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MICROBIOLOGICAL QUALITY CONTROL OF PHARMACEUTICAL PRODUCTS

White Paper

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Contamination of pharmaceutical products by objectionable microorganisms is a major risk within the pharmaceutical industry as it may impact product integrity and patient safety. To prevent contamination events from occurring, licensed pharmaceutical manufacturing companies worldwide are required to adhere to strict regulations and robust quality control procedures issued by their respective government agencies. These regulatory processes and procedures comprise various quality control methods, such as those described in the United States Pharmacopeia (USP), European Pharmacopeia (EP), and Japanese Pharmacopeia (JP). When properly followed, these procedures can help identify microbial contamination prior to product release, thus avoiding the pitfalls of product recalls.

Microbiological quality control is an essential part of the pharmaceutical manufacturing process. Pharmaceutical companies must safeguard the quality and safety of their products by thoroughly testing raw materials, equipment, environmental surfaces, and final preparations for microbial contaminants that may have been introduced inadvertently during or subsequent to the manufacturing process. Currently, there are a number of microbiological quality control assays recommended, including growth promotion testing, microbial enumeration testing, and antimicrobial effectiveness testing. Growth promotion testing, for example, is a common quality control assay used to establish the nutritional properties of culture media to ensure that microbial growth can be supported. This form of testing is important because culture media is frequently employed in various pharmacopeial quality control assays. If a batch of media is found to be unable to support microbial growth, the results of all assays for which the media was intended will be unreliable, and the pharmacopeial tests will fail.

Following growth promotion testing of culture media, approved batches of media can be used in other quality control assays such as the microbial enumeration test (USP <61>) or the antimicrobial effectiveness test (USP <51>)[1,2]. These particular tests are designed to determine whether a pharmaceutical product complies with an established specification for microbiological quality or demonstrates effective antimicrobial protection, respectively. In particular, the microbial enumeration test is recommended to ensure that the product contains less than the allowable concentration of an objectionable organism via direct plating, membrane filtration, or the most-probable-number method. In contrast, the antimicrobial effectiveness test is performed to confirm that the antimicrobial preservatives added to the final product are demonstrating an effective level of microbial growth inhibition.

For these aforementioned tests to provide reliable and accurate results, each of the pharmacopeia specifies a preselected list of fully authenticated and characterized microbial strains from a national culture collection as control input organisms. In support of this requirement, ATCC now provides the specified ATCC Genuine Cultures® in convenient, single-use, "mini" glycerol stocks. These quality control strains, known as ATCC® Minis, are supplied as a six pack of glass-free mini cryovials with a 2D barcode for easy storage and tracking, and peel-off labels for fast and reliable recordkeeping. Moreover, their ready-to-use format helps save both the time and expense associated with the production of frozen glycerol stocks. Each microorganism is authenticated using a polyphasic approach that balances traditional biochemical testing methods with automated genotypic and phenotypic analyses, ensuring consistent and reliable reference materials. Further, each strain is maintained and handled using procedures recommended by USP Chapter <1117>, Microbiological Best Laboratory Practices[3]. These laboratory practices ensure that each strain is maintained carefully, safely, and effectively to promote lot-to-lot consistency and optimal viability.

ATCC is committed to providing quality products and services to researchers worldwide. To date, ATCC has acquired and maintained a number of certifications and accreditations, including ISO 9001:2008 and ISO 13485:2003 certifications as well as ISO/IEC 17025:2005 and ISO Guide 34:2009 accreditations. These quality accreditations have allowed ATCC to evolve from a biological resource center to an innovative partner to the global scientific community.

Overall, to ensure product safety, pharmaceutical companies must be versed in the important role of microbiological testing in product research and development, process validation, manufacturing, and quality control. ATCC supports the maintenance of product integrity, reputation, and safety by providing top-quality, fully characterized strains in a ready-to-use, familiar format.

REFERENCES

1. The United States Pharmacopeia USP 37-NF 32. <61> Microbiological Examination of Nonsterile Products: Microbial Enumeration Tests, 2014.
2. The United States Pharmacopeia USP 37-NF 32. <51> Antimicrobial Effectiveness Tests, 2014.
3. The United States Pharmacopeia USP 37-NF 32. <1117> Microbiological Best Laboratory Practices, 2014.

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