



STANDARD OPERATING PROCEDURE

Department: Microbiology	SOP No.:
Title: Growth Promotion and Inhibition Test of Media	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

1.0 PURPOSE

- 1.1 To lay down the procedure for evaluating the growth promotion and Inhibition property of the sterilized media used for microbiological testing.

2.0 SCOPE

- 2.1 This Standard Operating Procedure is applicable in microbiology section at Quality Control Department of

3.0 RESPONSIBILITY

3.1 Microbiologist / Executive -QC

- 3.1.1 Responsible for the procedure for evaluating the growth promotion and Inhibition property of the sterilized media used for microbiological testing.

4.0 ACCOUNTABILITY

- 4.1 Head – Quality Control/Designee ensure proper control and compliance of the SOP.

5.0 DEFINITIONS

- 5.1 NA

6.0 PROCEDURE

- 6.1 Growth promotion test shall be performed whenever new medium is received / Batch No. or lot No. is changed / Make or Vendor is changed.
- 6.2 After procuring the Media, check the Media container for the following details i.e. manufacturing date, Expiry date, Code No and lot number.
- 6.3 Store all the Media in a cool dark place at NMT $25 \pm 5^{\circ}\text{C}$.
- 6.4 Before taking the media for use, perform the growth promotion (i.e. nutritive properties) or growth inhibition studies specific to the media as per Annexure-IV.
- 6.5 Whenever there is an approved and "in use" medium available, inoculate it with the same organism.
- 6.6 If the growth promotion qualities of the media is not the same as compared to the previously approved lot then discard that media.
- 6.7 Check the growth promotion qualities of the media (Using the organisms as mentioned in Annexure-IV) by any one of the following methods.



STANDARD OPERATING PROCEDURE

Department: Microbiology	SOP No.:
Title: Growth Promotion and Inhibition Test of Media	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

- 6.7.1 **For newly received agar media** containers transfer 1.0 ml of culture having a cell count of 10 to 100 cells in the dilution into two sterile petriplates and pour the media of New Container [B]. Swirl the plates and allow solidifying.
- 6.7.2 Similarly transfer 1.0 ml of culture of having a cell count of 10 to 100 cells in the dilution into two sterile petriplates and pour the prepared Previous Container media [A]. Swirl the plates and allow solidifying.
- 6.7.3 Incubate the plates at respective temperature, after incubation count the colonies and compare the count with the previous container results. After incubation record the results as per Annexure-II
- 6.7.4 The recovery in the growth promotion test for the new container must be at least 70% of the actual inoculum concentration obtained for the previous container.
- 6.7.5 **For agar media** prepare inoculum of known concentration (approximately 10 to 100 cells/ml) of the organism and then transfer it to the plate followed by pouring with the agar media. After incubation record the results as per Annexure-I.
- 6.7.6 **For selective agar media** carry out growth promotion test by streaking specified organism on the plate and observe for the characteristics of colonies and record the result in Annexure-I.
- 6.7.7 **In case of liquid media** or broth inoculate 1.0 ml of inoculum, in 100 mL of media or 0.1 mL of inoculum, in 10 ml of media by using the organisms as mentioned in Annexure-IV incubate the media, observe the growth and record the result in Annexure-III.
- 6.7.8 Liquid media are suitable, if should show clear visible growth in media.
- 6.7.9 Put an uninoculated Bottle/Tube/plate of media as a negative control to confirm the sterility of the media.
- 6.7.10 Label or mark using by marker the name of media, batch/lot no., organism used tested by and date on the Bottle/Tube/plate of media. (For GPT of daily prepared media, if more organisms are prescribed for testing, in that case, minimum two bacteria and one yeast/mould shall be used for testing on rotation basis.)
- 6.7.11 For solid media, the recovery of inoculated organisms should not be less than 70 % from the calculated value of inoculums added.

Note: *Before use of any batch of prepared media for testing if GPT is not possible to perform before testing, it can be performed simultaneously with testing.*

6.7.12 The shelf life of opened media bottle shall not be more than 12 months and for unopened bottle it is till the shelf life of the container.

6.7.13 Assign the batch Number to prepared media with respect to Growth Promotion Test as GPT/MMXXX/YY, Where

GPT - For Growth Promotion Test

/ - Slash

MM - Microbiological Media



PHARMA DEVILS

MICROBIOLOGY DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Microbiology	SOP No.:
Title: Growth Promotion and Inhibition Test of Media	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

XXX - 001, 002, 003, ----- to 999

/ - Slash

YY - Last 2 digits of the calendar year.

For example, first batch number for year 2022 shall stand as GPT/MM001/22.

Note: Growth promotion test shall be performed every finished (Prepared) lots of dehydrated medium.

7.0 ANNEXURES

Annexure-I : Media Growth Promotion and Inhibition Test For Agar Media.

Annexure-II : Newly Received Agar Media-Comparative Test Report.

Annexure-III : Growth Promotion/ Inhibition Test Record for Liquid Media.

Annexure-IV : Acceptance Criteria for the GPT for Culture Media.

8.0 ABBREVIATIONS

SOP : Standard Operating Procedure

QC : Quality Control

NA : Not Applicable

CC : Change Control

HOD : Head of Department

QA : Quality Assurance

Cfu : Colony forming unit

ATCC : American Type Culture Collection

MTCC : Microbial Type Culture Collection

NCTC : National Collection of Type Cultures

9.0 REFERENCE

NA

10.0 REVISION HISTORY

Revision no.	Effective date	Change Control Ref. No.	Description of change(s)
00			