

Contact plates filled with nutrient agar are used for sampling regular or flat surfaces and are directly incubated for the appropriate time and temperature for recovery of viable organisms. Specialized agar can be used for the recovery of organisms that have specific growth requirements. Microbial estimates are reported per contact plate.

The swabbing method can be used to supplement contact plates for sampling of irregular surfaces, especially irregular surfaces of equipment. The area that will be swabbed is defined with a sterile template of appropriate size. In general, it is in the range of 24–30 cm². After sample collection the swab is placed in an appropriate diluent or transport medium and is plated onto the desired nutrient agar. The microbial estimates are reported per swab of defined sampling area.

Surface monitoring is used as an environmental assessment tool in all types of classified environments. In ISO 5 environments for aseptic processing, surface monitoring is generally performed beside critical areas and surfaces. Component hoppers and feed chutes that contact sterile surfaces on closures and filling needles can be tested for microbial contamination. Often in conventional staffed clean rooms, these product contact surfaces are steam sterilized and aseptically assembled. The ability of operators to perform these aseptic manipulations are evaluated during process simulations or media fills, although true validation of operator technique in this manner is not possible. Surface monitoring on surfaces that directly contact sterile parts or product should be done only after production operations are completed. Surface sampling is not a sterility test and should not be a criterion for the release or rejection of product. Because these samples must be taken aseptically by personnel, it is difficult to establish with certainty that any contamination recovered is product related.

CULTURE MEDIA AND DILUENTS

The type of medium, liquid or solid, used for sampling or plating microorganisms depends on the procedure and equipment used. Any medium used should be evaluated for suitability for the intended purpose. The most commonly used all-purpose solid microbiological growth medium is soybean–casein digest agar. As previously noted, this medium can be supplemented with chemicals that counteract the effect of various antimicrobials.

IDENTIFICATION OF MICROBIAL ISOLATES

A successful environmental control program includes an appropriate level of identification of the flora obtained by sampling. A knowledge of the flora in controlled environments aids in determining the usual microbial flora anticipated for the facility and in evaluating the effectiveness of the cleaning and sanitization procedures, methods, agents, and recovery methods. The information gathered by an identification program can be useful in the investigation of the source of contamination, especially when recommended detection frequencies are exceeded.

Identification of isolates from critical and immediately adjacent areas should take precedence over identification of microorganisms from noncritical areas. Identification methods should be verified, and ready-to-use kits should be qualified for their intended purpose.

CONCLUSION

Environmental monitoring is one of several key elements required in order to ensure that an aseptic processing area is maintained in an adequate level of control. Monitoring is a qualitative exercise, and even in the most critical applications such as aseptic processing, conclusions regarding lot acceptability should not be made on the basis of environmental sampling results alone. Environments that are essen-

tially free of human operators generally have low initial contamination rates and maintain low levels of microbial contamination. Human-scale clean rooms present a very different picture. Studies conclusively show that operators, even when carefully and correctly gowned, continuously slough microorganisms into the environment. Therefore, it is unreasonable to assume that samples producing no colonies, even in the critical zone or on critical surfaces, will always be observed. Periodic excursions are a fact of life in human-scale clean rooms, but the contamination recovery rate, particularly in ISO 5 environments used for aseptic processing, should be consistently low.

Clean-room operators, particularly those engaged in aseptic processing, must strive to maintain suitable environmental quality and must work toward continuous improvement of personnel operations and environmental control. In general, fewer personnel involved in aseptic processing and monitoring, along with reduction in interventions, reduces risk from microbial contamination.

APPENDIX

Airborne Particulate Count (also referred to as *Total Particulate Count*): The total number of particles of a given size per unit volume of air.

Airborne Viable Particulate Count (also referred to as *Total Airborne Aerobic Microbial Count*): The recovered number of colony-forming units (cfu) per unit volume of air.

Air Changes: The frequency per unit of time (minutes, hours, etc.) that the air within a controlled environment is replaced. The air can be recirculated partially or totally replaced.

Air Sampler: Devices or equipment used to sample a measured amount of air in a specified time to quantify the particulate or microbiological status of air in the controlled environment.

Aseptic: Technically, the absence of microorganisms, but in aseptic processing this refers to methods and operations that minimize microbial contamination in environments where sterilized product and components are filled and/or assembled.

Aseptic Processing: An operation in which the product is assembled or filled into its primary package in an ISO 5 or better environment and under conditions that minimize the risk of microbial contamination. The ultimate goal is to produce products that are as free as possible of microbial contamination.

Barrier System: Physical barriers installed within an aseptic processing room to provide partial separation between aseptically gownned personnel and critical areas subject to considerable contamination risk. Personnel access to the critical zone is largely unrestricted. It is subject to a high level disinfection.

Bioburden: Total number and identity of the predominant microorganisms detected in or on an article.

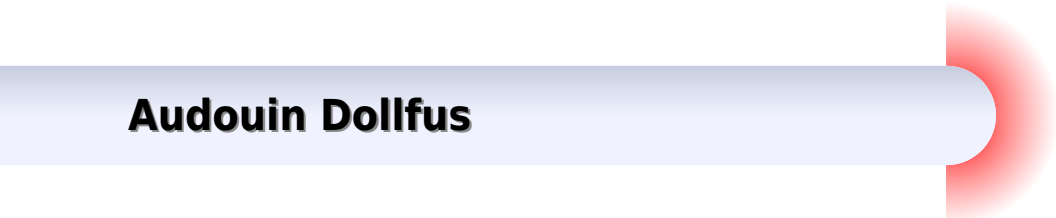
Clean Room: A room in which the concentration of airborne particles is controlled to meet a specified airborne particulate cleanliness Class. In addition, the concentration of microorganisms in the environment is monitored; each cleanliness Class defined is also assigned a microbial level for air, surface, and personnel gear.

Commissioning of a Controlled Environment: Certification by engineering and quality control that the environment has been built according to the specifications of the desired cleanliness Class and that, under conditions likely to be encountered under normal operating conditions (or worst-case conditions), it is capable of delivering an aseptic process. Commissioning includes media-fill runs and results of the environmental monitoring program.

Contamination Recovery Rate: The contamination recovery rate is the rate at which environmental samples

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Audouin Dollfus



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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, K. Lien Nguyen, 2024-09-22 Specification of Drug Substances and Drug Products is a fully comprehensive reference on Specification Setting for Pharmaceuticals There have been several recent developments in the ICH Guidelines which were not captured in previous editions notably the new guideline on Development of Analytical Procedure and the revisions to the validation guidelines and the specification guidelines This edition contains chapters discussing the unique requirements for the universal critical quality attributes as well as the specific tests required to characterize and control different types of products ranging in complexity from small molecules in immediate release oral dosage forms to complex products such as drug antibody conjugates and mRNA based products This substantially expanded revision of the 2nd edition will serve as practical comprehensive reference for scientists managers educators and consultants involved in the development and regulation of pharmaceutical products Presents critical assessment potential impact and application of the recent revisions to ICH guidelines on method validation Q2 as well as the latest guideline on Analytical Method Development Q14 and the special regional requirements in non ICH regions Addresses comprehensive treatment of the development and validation of analytical methodologies used in the analysis control and specification of a variety of different types of dosage forms ranging from traditional oral solid dosage forms to proteins mRNA based drugs vaccines and gene therapy This book will also address drug device combination products such as digital drug delivery systems transdermal systems and inhalation products Presents detailed treatment of latest statistical approaches including new approaches to the treatment of validation data method specification setting and shelf life prediction based on stability data Acoustics of Layered Media II Leonid M. Brekhovskikh, Oleg A. Godin, 2013-04-17 This is the sequel to our book Acoustics of Layered Media I Plane and Quasi Plane Waves Springer Ser Wave Phenom Vol 5 Taken together these two monographs present a systematic exposition of the theory of sound propagation in inhomogeneous media which starts from first principles and includes recent results More advanced topics are considered in this second volume Although the theory of wave beams and fields of localized sources is more sophisticated than the theory of quasi plane waves it embraces a much wider range of interesting problems that are also important for applications We exploit the results of Acoustics of Layered Media I as long as it is expedient to consider sound

fields as a superposition of plane or quasi plane waves However the knowledgeable reader will view this book as self contained Similar topics have been treated in the book by L M Brekhovskikh Waves in Layered Media the English version of the second edition of which was published by Academic Press in 1980 Since Waves in Layered Media became very popular we have tried here to retain its spirit However the majority of this text is devoted to new material which reflects the significant progress of the theory during recent years In particular acoustic fields in a moving fluid are considered and much attention is paid to sound propagation in range dependent environments which is currently on the leading edge of research activities

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Theory of Stability of Colloids and Thin Films B.V. Derjaguin,1989-06-30 Contents of this monograph include an examination of the state of the art and also a comprehensive review of the extended process continuing for some 50 years through which this branch of science came into being and continued to grow Topics include equilibrium and disjoining pressure of thin in **Surfaces and Interiors of Planets and Satellites** Audouin Dollfus,1970 Modern Synthetic Rubbers Harry Barron,1949 **Proceedings** Society of Chemical Industry (Great Britain). Chemical Engineering Group,1950 *Molecular Gas Lasers* B. Ю Баранов,1981

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