pharmacy Technicians Bonnie S. Bachenheimer,2019-08-15 Look no further than the new 5th edition of the best selling Manual for Pharmacy Technicians to master the practical skills and gain the foundational knowledge all technicians need to be successful It is the trusted training resource for pharmacy technicians at all levels *Cosmetic Microbiology* Philip A. Geis,2006-04-18 Cosmetics are unique products as diverse as foods and drugs but without the imposed limits of shelf life considerations and sterile manufacturing Furthermore unlike foods and drugs the cosmetic industry lacks the support of established academic programs or a significant body of publication instead its knowledge base has always fallen under t Pharmaceutical Manufacturing Handbook Shayne Cox Gad,2008-03-17 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 *A Laboratory Quality Handbook of Best Practices* Donald C. Singer,2001-09-25 Based on the work of a collection of experts from the laboratory science and quality assurance fields A Laboratory Quality Handbook of Best Practices and Relevant Regulations provides all of the information needed to run a successful laboratory that is in compliance with all regulations From sample tracking to accurate

documentation training to methods validation maintenance to calibration and out of spec responses to preparation for audits a combination of people instrumentation and documentation must work in sync for high quality results This handbook provides information that will help a laboratory achieve high quality results and compliance Contents Quality Assurance in the Laboratory History of Regulation Training in the Laboratory Laboratory Documentation and Data Sample Control and LIM Systems Methods Validation **Pharmaceutical Dosage Forms - Parenteral Medications** Sandeep Nema, John D. Ludwig, 2016-04-19 This three volume set of Pharmaceutical Dosage Forms Parenteral Medications is an authoritative comprehensive reference work on the formulation and manufacture of parenteral dosage forms effectively balancing theoretical considerations with the practical aspects of their development As such it is recommended for scientists and engineers in the **Veterinary Pharmacology and Therapeutics** Mr. Rohit Manglik, 2024-03-03 EduGorilla Publication is a trusted name in the education sector committed to empowering learners with high quality study materials and resources Specializing in competitive exams and academic support EduGorilla provides comprehensive and well structured content tailored to meet the needs of students across various streams and levels **Pharmaceutical Analysis for Small Molecules** Behnam Davani, 2017-07-12 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 **Emerging Non-Clinical Biostatistics in Biopharmaceutical Development and Manufacturing** Harry Yang, 2016-11-30 The premise of Quality by Design QbD is that the quality of the pharmaceutical product should be based upon a thorough understanding of both the product and the manufacturing process This state of the art book provides a single source of information on emerging statistical approaches to QbD and risk based pharmaceutical development A comprehensive resource it combines in depth explanations of advanced statistical methods with real life case studies that illustrate practical applications of these methods in QbD implementation **Federal Register** , 1994-08 **The Business Models Handbook** Paul Hague, 2023-08-03 Business frameworks sit at the heart of successful businesses The second edition of The Business Models Handbook brings together the most helpful and widely used models into one invaluable resource Business models add structure and clarity to business problems help practitioners overcome the everyday challenges they face and enable the organization to grow and be profitable Each chapter of this book focuses on an individual business framework giving an overview of 50 of the best known frameworks These cover essential business topics such as benchmarking competitive intelligence gap analysis and value chains In this second edition these include Kay's distinctive capabilities Customer Activity Cycle and the 3C framework It also covers the most recent developments in applying these models including how to embed them remotely Authored by a leading global market researcher with a background working on over 3 000 different research projects and supported by real world case studies for each model The Business Models Handbook is an invaluable resource for any professional or student Online resources include lecture slides that align with each chapter

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