PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Production	**SOP No.:**
Title: Selection Criteria for type of Cleaning in Production area	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

1.0 OBJECTIVE:

To lay down the procedure for Selection criteria for type of cleaning in production area.

2.0 SCOPE:

This procedure is applicable for Selection criteria for type of cleaning in production area.

3.0 RESPONSIBILITY:

Officer /Executive/Assistant Manager

Head Production: To ensure execution and compliance.

Head QA: To ensure the compliance.

4.0 PROCEDURE:

4.1 TYPE A:

Change over from one batch to next batch of the same product and same potency and of similar product with ascending potency.

4.1.1 Replace the “TO BE CLEANED” status label with “UNDER CLEANING” status label with date and signature of Production Officer.

4.1.2 Ensure that the main power supply is put OFF.

4.1.3 Dry-clean the equipment with a dry lint free cloth as per respective equipment cleaning SOP.

4.1.4 Replace the “UNDER CLEANING” status label with “CLEANED” status label with date and signature of Production Officer.

4.2 TYPE B:

This is a cleaning procedure for Change over of product with different actives / colour / descending potency or after maintenance of contact parts.

4.2.1 Follow the procedure from step no. 4.1.1 to 4.1.2.

STANDARD OPERATING PROCEDURE	
Department: Production	**SOP No.:**
Title: Selection Criteria for type of Cleaning in Production area	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

4.2.2 Intimate to Utility Department for collecting all the return air riser filters of respective area for cleaning, through filling the required details in the Intimation cum return air riser filter cleaning record as per Annexure-I. Dismantle and clean the equipment with purified water/sodium hydroxide / IPA / Sodium Lauryl Sulphate as per respective equipment cleaning SOP.

4.2.3 Replace the previous 'CLEANED' status label with current date 'CLEANED' status label with date and signature of Production Officer.

4.3 Swab Sample:

4.3.1 Swab sample shall be taken after type – B cleaning and every new product introduction in the facility. (Change over of product with different actives / colour / descending potency or after maintenance of contact parts.)

4.4 Frequency:

4.4.1 Type 'A' cleaning is applicable after completion of every batch of same product.

4.4.2 Type 'B' cleaning is applicable in case of product change over.

5.0 ANNEXURE (S):

ANNEXURE - I: Intimation cum Return air riser filter cleaning record.

6.0 REFERENCE (S):

SOP: Preparation, approval, distribution control, revision and destruction of Standard Operating Procedure (SOP).

7.0 ABBREVIATION (S) /DEFINITION (S) :

QA : Quality Assurance

SOP : Standard Operating Procedure

PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Production	**SOP No.:**
Title: Selection Criteria for type of Cleaning in Production area	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

REVISION CARD

S.No.	REVISION No.	REVISION DATE	DETAILS OF REVISION	REASON (S) FOR REVISION	REFERENCE CHANGE CONTROL No.
01	00	---	----	New SOP	---