



## STANDARD OPERATING PROCEDURE

<b>Department:</b> Quality Assurance	<b>SOP No.:</b>
<b>Title:</b> Growth Promotion Test	<b>Effective Date:</b>
<b>Supersedes:</b> Nil	<b>Review Date:</b>
<b>Issue Date:</b>	<b>Page No.:</b>

### 1.0 Objective

To lay down a procedure to perform Growth Promotions Studies.

### 2.0 Scope

This Standard Operating Procedure is applicable at Quality Control department.

#### Responsibility

Executive/Sr.Executive-QC : Shall be responsible for following the procedure for Growth Promotion Test.

Head -QC/Designee : Shall be responsible for the compliance of this SOP.

### 3.0 Abbreviations and Definitions

SOP : Standard Operating Procedure

QC : Quality Control

LAF : Laminar Air Flow

Pre-Incubated Culture medium : The culture medium which is used after incubation.

GPT : Growth Promotion Test

°C : Degree Centigrade

CFU : Colony forming units

ml : Milliliter

No. : Number

NMT : Not More Than

### 4.0 Procedure

4.1 Growth promotion test shall be performed for every lot of media autoclaved.

4.2 After procuring the Media, check the Media container for the following details i.e. manufacturing date, Expiry date, Code No and lot number.

4.3 Store all the Media in a cool dark place at NMT 25°C.

4.4 Before taking the media for use, perform the growth promotion studies (i.e. nutritive properties and inhibitory properties) specific to the media as per Annexure-1.



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4.5 Whenever there is an approved and "in use" medium available, inoculate it with the same organism.

4.5.1 **For Growth Promoting Properties of Liquid Media:** Inoculate the media with 1ml of the culture suspension of test strains (not more than 100 CFU). Incubate at the specified temperature for the shortest period of time as per the Annexure-1. Record the observation in Annexure-2.

4.5.2 **For Growth Promoting and Indicative Properties of Solid Media:** Inoculate the media with 1mL of the culture suspension of test strains (not more than 100 CFU) for Pour plate technique and 0.1 mL of the culture suspension of test strains (not more than 100 CFU) for Surface spread method. Incubate at the specified temperature for the shortest period of time as per the Annexure No.-1. Record the observation in annexure-2.

**Note:** Use Surface spread method for Selective and Differential media.

4.5.3 **For Inhibitory Properties of Liquid Media:** Inoculate the media with the culture suspension containing at least 100 CFU of test strain. Incubate at the specified temperature for not less than the longest period of time as per the Annexure No.-1. Record the observation in annexure-2.

4.5.4 **For Inhibitory Properties of Solid Media:** Inoculate the media with the culture suspension containing at least 100 CFU of test strain. Incubate at the specified temperature for not less than the longest period of time as per the Annexure No.-1. Record the observation in annexure-2.

**Note:** Use Surface spread method for Selective and Differential media.

4.6 Test each lot of prepared and sterilized media for its growth promotion properties.

4.7 For the media used in environmental monitoring and sterility testing, use all the test strains mentioned against the media as per Annexure No.-1 for growth promotion test.

4.8 Use any one of the environmental isolates for growth promotion test for each lot of dehydrated media used for environmental monitoring.

4.9 For water analysis, use all the organisms mentioned against the R2A media as per Annexure No.-1.



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4.10 For all other media, use any one of the test strains mentioned against the media as per Annexure No.-1 for growth promotion test.

4.11 Carry out the inhibitory properties for each lot of prepared selective and differential media.

4.12 Carry out negative control for every media.

5.1.4 After completion of incubation period, record the results / observations as per the Annexure No.-2.

5.1.5 If growth promotion / inhibition (if applicable) found failing, discard the lot and consider the test performed using that particular lot of media as invalid. Investigate the cause for failure of growth promotion or inhibition and include a corrective action plan in the investigation to prevent the re-occurrence of the problem. Do not use the non-conforming lot.

5.1.6 If ready to use prepared media are used, perform growth promotion, indicative and inhibitory properties (if applicable) each lot /batch.

Note: Attach Certificate of Analysis of Manufacturer to the Annexure No.-2.

5.1.7 Store all sterilized and pre-incubated media as per the validated conditions.

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

5.1.9 **Acceptance Criteria:**

5.1.10.1: For broth media: Shows turbidity in specific period of time and incubation as per annexure-1

5.1.10.2: For agar media: In specific period of time and incubation, the recovery from number of colonies inoculated do not alter by the factor of 2.

### 5.0 Forms and Records

5.1 Growth of microorganisms on microbiological media. : Annexure-1

5.2 Growth Promotion Test Record : Annexure-2

### 6.0 Reference

7.1 Hi-media manual

### 8.0 Distribution

8.1 Master Copy : Documentation Cell (Quality Assurance)



# PHARMA DEVILS

MICROBIOLOGY DEPARTMENT

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8.2 Controlled Copies : Quality Control, Quality Assurance

### 9.0 History

Date	Revision Number	Reason for Revision
	00	New SOP