

MicroBioLogics

Passages For USP Challenge Microorganisms

QUESTION

Potential customers for MicroBioLogics' assayed EZ-CFU™ and EZ-CFU™ One Step Microorganisms have raised the question,

“Why are the EZ-CFU™ and EZ-CFU™ One Step Microorganisms four passages from the reference culture when our laboratory is limited to only two passages?”

RESPONSE

The research, development, process design control, and distribution of EZ-CFU™ and EZ-CFU™ One Step Microorganisms are to serve as microorganism challenge materials as outlined in the U. S. Pharmacopeia and National Formulary (USP 28 – NF 23). The specifications and performance for these products is **four passages removed from the reference culture. . . a challenge of 10 CFU to 100 CFU per 0.1 mL.**

The specific reference is <71> **STERILITY TESTS; Growth Promotion Test.** The support references include:

1. **USP 28 – NF 23. Page 8**
Microbial Strains. “Where a microbial strain is cited and identified by its *ATCC catalog number, the specific strain shall be used directly or, if subcultured, shall not be used more than five passages removed from the original strain”.
2. **USP 28 – NF 23. Page 2242.**
Test Organisms. This section provides an excellent definition of passages where it states
“ . . . one passage is defined as the transfer of organisms from an established culture to fresh medium. All transfers are counted.”

EXCLUSIONS

In addition to <71> Sterility Tests, the Code of Federal Regulation (CFR) may mandate different microorganism challenges. The challenges may differ in the concentration (CFU) (e.g. final concentration of 100,000 CFU to 1,000,000 CFU) of the challenge or the number of passages (e.g. two passages) the challenge microorganism is removed from the original strain. These differences can exclude the use of the current offering of EZ-CFU™ Microorganisms.

SUMMARY

The research, development, process design control, and distribution of EZ-CFU™ and EZ-CFU™ One Step Microorganisms are to serve as microorganism challenge materials as outlined in the U. S. Pharmacopeia and National Formulary (USP 28 – NF 23).

FUTURE PRODUCT DEVELOPMENT

MicroBioLogics will continue to meet needs and demands for microbiology QA/QC products by inviting customers to submit requests for new products by filling out an Lyophilization Microorganism Request form (TSCS.272). This form can be obtained from MicroBioLogics Web Site and/or by contacting MicroBioLogics directly. **www.microbiologics.com 800-599-BUGS(2847)**

Thank you for your questions and the opportunity to serve your needs.

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