



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Title: Entry and Exit Procedure for Manufacturing Area in FFS Section

SOP No.:		Department:	Production	
		Effective Date:		
Revision No.:	00	Revision Date:		
Supersede Revision No.:	Nil	Page No.:	1 of 5	

1.0 OBJECTIVE:

To lay down a Procedure for Entry & Exit Procedure for Manufacturing Area in FFS section of I-Block.

2.0 SCOPE:

This SOP is applicable for Entry & Exit Procedure for Manufacturing Area in FFS Section.

3.0 RESPONSIBILITY:

Officer / Executive – Production

4.0 ACCOUNTABILITY:

Head – Production

5.0 ABBREVIATIONS:

IPA	Iso Propyl Alcohol
Ltd.	Limited
No.	Number
QA	Quality Assurance
SOP	Standard Operating Procedure

6.0 PROCEDURE:

6.1 INSTRUCTION:

6.1.1 Don't Push/Pull the door without pressing the push button of door inter locking of that particular door.

6.1.2 Don't press the emergency button until it really not required i.e. in any emergency condition.

6.2 ENTRY & EXIT PROCEDURE IN MANUFACTURING AREA FOR FFS SECTION :

6.2.1 ENTRY & GOWNING PROCEDURE IN MANUFACTURING AREA:

6.2.1.1 Record the Entry Details as per SOP, Annexure-I, Titled- **Area Entry And Exit Record**.

6.2.1.2 Follow the Pictorial Presentation as shown in **Annexure-I**, Title **“Entry & Gowning Procedure for Manufacturing Area (FFS Section)”**.

6.2.1.3 Remove Slippers and keep them at specified place in the Rack.

6.2.1.4 Press the **push** button of door interlocking, push the door with the help of elbow & enter into manufacturing Air Lock-I.



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6.2.1.5 Sanitize your hands with 70% IPA solution.

6.2.1.6 Press the button, push the door with the help of elbow and swing over the Cross over Bench to enter into the Air Lock-II.

6.2.1.7 Now Take one set of Specified area Garment containing Headgear, Boiler Suits and Booties from the Dress cabinet and wear it in sequence i.e. First Head Gear, then boiler suit & then Booties.

6.2.1.8 After gowning, wear hand gloves.

6.2.1.9 Sanitize your hands with 70% IPA solution and Check your Outfit of proper gowning in front of Mirror.

6.2.1.10 Press the push button, pull the door & enter inside the Manufacturing area.

6.2.2 EXIT & DE-GOWNING PROCEDURE FROM MANUFACTURING AREA (FFS SECTION)”.

6.2.2.1 Follow the Pictorial Presentation as shown in **Annexure-II**, Title “**Exit & De-Gowning Procedure from Manufacturing Area (FFS Section)”**”.

6.2.2.2 For exit, come near the door of manufacturing change room-II and Press push button to release the door.

6.2.2.3 Pull the door and come into Change room-II.

6.2.2.4 Remove Hand Gloves, Booties, Boiler Suits and Headgear in Sequence and place it in designated bin provided in change room-II.

6.2.2.5 To come out from change room –II, Press push button to release the door.

6.2.2.6 Pull the door and enter into the change room-I by swing over the cross over the bench.

6.2.2.7 For exit from Change room-I, Press the push button to release the door.

6.2.2.8 Pull the door and come into D-corridor.

6.2.2.9 Wear the D-class area slipper from slipper rack.

6.2.2.10 Record the Exit Details as per SOP, **Annexure-I**, Titled- **Area Entry And Exit Record**.



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7.0 ANNEXURES:

ANNEXURE No.	TITLE OF ANNEXURE	FORMAT No.
Annexure-I	Entry & Gowning Procedure For Manufacturing Area (FFS Section)	
Annexure-II	Exit & De-Gowning Procedure From Manufacturing Area (FFS Section)	

ENCLOSURES: SOP Training Record

8.0 DISTRIBUTION:

- Controlled Copy No.01 Quality Assurance
- Controlled Copy No.02 Production
- Master Copy Quality Assurance

9.0 REFERENCES:

SOP

10.0 REVISION HISTORY:

CHANGE HISTORY LOG

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



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ANNEXURE – I

ENTRY & GOWNING PROCEDURE FOR MANUFACTURING AREA (FFS SECTION)

STEP-1



Remove the slippers

STEP-02



press the door interlocking and enter in air lock-I

STEP-03



Hand sanitized with 70% IPA

STEP-04



press the door interlocking and enter in air lock-II

STEP-05



Take the dress and wear head gear and boiler suit.

STEP-06



wear the booties

STEP-07



wear the hand loves

STEP-08



Hand sanitized With 70% IPA

STEP-09



press the door interlocking and enter in Manufacturing room.



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ANNEXURE – II

EXIT & DE-GOWNING PROCEDURE FROM MANUFACTURING AREA (FFS SECTION)

STEP-01



press the door interlocking and enter in air lock-II

STEP-02



Remove the hand gloves

STEP-03



Remove the booties

STEP-04



Remove the boiler suit.

STEP-05



Remove the Head gear

STEP-06



press the door interlocking and enter in air lock-I

STEP-07



press the door interlocking and enter corridor

STEP-08



Wear the slippers