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Chapter 1117

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This chapter includes discussions on (1) the classification of a clean room based on particulate count limits; (2) microbiological evaluation programs for controlled environments; (3) training of personnel; (4) critical factors in design and implementation of a microbiological evaluation program; (5) development of a sampling plan; (6) establishment of microbiological Alert and Action levels; (7) methodologies and instrumentation used for microbiological sampling; (8) media and diluents used ...

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USP 31 Microbiological Tests / 62 Microbiological Examination3 containing respectively 0.1g, 0.01g, and 0.001g (or 0.1mL, Pseudomonas aeruginosa 0.01mL, and 0.001mL) of the product to be examined. Incubate at 30 ° to 35 ° for 24 to 48 hours. Subculture each of the cultures on aSample Preparation and Pre-Incubation—Prepare a sample

<62> Microbiological Examination Of ... - USP – NF | USP-NF

USP 41 – NF 36. November 13, 2017 . In accordance with USP ' s Rules and Procedures of the Council of Experts (“ Rules ”) and except as provided in Section 7.02 Accelerated Revision Processes, USP publishes proposed revisions to the United States Pharmacopeia and the National

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USP 35 General Information / 1116 Aseptic Processing Environments697 Table 4. A Two-Row by Two-Column Contingency Table with Microbial characterization:The use of colony growth, Respect to the Reference Culture Method and the Alternate cellular morphology, differential staining, and key diagnostic PCR Method (After ISO 5725-1 and 5725-2 2004)* features to characterize a laboratory ...