



STANDARD OPERATING PROCEDURE

Department: Microbiology	SOP No.:
Title: Personnel Qualification of Aseptic Area	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

1.0 OBJECTIVE:

To lay down the procedure for Personnel Qualification of Aseptic Area.

2.0 SCOPE:

This SOP is applicable for personnel monitoring during personnel qualification of Aseptic Area for Microbiology Section.

3.0 RESPONSIBILITY:

Officer / Executive – IPQA / Microbiology

4.0 ACCOUNTABILITY:

Head – QC

5.0 ABBREVIATIONS:

%	Percentage
<	Less Than
°C	Degree Centigrade
CFU	Colony Forming Unit
IPA	Iso Propyl Alcohol
Ltd.	Limited
Mm	Millimeter
No.	Number
Pvt.	Private
QA	Quality Assurance
QC	Quality Control
RODAC	Replicate Organism Detection and Counting
SOP	Standard Operating Procedure

6.0 PROCEDURE:

- 6.1 Sanitize the surface of aluminum foil with 0.22 μ filtered 70% IPA and makes the set of 10 plates and wrap in aluminum foil.
- 6.2 Put the set of plates in cleaned SS Container sanitized with 0.22 μ filtered 70% IPA.
- 6.3 Transfer the plates to the respective area and ensure that container should not open during transit from Microbiology lab to production area.
- 6.4 Label the plates with personnel Name, location and Date of Sampling.



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- 6.5** Open the lid of contact plate containing DNA media and take the sample by pressing the plate with uniform pressure for approximately 5 seconds on the surface which has to be monitor, after sampling, close the lid of plates.
- 6.6** For Finger Dab open the lid of petri plate containing DNA media and take the prints of fingertips after completion of activity from both gloves on two different plates close the lid of plates.
- 6.7** Perform the Personal Monitoring as per below mentioned location.
- Forehead(FH)
 - Chest (CH)
 - Right Armpit (RA)
 - Left Armpit (LA)
 - Right Elbow (RE)
 - Left Elbow (LE)
 - Waist (WT)
 - Right Thigh (RT)
 - Left Thigh (LT)
 - Right Booty (RB)
 - Left Booty (LB)
 - Right Hand Finger Dab (RF)
 - Left Hand Finger Dab (LF)
- 6.8** Pictorial diagram of above location mentioned in SOP, Title: **“Qualification for the Personnel entering in to Aseptic Area of Production and Microbiology Lab”**.
- 6.9** Finger Dab monitoring perform in Under LAF and gowning monitoring done in return change room Grade B.
- 6.10** After sampling sanitize the sampled area with 0.22 μ filtered 70% IPA. Ensure that there is no agar media traces left over the contact surface sampled.
- 6.11** After the completion of sampling transfer the media plates to Microbiology lab for incubation.
- 6.12** Incubate the plates at 20 to 25⁰C for NLT 72 hours in inverted condition.
- 6.13** After completion of 72 hours at 20 to 25⁰C then transfer the plates at 30 to 35⁰C for NLT 48 hours in inverted condition.
- 6.14** After completion of incubation; observed the microbial count with colony counter from both sides of plates.
- 6.15** If there is a holiday on the day of release/transfer of media plates, take the observation/ transfer of media plates on next working day.
- 6.16** Results shall be recorded as per the Annexure -I; **“Personnel Qualification Report of Aseptic Area”**.



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6.17 In case a Microbiologist/IPQA is to be qualified for Aseptic Area operation; he shall perform his personnel monitoring by himself.

6.18 ACCEPTANCE CRITERIA:

Grade	Alert limits	Action limits	Specified Limits
A	<1 cfu/Plate	<1 cfu/Plate	<1 cfu/Plate
B	3 cfu/Plate	4 cfu/Plate	5 cfu/Plate

7.0 ANNEXURES:

ANNEXURE No.	TITLE OF ANNEXURE	FORMAT No.
Annexure-II	Personnel Qualification Report of Aseptic Area	

ENCLOSURES: SOP Training Record.

8.0 DISTRIBUTION:

- Controlled Copy No. 01 Quality Assurance
- Controlled Copy No. 02 Microbiology
- Master Copy Quality Assurance

9.0 REFERENCES:

- European Union GMP Annexure -10
- United States Pharmacopeia 39 NF 34; Chapter No. 1116

10.0 REVISION HISTORY:

CHANGE HISTORY LOG

Revision No.	Change Control No.	Details of Changes	Reason for Change	Effective Date	Updated By



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ANNEXURE – I
PERSONNEL QUALIFICATION REPORT OF ASEPTIC AREA

Name of Personnel		Department Name	
ACS/Emp. Code No.		Designation	
Date & Time of 1st Day Qualification		Date & Time of Qualification Completed (1st Day)	
Date & Time of 2nd Day Qualification		Date & Time of Qualification Completed (2nd Day)	
Date & Time of 3rd Day Qualification		Date & Time of Qualification Completed (3rd Day)	
Name of Media Used	DNA	Autoclaved Media Lot No.:	
Incubator ID (20-25°C)		Incubator ID (30 -35°C)	

S.No.	Location	Grade	1 st day			2 nd day			3 rd day		
			TFC	TBC	TMC	TFC	TBC	TMC	TFC	TBC	TMC
1	Fore Head	B									
2	Chest	B									
3	Right Armpit	B									
4	Left Armpit	B									
5	Right Elbow	B									
6	Left Elbow	B									
7	Waist	B									
8	Right Thigh	B									
9	Left Thigh	B									
10	Right Booty	B									
11	Left Booty	B									
12	Right Hand Finger Dab	A									
13	Left Hand Finger Dab	A									

Observed By (Sign & Date):	
Checked By (Sign & Date):	

LIMITS

Grade	Alert limits	Action limits	Specified Limits
A	<1 cfu/Plate	<1 cfu/Plate	<1 cfu/Plate
B	3 cfu/Plate	4 cfu/Plate	5 cfu/Plate

Remarks: The Personal monitoring results are Complies / does not comply as per prescribed limits.

Reviewed By:
(Sign & Date)