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Technical Regulatory Topic

New ASTM Standard: E3251- 20 Standard Test Method for Microbial Ingress Testing on Single-Use Systems

Integrity of Single-Use Systems

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Introduction

At the end of May 2020, a new ASTM International standard practice on integrity of single-use systems (SUS) was published. This document, “E3251-20, Standard Test Method for Microbial Ingress Testing on Single-Use Systems” follows the publication of the closely related ASTM standard “E3244-20, Standard Practice for Integrity Assurance and Testing of Single-Use Systems”. It is the second standard produced by the collaboration of about 30 people from the ASTM Committee E55 on Manufacture of Pharmaceutical and Biopharmaceutical Products, gathering SUS suppliers, end users and FDA.

The aim of microbial ingress testing of sterile SUS used in biopharmaceutical manufacturing is two-fold.

1. Firstly, it is used to evaluate the ability of a SUS fluid path to remain sterile after a SUS has been challenged by microbial exposure.
2. Additionally, microbial ingress testing can be used to determine the maximum allowable leakage limit (MALL) that does not allow microbial ingress under specific test conditions.

Both purposes for microbial ingress testing can either be conducted by liquid immersion or aerosol exposure. The type of exposure should be determined according to the SUS use-case conditions and a risk assessment.

Scope

The standard practice outlined in this document applies to microbial ingress risk assessment of a SUS or its individual components that require integrity testing either by the assembly supplier or the end user of the assembly, based on a potential risk of a breach to the product or manufacturing process.

Content

This practice describes how to perform an ingress test based on an aerosol exposure or a liquid exposure with some examples of possible setups. The aerosol exposure test is based on nebulization of the chosen test microorganism and allowing settling of the aerosol on the test article. The liquid exposure is based on immersion of the test article in a fluid containing the test organism.

References

1. United States Pharmacopeia, < 1207 > Package Integrity Evaluation - Sterile Products, 01–AUG–2016.
2. ASTM E3244, Standard Guide for Integrity Assurance and Testing of Single-Use Systems.
3. ASTM D4169, Standard Practice Testing of Shipping Containers and Systems.

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