



### STANDARD OPERATING PROCEDURE

**Title:** Entry and Exit Procedure in Microbiology Laboratory

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

1. **Purpose:** The purpose of this SOP (Standard Operating Procedure) is to describe the procedure for entry and exit to microbiological Laboratory.
  2. **Scope:** This procedure is applicable to reduce the environmental bio-burden in Microbiological Laboratory.
  3. **References, Attachments & Annexures:**
    - 3.1. **References:** In – house
    - 3.2. **Attachments:** None
    - 3.3. **Annexures:** None
  4. **Responsibilities:**
    - 4.1. **Microbiologist:**
      - 4.1.1. To perform the activity as per SOP
      - 4.1.2. To maintain the records as per SOP
    - 4.2. **QC Head or designee:**
      - 4.2.1. To check the SOP
      - 4.2.2. To give the training to all concern persons
    - 4.3. **Quality Assurance:**
      - 4.3.1. To check the SOP
      - 4.3.2. To ensure proper implementation of SOP
    - 4.4. **Regulatory Affairs, Quality Head , Plant Head:**
      - 4.4.1. To review and approve the SOP
  5. **Distribution:**
    - 5.1.1. Quality Assurance
    - 5.1.2. Quality control ( Microbiology Section)
  6. **Abbreviations & Definition of Terms :**
    - 6.1. **Abbreviations :**
      - 6.1.1. SOP: Standard Operating Procedure
      - 6.1.2. LAF: Laminar Air Flow.
      - 6.1.3. IPA: Iso Propyl alcohol
    - 6.2. **Definition of Terms :** None
  7. **Procedure:**
    - 7.1. **Entry procedure into the Microbial testing area (LAF room)**
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# PHARMA DEVILS

MICROBIOLOGY DEPARTMENT

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- 7.1.1. Entry into Microbial testing area (LAF room) is restricted except authorized person and visitor entered along with authorized person.
  - 7.1.2. Personnel shall open the door by pushing the door of Airlock-I.
  - 7.1.3. Ensure that the door of Air lock-I is closed.
  - 7.1.4. Personnel shall remove the laboratory aprons / cap and hang/place them up in Airlock-1.
  - 7.1.5. Personnel shall remove the laboratory slippers in crossover bench.
  - 7.1.6. After crossing the crossover bench personnel shall wear new slipper from the crossover bench.
  - 7.1.7. Personnel shall sanitize the hands using the wall mounted disinfectant (IPA 70%)
  - 7.1.8. Personnel shall enter into Airlock-II by pulling the door of Airlock-II.
  - 7.1.9. Personnel take a sterile dress from dress cabinet and wear it with following sequence.
    - 7.1.9.1 Wear head mask and ensure that hair and nose is covered properly.
    - 7.1.9.2 Wear dangry / gown properly.
    - 7.1.9.3 Wear booty and tie it in such a way that it covers the ankle part of the gown.
    - 7.1.9.4 Wear short hand gloves (Do not use the gloves which are ruptured or having pinholes.)
    - 7.1.9.5 Tug in the sleeve ends properly inside the gloves.
    - 7.1.9.6 Watch out yourself in mirror either wearing dress proper or not.
  - 7.1.10. Personnel entered into the LAF room by pulling the LAF door.
  - 7.2. **Exit procedure from the Microbial testing area (LAF room):**
    - 7.2.1. After the completion of work, personnel shall exit from the LAF room by pushing the door and enterd into Airlock-II.
    - 7.2.2. Pesonnel shall remove the hand gloves into waste bin then exit from Airlock - II to Airlock -I by pushing the door.
    - 7.2.3. Personnel shall remove the slipper in crossover bench and wash the hand with 70% IPA then cross the crossover bench.
    - 7.2.4. Personnel shall wear slipper from crossover bench.
    - 7.2.5. Personnel shall remove the used dress and drop in the used SS garment bin or hang in Air Lock-I
    - 7.2.6. Personnel shall take the laboratory apron/cap and wear them.
    - 7.2.7. Personnel shall exit from the Air Lock-I by pulling the door of Airlock-1.
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### 8. History:

Version No.		Effective Date	
1.	New company name and logo incorporated.		

Version No.		Effective Date	

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