

Second Edition

Microbial Limit and Bioburden Tests

Validation Approaches and
Global Requirements

Lucia Clontz



Microbial Limit And Bioburden Tests Validation Approaches And Global Requirementssecond Edition

Lucia Clontz



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Microbial Limit and Bioburden Tests Lucia Clontz,1997-10-31 This invaluable book guides readers through the microbial limit testing methodologies of the major world markets including the US Pharmacopeia the European Pharmacopoeia British Pharmacopoeia and Japanese Pharmacopoeia It compares and contrasts various methods and provides easy to follow approaches to validation of these test methodologies Packed with practical guidance on all aspects of bioburden evaluation both for product and for support mechanisms the book covers microbial ecology preservation of pharmaceuticals water equipment surfaces and environment Rapid Test methods and handling of aberrant data in the lab Features *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

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