



PHARMA DEVILS

WAREHOUSE DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Warehouse	SOP No.:
Title: Entry & Exit in Sterile RM Sampling Cum Dispensing Area	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

1.0 OBJECTIVE:

To lay down a Procedure for Entry and Exit Procedure in the Sterile RM Sampling cum Dispensing Area.

2.0 SCOPE:

This SOP is applicable during Entry and Exit Procedure in the Sterile RM Sampling cum Dispensing Area of Raw Material Store in Injection section.

3.0 RESPONSIBILITY:

Officer / Executive-Warehouse

4.0 ACCOUNTABILITY:

Head-Warehouse

5.0 ABBREVIATIONS:

DR Door Release
IPA Isopropyl Alcohol
Ltd. Limited
No. Number
Pvt. Private
QA Quality Assurance
SOP Standard Operating Procedure

6.0 PROCEDURE:

6.1 ENTRY PROCEDURE:

- 6.1.1 Remove the street garments in Change room on ground floor and hanging in dress cabinet.
- 6.1.2 Make Entry in “Sterile RM Sampling Cum Dispensing Area Entry - Exit Record” for format shown in Annexure-I.
- 6.1.3 Remove slippers & keep in slipper rack.
- 6.1.4 For enter inside entry as per Annexure-II “Entry & Gowning procedure for sterile RM sampling cum dispensing area”.
- 6.1.5 For enter inside the Entry Air Lock-1, Press “DR” button and push the door with the help of elbow.
- 6.1.6 Remove Garments, Wrist Watch, Ring etc. (Except Inner Garments) and keep them in Garment Cabinet provided in Entry Air Lock-1 for the same.
- 6.1.7 Sanitize the hands with 70% IPA solution provided in the area.
- 6.1.8 For entry in Entry Air Lock-2, press “PUSH” button to release the door on.



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- 6.1.9 Push the door with the help of elbow and enter inside the Entry Air Lock-2.
- 6.1.10 Sanitize the hands with 70% IPA solution provided in the area.
- 6.1.11 Take sterile Hand Gloves and Wear.
- 6.1.12 Take the sterile inner garments from Dynamic Garment Storage Cabinet & wear in sequence as per Annexure-II.
- 6.1.13 Take the Sterile Garments from Dynamic Garment Storage Cabinet and Put on Sterile Head Gear, Boiler Suit in sequence, without touching the floor as per Annexure-II.
- 6.1.14 Wear booties over boiler suit.
- 6.1.15 Check and ensure for proper outfit in the mirror.
- 6.1.16 Sanitize the hand with 70% IPA solution provided.
- 6.1.17 Press “DR” button to release the door of Entry Air Lock-3.
- 6.1.18 Push the door with help of elbow and enter into Entry Air Lock-3.
- 6.1.19 Wear second pair of sterilized Hand Gloves and swing over the cross over bench.
- 6.1.20 Sanitize the worn hand gloves with 70% IPA solution provided
- 6.1.21 Push the door with help of elbow of Sampling cum Dispensing Room and enter into the room.

6.2 EXIT PROCEDURE:

- 6.2.1 Press “DR” button and push the door enter into Return Air lock-1.
- 6.2.2 Press “DR” button and pull the door enter into Return Air lock-2.
- 6.2.3 For exit procedure as per Annexure –III, “Exit & De-Gowning procedure for sterile RM sampling cum dispensing area”.
- 6.2.4 Remove the hand gloves and put into “Designated Bin”.
- 6.2.5 Remove the Booties first and put used booties into “Designated Bin”.
- 6.2.6 Remove Boiler suit, Inner and head gear and put into “Used Garment Bin”.



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- 6.2.7** Open the dress cabinet and Take Company garment (Uniform) and wear it.
- 6.2.8** For exit outside the Sterile RM Sampling cum Dispensing area, press ‘DR’ button to release the door, pull the door and come out in the store area and wear the slippers from slipper rack.
- 6.2.9** Record the out time in “Sterile RM Sampling cum Dispensing Area Entry - Exit Record” format shown in **Annexure-I**.

7.0 ANNEXURES:

Annexure No.	Title of Annexure	Format No.
Annexure-I	Sterile RM Sampling cum Dispensing Area Entry - Exit Record	
Annexure-II	Entry & Gowning Procedure For Sterile RM Sampling cum Dispensing Area	
Annexure-III	Exit & De-Gowning Procedure For Sterile RM Sampling cum Dispensing Area	

ENCLOSURES: SOP Training Record

8.0 DISTRIBUTION:

- Controlled copy No.01 Quality Assurance
- Controlled copy No.02 Warehouse
- Master copy Quality Assurance

9.0 REFERENCES:

Schedule M of Drug and cosmetic act 1940

10.0 REVISION HISTORY:

CHANGE HISTORY LOG

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

