

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

Lucia Clontz



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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 **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 *USP, NF.* ,2005 A Laboratory Quality Handbook of Best Practices Donald C. Singer,2001 **The United States Pharmacopeia, the National Formulary** ,2007 The USP NF is a combination of two compendia the United States Pharmacopeia USP and the National Formulary NF It contains standards for medicines dosage forms drug substances excipients biologics compounded preparations medical devices dietary supplements and other therapeutics The current version of USP NF standards deemed official by USP are enforceable by the U S Food and Drug Administration for medicines manufactured and marketed in the United States **Principles of Pharmacy** Henry V. Arny,1926 **A Comprehensive Treatise on Inorganic and Theoretical Chemistry** Joseph William Mellor,1980 **International Income Taxation** Richard Crawford Pugh,2004-07 This volume includes selected provisions of the Internal Revenue Code and Treasury Department Income Tax Regulations directly related to the U S taxation of foreign entities and the U S taxation of domestic entities that have income from sources outside the country It offers a convenient source for important international tax materials The Code and Regulations sections included are those deemed to be essential to International Tax teachers students and practitioners *Mosby's Pharmacology in Nursing* Leda M. McKenry,Evelyn Salerno,1998 This pharmacology text for nurses covers the principles of pharmacology drug classes and individual drugs Chapters new to this 20th edition highlight important variations on interactions dosage and administration and side effects regarding maternal child and geriatric pharmacology **United States Tax Reporter** ,1990 **Western Druggist** ,1900 *Food Protection Trends* ,2009 RIA Federal Tax Regulations January 2007 Kenneth Grant,2007-02 *Code of Federal Regulations, Title 21, Food and Drugs, PT. 170-199,*

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