



STANDARD OPERATING PROCEDURE

Department: Microbiology	SOP No.:
Title: Guidelines for Good laboratory practices in Microbiology Laboratory	Effective Date:
Supersedes: Nil	Review Date:
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1.0 OBJECTIVE:

To provide guidelines for Good laboratory practices (GLP's) to be followed in Microbiology Laboratory.

2.0 SCOPE:

This procedure is applicable to the practices adopted in Microbiology laboratory.

3.0 RESPONSIBILITY:

Microbiologist - Quality Control.

Head - Quality Control.

4.0 PROCEDURE:

4.1 Health.

4.2 Personnel hygiene:

4.2.1 All staff should be neat and clean. Clean laboratory apron should be worn.

4.2.2 Hair should be kept clean and covered with a cap while working in the Laboratory.

4.2.3 All staff should change their footwear just before entering the Microbiology Laboratory.

4.2.4 Nails of persons working in the Microbiology Laboratory should be regularly trimmed.

4.2.5 Jewellery and unnecessary cosmetics should not be worn in microbiology testing area.

4.3 Activity of personnel:

4.3.1 The number of persons working in clean zones should be kept to the minimum as practical.

4.3.2 Staff should not move unnecessarily in microbiology testing areas because movement increases particulate and bacterial shedding.

4.3.3 Persons engaged in maintenance work should observe the same precautions and hygiene standards as laboratory personnel.

4.4 Personnel garments:

4.4.1 Staff working in microbiology testing area should change into special Garments which are non-Shedding, comfortable to wear and loose fitting.



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4.4.2 The garments should have no external pockets of unnecessary tucks. Edges of the garments should be sealed and seams should be all enveloping.

4.4.3 The garments should be cleaned in such a way that they do not gather Contaminants, which can later be shed while working.

4.4.4 Before use the garments should be sterilized.

4.4.5 Clean sterilized garment should not be re used and should be used only after washing and sterilization.

4.5 General care to be taken during work:

4.5.1 The dynamic pass- box should be used for transfer of any material to and from the sterility testing area and microbiological testing area.

4.5.2 Personnel should not lean into the laminar airflow bench or place his / her hands on the bench.

4.5.3 No articles/ glassware should be placed on top of the laminar airflow bench.

4.5.4 Cleaned and dried glassware should be used for media preparation.

4.5.5 Sterile petri-plates should be handled with care. Petriplates should be opened only in the laminar airflow bench.

4.5.6 After un-cleaned operation e.g. media destruction cycle, area cleaning to be done.

4.5.7 All clean operations like unloading and shifting of material after MLT test will be done in close containers, whereas the unclean operations like transferring of incubated plates will be done in open trays.

4.5.8 Some samples will demonstrate the microbial growth and requires further laboratory analysis to identify the contaminant. When growth is detected the sample should be taken in testing area under LAF.

4.5.9 Subculturing, staining, identification and investigational work should be conducted in testing area under LAF and all the precautions as per step No.4.6 need to be follow at the time of culture handling.

4.5.10 If possible, any sample found to contain growing colonies should not be opened in the clean



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zone of laboratory.

4.5.11 While pouring the hot media it should be checked the temperature of media should not be high so that it will harm the positive culture added for the recovery enumeration.

4.5.12 After addition of sample for Microbial limit test the culture media should be added within 20 minutes, to avoid the drying of the sample.

4.6 Precautions followed during Positive Culture Handling:

4.6.1 Intact culture glassware and culture packets/culture vials (Bioballs) shall be mopping the outside surface with filtered 70 % v/v IPA under laminar air flow to minimize the cross contamination.

4.6.2 Culture handling activity includes sub culturing, growth promotion test, biological indicator test, antibiotic assay and culture dilution activity shall be performed only after routine microbiological activities such as raw materials, finish products, water analysis, and plate preparation.

4.6.3 If positive cultures handle in microbiology testing area before routine analysis, clean area with routine disinfectant than only proceed further routine analysis.

4.6.4 After completion of culture handling activity remove sterile gown in Change Room-I and packed in bag and wash separately these garments in garment washing machine located in microbiology testing area.

4.6.5 Open only one culture at a time under Laminar air flow and closed immediately after use.

4.6.6 Culture handling activity shall be followed by cleaning of microbiology testing area as per reference SOP: Maintenance of microbial cultures and Microbial culture dilution.

5.0 ANNEXURE (S):

Nil

6.0 REFERENCE (S):

SOP: Maintenance of microbial cultures and Microbial Culture Dilution.



PHARMA DEVILS

MICROBIOLOGY DEPARTMENT

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7.0 ABBREVIATION (S)/ DEFINATION (S):

GLP : Good Laboratory Practices

QC : Quality Control

REVISION CARD

S.No.	REVISION No.	REVISION DATE	DETAILS OF REVISION	REASON (S) FOR REVISION	REFERENCE CHANGE CONTROL No.
1	00	---	---	New SOP	---