



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 Qualification of Aseptic Area in Microbiology Section of Quality Control Department.

3.0 RESPONSIBILITY:

Officer / Executive – Microbiologist

4.0 ACCOUNTABILITY:

Head – QC

5.0 PROCEDURE:

- 5.1 When a new personnel is going in aseptic area to perform any activity; he shall be initially qualified then only he can perform any activity in the area.
- 5.2 For a personnel qualification a new personnel shall enter inside the aseptic area as per the respective SOP of entry and exit procedure.
- 5.3 The personnel whose qualification is to be done; shall go in Grade B of aseptic area where a Microbiologist shall perform his personnel monitoring by contact plate method for his personnel qualification.
- 5.4 Pre-incubated 55 mm size RODAC plates having De Engley Agar shall be used for personnel monitoring.
- 5.5 Label the RODAC plates with personnel Name, Department and Date of Sampling.
- 5.6 Open the RODAC Plate and take impression of the personnel's Forehead, Chest, Left arm pit, Right arm pit, Waist, Left Finger Dab and Right Finger Dab.
- 5.7 During sampling, press the contact plate with uniform pressure to make contact of the entire media surface. After taking impression close the lid of plate.
- 5.8 Take precaution that no media's traces should left on the personnel. Disinfect all the sampling locations with filtered 70% IPA Solution to remove media spillage, if any.
- 5.9 After the completion of sampling transfer all media plates to Microbiology lab for incubation.
- 5.10 Personnel details shall be recorded as per Annexure-I; **“Log Book for Personnel Qualification of Aseptic Area”**.



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5.11 Incubate the media plates at 20⁰C to 25⁰C for 72 hours and then at 30⁰C to 35⁰C for 48 hours.

5.12 Results shall be recorded as per the Annexure -II; “**Personnel Qualification Report of Aseptic Area**”.

5.13 Personnel Monitoring of a personnel shall be performed for consecutive three days in the same area. If the results of all three consecutive days meet the acceptance criteria then only he will be qualified to enter for working in Aseptic Area.

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

5.15 ACCEPTANCE CRITERIA:

Grade	Limit
A	<1 cfu/Plate
B	<5 cfu/Plate

6.0 REFERENCES:

European Union GMP Annexure -10
United States Pharmacopeia 37 - NF 32; Chapter No. 1116

7.0 ANNEXURES:

ANNEXURE No.	TITLE OF ANNEXURE	FORMAT No.
Annexure-I	Log Book for Personnel Qualification of Aseptic Area	
Annexure-II	Personnel Qualification Report of Aseptic Area	

8.0 DISTRIBUTION:

- Controlled Copy No. 01 Head Corporate Quality Assurance
- Controlled Copy No. 02 Head Quality Control
- Master Copy Quality Assurance

9.0 ABBREVIATIONS:

SOP Standard Operating Procedure
No. Number
Pvt. Private
Ltd. Limited
QA Quality Assurance



PHARMA DEVILS

MICROBIOLOGY DEPARTMENT

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QC	Quality Control
RODAC	Replicate Organism Detection and Counting
mm	Millimeter
%	Percentage
IPA	Iso Propyl Alcohol
°C	Degree Centigrade
CFU	Colony Forming Unit
<	Less Than

10.0 REVISION HISTORY:

CHANGE HISTORY LOG

Revision No.	Details of Changes	Reason for Change	Effective Date	Updated By
00	New SOP			



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ANNEXURE – II
PERSONNEL QUALIFICATION REPORT OF ASEPTIC AREA

Name of Personnel:		Department Name:			
Date of Qualification Initiated:		Date of Qualification Completed:			
Name of Media Used:		Autoclaved Media Lot No.:			
Incubator ID (20⁰C -25⁰C):		Incubator ID (30⁰C -35⁰C):			
S.No.	Location	Limit	Observation After 72 hrs.	Observation After 120 hrs.	Remarks
1	Fore Head	<5 CFU/Plate			
2	Chest	<5 CFU/Plate			
3	Left Arm Pit	<5 CFU/Plate			
4	Right Arm Pit	<5 CFU/Plate			
5	Waist	<5 CFU/Plate			
6	Left Finger Dab	<1 CFU/Plate			
7	Right Finger Dab	<1 CFU/Plate			

Remarks: Observed results are found within acceptance criteria. So the personnel is qualified for working in Aseptic Area.

Done By/Date:

Checked By/Date: