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A Full Service Microbiology Laboratory

Microbiological Examination of Nonsterile Products

Overview:

As described in USP <61>, this microbial enumeration test provides a quantitative evaluation of the microbial content of a sample, also known as microbial bioburden testing or microbial limits testing. USP <62> is the method used to determine the presence or absence of objectionable organisms or pathogens within a sample. Both tests are primarily designed to determine whether a sample complies with an established specification for pharmaceutical microbiological quality.

USP <61> Testing: Microbial Enumeration Tests

The USP <61> test provides enumeration of mesophilic bacteria and fungi that may grow under aerobic conditions. This test provides the total number of aerobic organisms, yeast, and mold present within a sample. The sample is typically diluted, plated, and then incubated. Microbial enumeration of the sample can be achieved by membrane filtration, pour plate, surface spread, or the Most Probable Number (MPN) methods. Short-hand abbreviations for USP <61> testing may be encountered as follows:

- TAMC: *Total Aerobic Microbial Count*
- TYMC: *Total Yeast & Mold Count*

USP <62> Testing: Tests for Specified Microorganisms

The USP <62> test is performed to determine the presence or absence of a specified list of microorganisms: *Escherichia coli, Salmonella species, Staphylococcus aureus, Pseudomonas aeruginosa,* Bile-Tolerant Gram Negative Bacteria, *Candida albicans, and/or Clostridium species.* As compared to USP <61>, the sample is first enriched and then streaked onto the appropriate selective agar based upon the organism (s) above.

Suitability Testing

The USP <61> and/or <62> suitability test is used to establish the method, which in the presence of the product, allows the detection of the microorganism (s).

Chain of Custody

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