

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

Behnam Davani



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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 *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,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

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Regulation Training in the Laboratory Laboratory Documentation and Data Sample Control and LIM Systems Methods Validation

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

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

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Handbook of Validation in Pharmaceutical Processes, Fourth Edition James Agalloco, Phil DeSantis, Anthony Grilli, Anthony Pavell, 2021-10-28 Revised to reflect significant advances in pharmaceutical production and regulatory expectations Handbook of Validation in Pharmaceutical Processes Fourth Edition examines and blueprints every step of the validation process needed to remain compliant and competitive This book blends the use of theoretical knowledge with recent technological advancements to achieve applied practical solutions As the industry s leading source for validation of sterile pharmaceutical processes for more than 10 years this greatly expanded work is a comprehensive analysis of all the fundamental elements of pharmaceutical and bio pharmaceutical production processes Handbook of Validation in Pharmaceutical Processes Fourth Edition is essential for all global health care manufacturers and pharmaceutical industry professionals Key Features Provides an in depth discussion of recent advances in sterilization Identifies obstacles that may be encountered at any stage of the validation program and suggests the newest and most advanced solutions Explores

distinctive and specific process steps and identifies critical process control points to reach acceptable results New chapters include disposable systems combination products nano technology rapid microbial methods contamination control in non sterile products liquid chemical sterilization and medical device manufacture

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

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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

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