USP Microbial Examination of Non-Sterile Products

BioScreen Technical Bulletin: # 2009-01

Introduction

The United States Pharmacopeia has made significant changes to the Microbial Limits Test Chapter <61> starting with the USP 29 Supplement 2. These changes go into effect May 1, 2009. These new chapters have listed additional tests that are suggested and also made changes to some of the existing tests. Items that have been changed are listed in italics type blue color below.

The test is now covered by two different chapters.
<61> Microbiological Examination of Nonsterile Products: Microbial Enumeration Tests

<62> Microbiological Examination of Nonsterile Products: Tests for Specified Microorganisms

Chapter <61>

This chapter now has a section on Suitability of the Counting Method in the Presence of Product and Neutralization/Removal of Antimicrobial Activity. This was previously listed as the Preparatory (validation) section and also referred to Chapter <71> for validation of membrane filtration tests.

The procedure also defines different sample preparation method depending on the type of sample.

- Water-Soluble Products
- Nonfatty Products Insoluble in Water
- Fatty Products
- Fluids or Solids in Aerosol Form
- Transdermal Patches

The new criteria for verifying the suitability of the Membrane Filtration method or the Plate-Count method is that a mean count of any of the test organisms not differing by a factor greater than 2 from the value of the control defined in Inoculation and Dilution in the absence of product must be obtained.

Sample Size

The previous chapter only listed specified to use 10 g or 10 mL of the sample per each test.

The new chapter has the following recommendations:
Fluids, or solids in aerosol form – sample 10 containers
Transdermal patches – sample 10 patches
All Other products – 10 g or 10 mL
Neutralization Test – 5 g or 5 mL

Other criteria are also specified in the chapter for active substances or small batches of product.

Examination of Product

This remains relatively unchanged with the use of two tests.

- Total Aerobic Microbial Count TAMC – Test for Bacteria
- Total Yeast and Mold Count TYMC – Test for Yeast and Molds

As before, each of these can be performed by Membrane Filtration, Plate Count Method, Surface-Spread Method or Most-Probable-Number Method.

The most common procedure is the Pour-Plate Method in which the sample is dilution in an appropriate buffer or media and then an aliquot is placed on a sterile Petri dish. The appropriate media is then added to the Petri dish with the sample and this is incubated for 3 to 5 days for TAMC and 5 to 7 days for TYMC.

Previously the TAMC was only incubated for 2 to 3 days.

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Chapter <62>

This is an entirely new chapter in the USP. It is divided into various sections.

Growth-Promoting and Inhibitory Properties of the Media and Suitability of the Test

Sample Size

The new chapter has the following recommendations:
Transdermal patches – sample 50 patches
All Other products – 50 g or 50 mL
Neutralization Test – 5 g or 5 mL

Other criteria are also specified in the chapter for active substances or small batches of product.

Examination of Product

Each of the microorganisms listed below must be tested vs. the product to prove that antimicrobial activity can be neutralized. The Bile-Tolerant Gram-Negative Bacteria test, *Clostridia sp test and Candida albicans* test are new.

- Bile-Tolerant Gram-Negative Bacteria
- *Escherichia coli*
- *Salmonella*
- *Pseudomonas aeruginosa*
- *Staphylococcus aureus*
- *Clostridia*
- *Candida albicans*

Summary of Changes

Analysis	Current Procedure	New Procedure Effective May 1, 2009
Total Aerobic Plate Count	2 to 3 days incubation	3 to 5 days incubation*
Total Yeast and Mold Count	5 to 7 days incubation	No Change *
Detection of Bile Tolerant Gram Negative Bacteria	N/A	New Requirement – two different procedures: MPN or Presence/Absence
Detection of *Escherichia coli*	Test product in a nonselective broth and agar	Additional new selective enrichment broth
Detection of *Salmonella*	Test product in nonselective broth and three selective agar	New selective enrichment broth and agar
Detection of *Staphylococcus aureus*	Test product in a nonselective broth and agar	No Change*
Detection of *Pseudomonas aeruginosa*	Test product in a nonselective broth and agar	No Change*
Detection of *Clostridia*	N/A	New Requirement
Detection of *Candida albicans*	N/A	New Requirement

What does this mean for your product?

While these chapters have been revised it may not necessarily mean that all of the tests are applicable for your products. It is necessary for each client to make this determination either based on what is specified in the individual monograph for each product or based on your internal Standard Operating Procedures.

BioScreen Testing Services will be offering these additional tests staring February 2008. However, the decision to request these new tests will be left up to the client.

Summary of Changes

* These tests have no significant or no changes between the two procedures. If the test has been previously validated, BioScreen does not recommend revalidation. Please verify with your QA or regulatory staff regarding revalidation.

All other tests should be validated due to the changes to the method.

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