DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Line Clearance	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

1.0 OBJECTIVE:

To lay down the procedure for the line clearance of the area/ equipment prior to start of operation /stage during the manufacturing or packing to avoid any contamination of the previous product to the next product.

2.0 SCOPE:

This SOP is applicable to all the stages of manufacturing and packing operations carried out in the production and dispensing activities in the stores.

3.0 RESPONSIBILITY:

Concerned Stores personnel, Production personnel and Quality Assurance personnel.

4.0 DEFINITION(S):

NA

5.0 PROCEDURE:

5.1 On request from the concerned area supervisor for line clearance to next process, the QA person will check all the points, which can create the contamination or risk of mixing to another process/product.

5.2 Area/equipment shall be cleaned as per SOP and ‘cleaned and ready for use’ label shall be put for area/equipment.

5.3 The record of the cleaning of the area/equipment shall be completed for the relevant entries.

5.4 The equipment cleaning shall be logged in the respective equipment usage/operation logbooks.

5.5 No equipment shall be used after the validity date of the cleaning.

5.6 Status label of previous product on container/equipment shall not be available.

5.7 All the materials (utensils, tools, containers, dresses, document etc.) shall be removed from area, which is used in previous product.

5.8 All the required materials are available in sequential order for next process.

5.9 Ensure that the temperature and relative humidity of the area shall be maintained as given in the BMR/BPR.

5.10 Ensure that the temperature and relative humidity record shall be completed until that stage/time.

5.11 Ensure that the stereos of only the current product are available in the area and all previous product stereos are removed.

5.12 Ensure that all the secondary packing materials of the previous product should not be available in the area and only the next product packing materials should be available.

5.13 Ensure that the balance(s) are calibrated before the use and the record completed.

5.14 Ensure that BMR/BPR shall be completed until that stage/time before giving line clearance for next process.

5.15 If the entire requirements are fulfilled, then give the line clearance by signing at proper place.

5.16 Check the line clearance as per “Checklist for line clearance” (Annexure I).

6.0 ABBREVIATION(S):

BMR : Batch Manufacturing Record

BPR : Batch Packing Record

QA: Quality Assurance

SOP: Standard Operating Procedure

7.0 REFERENCE(S):

NA

8.0 ANNEXURE(S):

Annexure –I: Checklist for line clearance.

9.0 REVISION CARD:

S.No.	REVISION No.	REVISION DATE	DETAILS OF REVISION	REASON (S) FOR REVISION