



STANDARD OPERATING PROCEDURE

Department: Microbiology	SOP No.:
Title: Personnel Monitoring in Microbiology Testing Area	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

1.0 OBJECTIVE:

To lay down the procedure for Personnel monitoring in Microbiology testing area.

2.0 SCOPE:

This SOP is applicable for Personnel monitoring in Microbiology testing area.

3.0 RESPONSIBILITY:

QC – Microbiologist

Head – Quality Control

4.0 PROCEDURE:

4.1 Principle:

4.1.1 This procedure elaborates methods of determination of the bio-load (Total Viable aerobic microbial Count) of hand gloves and garments.

4.1.2 By contact plate method personnel monitoring is to be done.

4.2 Requirements:

4.2.1 RODAC plates

4.2.2 Laminar air flow bench

4.2.3 Colony counter

4.2.4 Incubators

4.2.5 Petri plate

4.3 Precaution:

4.3.1 Use pre incubated sterile Soybean casein digest agar with 0.1 % Tween – 80 plates for personnel monitoring.

4.3.2 Don't use the sterile gown once it has been sampled by using contact plate.

4.3.3 Don't use plates preincubated less than 48 hours for personnel monitoring.

4.4 Procedure for Plate preparation:

4.4.1 Prepare Media plates as per ref. SOP.

4.4.2 Check the plates for any contamination, if so discard the plates. As ref. SOP.



STANDARD OPERATING PROCEDURE

Department: Microbiology	SOP No.:
Title: Personnel Monitoring in Microbiology Testing Area	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

- 4.4.3 Mark the plates with Person Name, Sampling Location No., and Date and sign.
- 4.4.4 Wrap the required plates in aluminum foil or wrapping paper.
- 4.4.5 Transfer the plates to microbiology testing area through pass box meant for material entry. Remove the aluminum foil or wrapping paper of plates under dynamic pass box.
- 4.4.6 Enter to microbiology testing area by following the entry procedure as per SOP.
- 4.4.7 Take the plates from pass box and transfer to analysis area.

4.5 Procedure for personal gear:

- 4.5.1 Each person shall be monitored for seven sampling location i.e headgear, hand (left & right), booties (left & right) as per Annexure-I in microbiology testing area on weekly basis.
- 4.5.2 Immediately after sampling, spray filtered 70% v/v IPA on the sampling location and mop it with sterile lint free duster.
- 4.5.3 Transfer the plates to incubator room and incubate the plates at 20°C to 25°C 72 hours, followed by 30°C to 35°C for 48 hours.
- 4.5.4 Count the number of colonies on each plate using Colony counter and record the number of colonies as CFU/ plate as per Annexure-II.

4.7 Limit:

Test	Grade	Bacteria (Cfu / plate)		
		Alert Limit	Action Limit	Specification Limit
Personnel gears	Grade A #	-----	-----	<1
	Grade B	3	4	5
	Grade C	10	15	20

#Note: Any count observed in any location in Grade A shall trigger investigation as per reference SOP.

- 4.8 In case the result exceeds the Action Level proceed as per reference SOP.
- 4.9 Prepared the trends on monthly basis

5.0 ANNEXURE (S) :

- Annexure-I: Layout Diagram of Personnel Monitoring.
- Annexure-II: Personnel Monitoring Report for aseptic activity.



STANDARD OPERATING PROCEDURE

Department: Microbiology	SOP No.:
Title: Personnel Monitoring in Microbiology Testing Area	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

6.0 REFERENCE (S):

SOP: Procedure for preparation of media.

SOP: Disposable of microbial culture media and cleaning of glassware used for culture media.

SOP: Investigation of out of specification test results.

Pharmacopoeia: As per current versions of IP,BP,USP and EP

SOP: Preparation, Approval, Distribution control, revision and Destruction of Standard operating Procedure (SOP).

7.0 ABBREVIATION (S) / DEFINITION (S):

CFU : Colony Forming Unit.

SCDA (T): Soyabean Casein Digest Agar with 0.1 % Tween – 80.

IPA : Iso Propyl Alcohol.

IP : Indian pharmacopoeia

BP : British pharmacopoeia

USP :United States pharmacopoeia

EP : European pharmacopoeia

REVISION CARD

S.No.	REVISION No.	REVISION DATE	DETAILS OF REVISION	REASON (S) FOR REVISION	REFERENCE CHANGE CONTROL No.
01	00	---	---	New SOP	---



STANDARD OPERATING PROCEDURE

Department: Microbiology

SOP No.:

Title: Personnel Monitoring in Microbiology Testing Area

Effective Date:

Supersedes: Nil

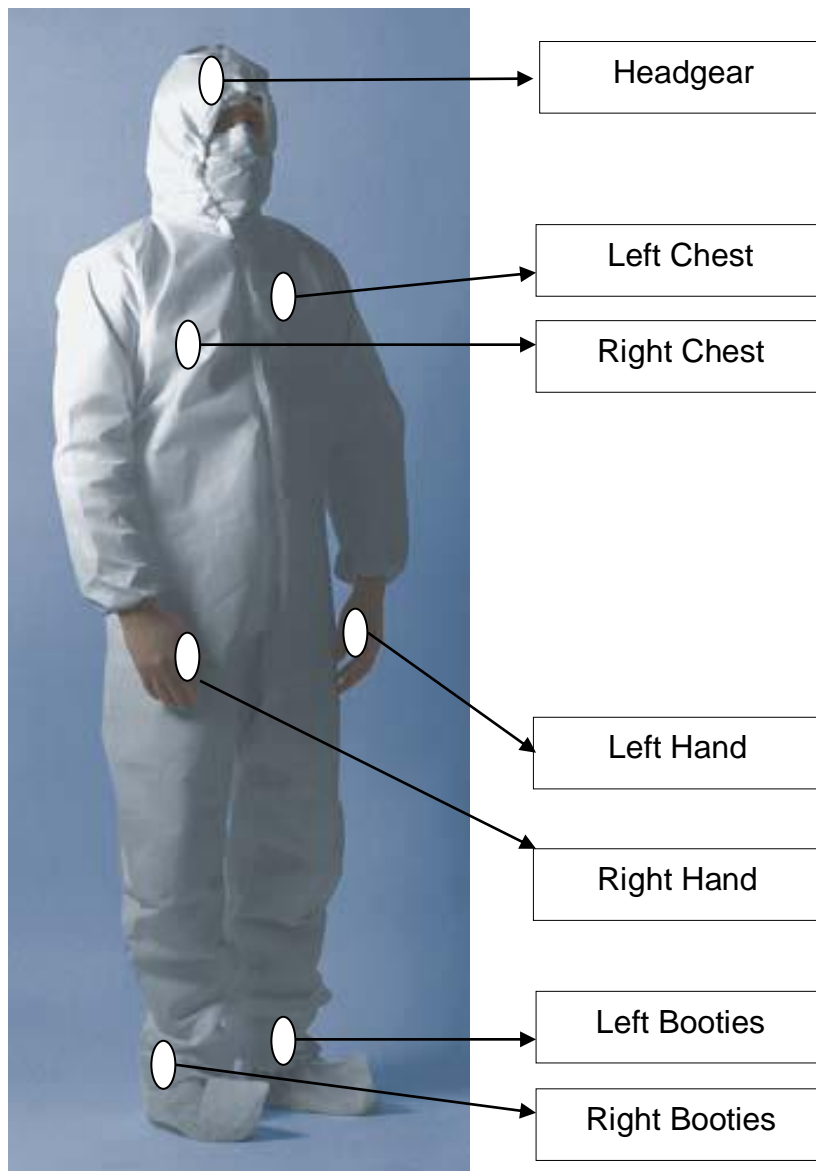
Review Date:

Issue Date:

Page No.:

Annexure I

LAYOUT DIAGRAM OF PERSONAL MONITORING





STANDARD OPERATING PROCEDURE

Department: Microbiology	SOP No.:
Title: Personnel Monitoring in Microbiology Testing Area	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

Annexure II

PERSONNEL MONITORING REPORT FOR ASEPTIC ACTIVITY

Product			
Batch. No.		Date of Testing	
A.R. No.		Activity	
Method	Personnel Monitoring by Contact Plate	Sampled By	

Name of Person	Headgear CFU/Plate	CHEST CFU/Plate		Hand CFU/Plate		Booties CFU/Plate	
	Centre	RIGHT	LEFT	RIGHT	LEFT	RIGHT	LEFT

Limit:

Test	Grade	Bacteria (cfu / plate)		
		Alert Limit	Action Limit	Specification Limit
Personnel gears	Grade A #	-----	-----	<1
	Grade B	3	4	5
	Grade C	10	15	20

Media Used	Soybean Casein Digest Agar (SCDA)		
Lot No/load No.			
Incubator No.			
Temperature range	20° – 25°C		30° – 35°C
Incubation started on (Date/Time)			
Incubation completed on (Date/Time)			

Observation: Bioburden is found within / out of specified limit

Remark: Complies / Does not Complies

Observed By:	Date of Report	Checked by:
(Sign. & Date):		(Sign. & Date):