



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Entry and Exit of Visitors into Production Area	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

Vernacular SOP: No

1.0 OBJECTIVE:

1.1 To lay down a procedure for entry and exit of visitors into production area.

2.0 SCOPE:

2.1 This procedure is applicable to entry and exit of visitors in the Production area.

3.0 RESPONSIBILITY:

3.1 Visitor's : To follow the change room procedures

3.2 Head Production : SOP compliance

3.3 Personnel and Administration: Maintain Cleaning

4.0 DEFINITION(S):

4.1 NA

5.0 PROCEDURE:

5.1 Entry procedure into primary change room

5.1.1 Enter into primary change room.

5.1.2 Wash hands with water in the sink provided in the respective wash room and dry them.
Disinfect hands with 70% v/v IPA solution before cross the cross over bench if required.

5.1.3 Collect cap and shoe cover.

5.1.4 Wear cap and then shoe cover while crossing over the bench. (Cross over the bench by sitting on the bench and swinging the legs alternately. Ensuring that shoe cover does not touch the floor at the entry side).

5.1.5 Remove personal belongings (like wrist watch, wallet, Jewelry and bindi etc.) and put them in the individual locker. If nose piercings/pins not removable, cover it by wearing nose mask.

5.1.6 Collect and wear the apron. Wear beard mask if required.



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- 5.1.7 Check the attire in the mirror for proper gowning.
- 5.1.8 Disinfect hands with 70% v/v IPA solution provided before entering into the production area.
- 5.1.9 Both male and female those who are meant to visit packing line, no need to enter the secondary change room and must go directly to the packing hall from the primary change room.

5.2 Entry procedure into manufacturing area through secondary change room

- 5.2.1 Enter in to the secondary change room.
- 5.2.2 Collect the secondary overgrown, second cap, nose mask and shoe cover
- 5.2.3 Wear additional cap over the first cap and then fresh shoe covers over the earlier one while crossing cross over bench. (Cross over the bench by sitting on the bench and swinging the legs alternately. Ensuring that shoe cover does not touch the floor at the entry side).
- 5.2.4 Wear Trouser/ wrap around, secondary over gown and then nose mask.
- 5.2.5 Check the attire in the mirror for proper gowning.
- 5.2.6 Disinfect hands with 70% v/v IPA solution provided before entering into the manufacturing area.

Note:

1. Entry of visitors into manufacturing cubicle with activity under process is not allowed with visitors secondary over gown. The visitors shall follow SOP (“Entry & Exit of male and female staff in the Production area”) for entry and exit in the manufacturing cubicle with active under progress.
2. To enter from one cubicle to another with different products under manufacturing, fresh gowning to be used for each entry into the manufacturing area.

5.3 Exit Procedure from manufacturing area

- 5.3.1 Enter in to the secondary change room.
- 5.3.2 Remove the outer shoe cover while crossing over bench and discard in waste bin.
- 5.3.3 Remove additional cap and discard in the waste bin.



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- 5.3.4 Remove secondary gowns, Trouser/ wrap around.
- 5.3.5 Discard in the cabinet provided.
- 5.3.6 Discard nose mask in the waste bin provided.
- 5.3.7 Disinfect hands with 70% v/v IPA solution provided before exit from the secondary change room.

5.4 Exit Procedure from primary change room

- 5.4.1 Enter into the primary change room.
- 5.4.2 Remove the shoe covers while crossing the bench and discard in waste bin.
- 5.4.3 Remove cap, beard mask, nose mask and discard in the waste bin.
- 5.4.4 Remove apron and discard them in bin provided for used apron.
- 5.4.5 Collect the personal belongings from the lockers provided and exit from the primary change room.

6.0 ABBREVIATION(S):

- 6.1 SOP : Standard Operating Procedure
- 6.2 No. : Number
- 6.3 IPA : Isopropyl Alcohol
- 6.4 v/ v : Volume by Volume

7.0 RERERENCE(S):

- 7.1 SOP: Entry & Exit of male and female staff in the Production area

8.0 ANNEXURE(S):

- 8.1 NA

9.0 DISTRIBUTION:

- 9.1 **Master copy** : Quality Assurance.



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9.2 **Controlled copy (s):** Production department (01), Personnel and Administration department (01), Quality Assurance department (01).

9.3 **Reference copy (s) :** Production (05), Quality Assurance (01).

10.0 REVISION HISTORY:

S.No.	Version No.	Change control no.	Reason (s) for revision	Details of revision	Effective date
1.0	00	NA	NEW SOP	NA	NA