



ORIGINAL

SOP #	VC-NPR-001	TITLE:	Effective:	09/09/13
Revision #	01	Personnel Hygiene and Entry Procedure in the Production Area	Status:	APPROVED
Superseded By:	Amrita Gupta		Total Pages:	02

REVIEWED BY/DATE:	QUALITY APPROVAL/DATE:
<i>[Signature]</i> 10/18/21.	<i>[Signature]</i> 10/18/21

1. Purpose:

To provide a documented procedure for entry into the production area with respect to personnel hygiene and cGMP standards

2. Scope:

This SOP applies to all employees and visitors and describes adequate gowning procedure while entering in the cGMP manufacturing area, which help to minimize the risk of possible contamination.

3. Responsibility: Human Resources, Production Supervisor/Manager, Quality Assurance

4. Reference: 21CFR 111 Subpart B 111.10; 111.14 (b)(1), USP<797>

5. Procedure:

- a. Personnel hygiene is very important for the safety of the products manufactured.
- b. All employees should punch in five minutes before the start of the work.
- c. Beverages such as, coffee, tea or soda or edible products such as tobacco, chewing gum, candy or food of any kind cannot be carried into or stored in the production areas. These products cannot be consumed in a production area irrespective of whether a production activity is being carried out or not.
- d. No portable entertainment instrument such as radios, cassette players, headphones or pocket television are allowed while engaged in any production activity.
- e. Remove outer garments (including coats or jackets, hat, scarves or sweaters), cosmetics and visible jewelry, before entering into cGMP production area.
- f. Each employee should wash their hands before entering production area. If required, use hand sanitizer to sanitize your hands frequently in the production area. Please refer SOP-VC-NQA-001.
- g. Hair nets / Beard cover / Shoe covers/ Safety Back support belt/ Mask / Safety glass / Lab Coat/Gloves must be worn, by each employee in grey area, before entering the production area.
- h. Factory uniforms are strictly for usage in factory premises and personnel must be discouraged from going outside of production area with the uniform on.
- i. Upon completion of the work, personnel must exit the work area and change clothing in the reverse manner as they had started out the day. Uniforms shall not be worn into the restrooms.
- j. All visitors/contractors entering in the premises must follow relevant SOP-VC-GEN-019.
- k. All Visitors have to follow same procedure for entry in to the production area like the regular employees.

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- l. While touring the premises, visitors must be accompanied by a sponsoring employee at all times. They should not be left alone at any point of time in production area. Please refer to SOP-VC-GEN-019.

6. Archiving SOP:

All original documents are to be archived by QA & controlled copies are to be submitted to concerned departments.

7. Revision History:

Rev. No.	Revision Details	Reference/CCF No.	Effective Date:
00	New Procedure	N/A	11/15/12
01	Remove entry procedure for visitors, since separate SOP for Visitor's policy and Access control established. (SOP-VC-GEN-019).	13/GEN/005	09/09/13
01	Periodic Review	SOP # VC-GEN-001	06/22/16
01	Periodic Review	SOP # VC-GEN-001	10/18/18
01	Periodic Review	SOP # VC-GEN-001	10/18/21