PHARMA DEVILS

MICROBIOLOGY DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Microbiology	**SOP No.:**
Title: Gowning Qualification for Entry to Critical Area	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

1.0 Objective

To lay down a procedure for gowning qualification of persons entering in the Critical area (Clean room of Grade B and Grade C) like manufacturing, and testing areas.

2.0 Scope

This procedure is applicable at Quality Control department of formulation plant.

3.0 Responsibility

Executive/Officer - Microbiology : Shall be responsible to follow the procedure for Gowning Qualification for Entry to Critical Area.

Head - QC/Designee : Shall be responsible for the compliance of this SOP.

4.0 Abbreviations and Definitions

QC : Quality Control

5.0 Procedure

5.1 Persons are allowed to work/stay in aseptic area only after successful completion of gowning qualification (i.e. after microbial results)

5.2 Only medically certified employees are eligible for gowning qualification.

5.3 Disinfect the sampling kit with suitable disinfectant solution using lint free cloth.

5.4 Prepare the sampling Kit with all requirements that should include the contact plates required for monitoring. Enter the area as per the entry and exit procedure specified for that area.

5.5 Gowning qualification shall be conducted by already qualified person.

5.6 Perform personnel monitoring, in return change room grade B or grade C during exit from the area. Note down the observations as per checklist for gowning procedure, while the person to be qualified is performing gowning.

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5.7 Take surface monitoring by contact plates from the locations as per the SOP titled "Personal Monitoring".

5.8 Incubate the Soyabean casein digest agar plates at 20-25ºC for initial 3 days and at 30-35 º C for later 2 days.

5.9 Counts for bacteria and fungi should be taken at the end of 5 days and record the result as per Annexure-1.

5.10 In case of any out of specification results perform the investigation and take the necessary corrective action.

6.0 Forms and Records

6.1 Personal Monitoring Report : Annexure-1

6.2 Certificate : Annexure-2

7.0 Distribution

7.1 Master Copy : Documentation Cell (Quality Assurance)

7.2 Controlled Copies : Quality Control, Quality Assurance

8.0 History

Date	Revision Number	Reason for Revision
	00	New SOP