



PHARMA DEVILS

MICROBIOLOGY DEPARTMENT

STANDARD OPERATING PROCEDURE

Title: Entry and Exit Procedure for Sterility Area of Microbiology Laboratory

SOP No.:		Department:	Microbiology
		Effective Date:	
Revision No.:	00	Revision Date:	
Supersede Revision No.:	Nil	Page No.:	1 of 3

1.0 OBJECTIVE

To lay down procedure for entry and exit procedure to be followed in sterility area of microbiology laboratory.

2.0 SCOPE

This SOP is applicable entry and exit in sterility area of microbiology laboratory.

3.0 RESPONSIBILITY

Prepared by - Executive Microbiology

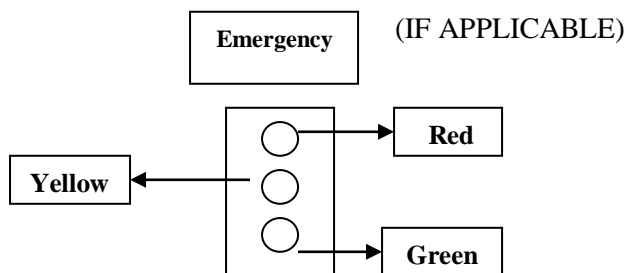
Checked by - Assistant Manager Microbiology / QC

Approved by - Head QA, QC

4.0 PROCEDURE

4.1 Operation of Interlocking System

4.1.1 The interlocking system contains the following press buttons, which function as follows.



- Red light indicates that the door is not release / closed.
- Green light indicates that the door is released / opened.

4.1.2 For entry in the respective areas operate the interlocking system.

4.1.3 Press the yellow button provided on the panel.

4.1.4 The Green light below the yellow button become activates which indicates the door is release for entry.

4.1.5 Open the door and enter in to the respective area.

4.1.6 If one door is open then the other door automatically becomes lock till the first becomes close.

4.1.7 Incase of emergency press the emergency button provided on the top of the panel of the interlocking system, which deactivate the interlocking system.

4.2 Entry Procedure in Sterility Testing Area



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- 4.2.1 Operate the interlocking system as mentioned under section 4.1.
- 4.2.2 From the corridor enter into the change room -1.
- 4.2.3 Remove the factory uniform & shoes in the change room -1 and keep them in the shelf assigned for it.
- 4.2.4 Wipe the hands with 70% IPA or any other approved disinfectant solution and allow the hands to dry.
- 4.2.5 Enter in the change room - 2 by pushing the door with elbows.
- 4.2.6 Wear sterile hand glove and wipe with 70% IPA or any other approved disinfectant solution and allow the hands to dry.
- 4.2.7 Take out one sterilized garment bag from the sterile garment storage cabinet, which contains head cover, boiler suit and booties.
- 4.2.8 First of all wear head cover and ensure that the hair is completely covered.
- 4.2.9 Take out the boiler suit from the bag and wear it.
- 4.2.10 Ensure that while wearing, the garment is not to touch to the floor.
- 4.2.11 Ensure that the head cover is completely tucked inside the boiler suit. Then tighten the belt around the waist and wear the booties.
- 4.2.12 Enter in the change room - 3 by pushing the door with elbow.
- 4.2.13 In the change room - 3 wipe with 70% IPA or any other approved disinfectant solution and allow the hands to dry.
- 4.2.14 Wear the secondary sterile gloves in the change room - 3.
- 4.2.15 Enter in the sterile corridor by pushing the door with elbow.
- 4.2.16 From the sterile corridor enters in to the respective area (Sterility testing room / cooling zone) by pushing the door with elbow.
- 4.3 Exit Procedure from Sterility Testing Area**
- 4.3.1 Operate the interlocking system as mentioned under section 4.1.
- 4.3.2 After completion of work exit from the sterility testing room /cooling zone and enter in the sterile corridor by pulling the door.
- 4.3.3 From the sterile corridor enter in the change room - 4 by pulling the door.
- 4.3.4 Remove the hand glove and put them into the used gloves bin.
- 4.3.5 Remove booties, boiler suit and lastly the head cover and put them in to the used garment bin.
- 4.3.6 From the change room - 4 enter in the change room - 1 by pulling the door.



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4.3.7 In the change room - 1, wipe the hands with 70% IPA or any other approved disinfectant solution.

4.3.8 In the change room - 1 wear the factory shoe and factory uniform.

4.3.9 Exit from the change room -1 by pulling the door and enter in to the corridor.

5.0 SAFETY & PRECAUTIONS

5.1 Always wear hand gloves headgear and nose mask before entry in the area.

5.2 Always wipe the hands with 70% IPA or any other approved disinfectant solution before entry and before exit the areas.

5.3 Red button is to be press only in case of emergency.

6.0 REVISION HISTORY

Revision No.	Reason for Revision	Superseded from & date
00	First Issue	-----

7.0 REFERENCES

Not applicable.

8.0 ABBREVIATIONS

SOP : Standard Operating Procedure

% : Percentage

IPA : Iso Propyl Alcohol

9.0 ANNEXURES

Not applicable