Test Report

Nico. Date: 1

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

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

Sample	Test Item	Test Result cfu/g	Rating
	Total Aerobic Microbial Count	6.4 x 103	- 6
001	Total Combined Yeasts & Molds Count	3.4 x 102	NC
	Total Viable Count	6.8 x 103	

"cfu/ml(g)" means "colony forming unit per millittre"

- NC means no comment

(02) Microbial Enumeration Test - Test for Specific [U.S. Pharmacopoela (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 (millitre).

"Detected/g/ml) means Detected per gram (millitre)

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

Test Method California Technical Bulletin 117-2013 section 3

Resilient Filling Material Tested Item(s)

Initial test result:

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

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Celso Gomes, Michel Rautureau

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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 quidelines 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

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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 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 <u>A Laboratory Quality Handbook of Best Practices</u> 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

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