



STANDARD OPERATING PROCEDURE

Department: Production

SOP No.:

Title: Procedure for Area line clearance

Effective Date:

Supersedes: Nil

Review Date:

Issue Date:

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1.0 OBJECTIVE:

To lay down the procedure for Procedure for Area line clearance.

2.0 SCOPE:

This procedure is applicable for clearance of line, area and equipments for production department.

3.0 RESPONSIBILITY:

Production: Officer /Executive/Assistant Manager.

Head Production: To ensure execution & compliance.

Head QA: To ensure the compliance.

4.0 PROCEDURE:

4.1 Definition:

4.1.1 Area Clearance is defined as the clearance certification for the area, to be used for the next batch/product, performed by the concerned supervisor and checked by QA supervisor before starting a new batch/product.

4.1.2 Equipment Clearance is defined as the clearance certification for the equipment, to be used for the next batch/product, performed by the concerned supervisor and checked by QA supervisor before starting a new batch/product

Start-up Clearance is the checks performed by the concerned supervisor and checked by QA supervisor before starting a new batch/product.

4.1.3 **Procedure for Area, Equipment and Start-up clearance:** Procedure for area, equipment and start up clearance starts after the concerned operator performs the cleaning activity.

Area Clearance: The concerned supervisor shall visually ensure the area and then it should be counter checked by QA supervisor:

Cleanliness of area as per SOP of 'Cleaning and sanitization in Production area' SOP.



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- 4.2.1 Ensure proper status label of area as per SOP of 'Status Labeling in Production department' SOP.
- 4.2.1.1 Absence of all items of previous batch/product.
- 4.2.1.2 Absence of identification tags/labels/documents of previous batch/product.
- 4.2.1.3 Absence of previous batch/product/its rejects/in process containers.
- 4.2.1.4 Waste bins should be cleaned properly.
- 4.2.1.5 **Equipment clearance:** The concerned supervisor shall visually ensure the equipment and then it should be counter checked by QA supervisor:
- 4.2.1.6 Cleanliness of equipment as per respective equipment SOP.
- 4.2.2 Ensure proper status label of equipment as per SOP of 'Identification and Status Labeling Procedure' SOP.
- 4.2.2.1 Absence of previous batch/product/its rejects/in process containers.
- 4.2.2.2 Ensure the updating of cleaning time in sequential log/line clearance record for equipment.
- 4.2.2.3 Filling of sequential log and BMR/BPR for area/line clearance.
- 4.2.2.4 **Start up clearance:** Start up clearance should perform after completion of area and equipment clearance, before starting the operation of new batch/product. The concerned supervisor shall ensure the following:
- 4.2.3 Ensure that area and equipment clearance has been performed.
- 4.2.3.1 Ensure proper environmental condition as per BMR/BPR.
- 4.2.3.2 Ensure that the Balance/Check-weigher is calibrated /daily performance checks done.
- 4.2.3.3 Ensure that the equipment is assembled with proper change parts and ensure the proper fittings of all accessories.
- 4.2.3.4 Ensure the BMR/BPR is available with the products.
Ensure the proper status of the product and container to be taken for next steps.
- 4.2.3.5 Check all the above-mentioned points before starting the manufacturing process in
- 4.2.3.6 the area/machine, Before starting the process, take area and equipment clearance from QA supervisor get signed in the Cleaned label and/or Line Clearance Record



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and/or BMR/BPR.

4.2.3.7 If QA supervisor is not available, then clearance can be given by any other production Executive.

4.2.3.8 **Responsibility for Production:**

4.3 To maintain the area cleanliness as per defined procedure.

4.3.1 To maintain the equipment clearance/cleanliness as per defined procedure.

4.3.2 To make entry in BMR/BPR for area & equipment clearance.

4.3.3 To maintain the activity in equipment Sequential log/Line Clearance Record.

4.3.4 **Responsibility for Quality Assurance:**

4.4 To check the area cleanliness as per defined procedure.

4.4.1 To check the equipment clearance as per defined procedure.

4.4.2 To check entry in BMR/BPR for area & equipment clearance.

4.4.3 To check proper filling of area and equipment sequential log.

5.0 ANNEXURE (S) :

ANNEXURE –I: Equipment Sequential log.

6.0 REFERENCE (S):

In-House

7.0 ABBREVIATION (S) / DEFINITION (S):

BMR: Batch manufacturing record.

BPR: Batch Packing Record.

QA: Quality Assurance.

Prod.: Production



PHARMA DEVILS
PRODUCTION DEPARTMENT

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REVISION CARD

S.No.	REVISION No.	REVISION DATE	DETAILS OF REVISION	REASON (S) FOR REVISION	REFERENCE CHANGE CONTROL No.
1	00	----	----	New SOP	-----