



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Entry & Exit of Personnel in Core Area Through Access Control System	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 & exit of personnel in core area through access control system.

2.0 SCOPE:

2.1 This SOP is applicable for entry and exit of personnel in core are through access control system.

3.0 RESPONSIBILITY:

3.1 Technical associate : Follow the procedure of Entry & Exit of Personnel in Core Area Through Access Control System

3.2 Officer, Executive : Follow the procedure of Entry & Exit of Personnel in Core Area Through Access Control System

3.3 Department HOD (Production) : Compliance to the procedure & SOP compliance

3.4 Department HOD (QA) : Compliance to the procedure & SOP compliance

4.0 DEFINITIONS:

4.1 NA

5.0 PROCEDURE:

5.1 Entry and Exit procedure

5.1.1 Access (Biometric) control system is installed and shall be used to control and restrict the movement of working personnel across different cubical of core area.

5.1.2 The entry and Exit in core area shall be permitted to specified personnel only through access control system by authorized area In-charge/Head (Production /QA).

5.1.3 The access authorization shall be provided on weekly basis.

5.1.4 In case of change in production plan of any area or absence of any staff in between the week then permission for other staff person shall be provided as required basis.

5.1.5 For entry in the core cubicle (if applicable), Person shall be put his finger on scanner(register finger during joining) of finger access device and long beep sound will be generated and door will open with message ACCESS AUTHORIZED or Green Light.



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- 5.1.6 Manager, Shift in-charge of Production/IPQA shall be permitted to enter in all access controlled area to supervise the work. Secondary gown shall be replaced for every entry in each area as per SOP (“Entry and Exit of male and female staff in the production area”).
- 5.1.7 For any breakdown or maintenance work or preventive maintenance in access controlled area, engineering persons shall enter upon authorized by allotted persons/area in charge/department head.
- 5.1.8 Any other person like QC personal, IT personal etc. shall be entered in controlled accessed area with supervision of authorized person in respective area / shift in charge/department head.
- 5.1.9 In case of access control machine is under breakdown or any network failure then intimate to engineering or IT person for rectification. Till time only manual entry of authorized person or persons with supervision by authorized person are allow to entry the controlled access area.
- 5.1.10 Head Operation and his designee / Head QA and his designee is authorized to allow entry to visitor and auditor in controlled access area .They shall be follow gowning procedure as per SOP (“Entry and Exit of male and female staff in the production area”) and then enter in to area along with HOD.

6.0 ABBREVIATION (S):

- 6.1 IPQA: In Process Quality Assurance
- 6.2 HOD: Head of Department
- 6.3 QC: Quality Control

7.0 REFERENCE (S):

- 7.1 SOP: Entry and Exit of male and female staff in the production area.

8.0 ANNEXURE (S):

Annexure no.	Title of Annexure	Format No.	Mode of execution
			NA

9.0 DISTRIBUTION COPY:

- 9.1 **Master Copy** : Quality Assurance
- 9.2 **Control Copy (s)** : Quality Assurance (01), Production (02), Quality Control (01).
- 9.3 **Reference copy (s)** : Production Department (03)



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10.0 REVISION HISTORY:

S.No.	Version No.	Change Control No.	Reason (s) for Revision	Details of Revision	Effective Date
1.	00		New	To provide the access Controller in Granulation area-I, II, III, IV, Pilot Plant & Roll compacter.	