STANDARD OPERATING PROCEDURE	
Department: Microbiology	**SOP No.:**
Title: Post Sterility Growth Promotion Test	**Effective Date:**
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1.0 PURPOSE

To lay down procedure for Post Sterility Growth Promotion Test of Media after completion of Sterility Test.

2.0 SCOPE

This SOP is applicable for performing Post Sterility Growth Promotion Test of Media after completion of Sterility Test.

3.0 RESPONSIBILITY

Trained Microbiologist is responsible to perform the test as per SOP and Section In-Charge is responsible for conformance to SOP.

4.0 PROCEDURE

4.1 Frequency

4.1.1 This test shall be performed for each product on annual basis.

4.1.2 The test shall be performed preferably on higher strength presentation and if performed on higher strength then testing of lower strength presentations is not required.

4.1.3 The test can be performed together three sets of canisters of three batches if the sterility of all the three batches is being completed within a week's time. In such cases store the canisters at below 25°C till the test is initiated. If three batches are not available at a time as above, then test can be performed at different points by inoculating one challenge organism for each medium at a time.

4.2 Culture Inoculum:

4.2.1 Use standardized inoculum prepared as per SOP of following organisms for each media.

4.2.2 Fluid Thioglycollate Medium (FTM):

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- *Staphylococcus aureus* ATCC 6538
- *Pseudomonas aeruginosa* ATCC 9027
- *Clostridium sporogenes* ATCC 11437 or 19404

4.2.3 Soybean Casein Digest Medium (SCM):

- *Bacillus subtilis* ATCC 6633
- *Candida albicans* ATCC 10231
- *Aspergillus brasiliensis (Aspergillus Niger)* ATCC 16404

4.2.4 Along with above organisms, use an environmental isolate for each medium.

4.2.5 The inoculum used shall be 10 – 100 CFU.

4.3 Test Procedure

4.3.1 After completion of sterility test, take media canisters to bio safety cabinet and disinfect the tubing near

4.3.2 With help of sterile syringe inoculate 10 – 100 CFU of the challenge organism to the media by piercing the needle into canister tubing.

4.3.3 Repeat above step for all organisms for each medium if three batches are taken at a time. If single set of canister is taken then inoculate one organism to SCM and one organism to FTM as per 4.2. In the later case, the challenge organism is to be changed in sequence to include all the organisms.

4.3.4 Incubate the canisters at respective conditions i.e., SCM at 22.5 ± 2.5°C and FTM at 32.5 ± 2.5°C for not more than 5 days.

4.3.5 Observe the inoculated canisters for growth.

4.3.6 Acceptance Criteria and Interpretation of Results

4.3.6.1 Clear visible growth should be observed with in 3 days for bacterial culture and within 5 days incase of yeast and fungal cultures.

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4.3.6.2 If clear visible growth is not obtained within 5 days for both bacterial and fungal cultures, then the test is considered invalid.

4.3.6.3 Invalid post sterility growth promotion test may be repeated once and if visible growth is not obtained in repeat test, then sterility test method should be modified and revalidated.

5.0 ABBREVIATIONS AND DEFINITIONS

QCM	Quality Control Microbiology
QAD	Quality Assurance Department
Rev.	Revision
LAF	Laminar Air Flow
%	Percent
°C	Degree centigrade
gm	gram
mL	Milli litre
CFU	Colony Forming Unit
SCM	Soybean Casein Digest Medium
FTM	Fluid Thioglycollate Medium

Post Sterility Growth Promotion Test (Stasis Test): Test to evaluate the ability of the sterility test medium after completion of 14 days incubation to promote growth or microbial recovery when inoculated with small numbers of organisms. This test is intended to demonstrate that the media support the growth for the full incubation period.

6.0 REFERENCE DOCUMENTS

SOP: Preparation of Culture Inoculum
SOP: Sterility Testing by Membrane Filtration
Guidelines for Sterility Testing of Therapeutic Goods – TGA, 2006

7.0 ANNEXURE / ATTACHMENTS

Annexure I: Form 1 – Post Sterility Growth Promotion Test Report.

8.0 REVISION LOG:

Revision Number	Effective Date	Reason for Revision
00		New Document