PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Production	**SOP No.:**
Title: Cleaning and Operation of De-foiling machine of Strip Pack	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

Vernacular SOP: No

1.0 OBJECTIVE:

1.1 To lay down a procedure for Cleaning and Operation of De-foiling machine of Strip pack.

2.0 SCOPE:

2.1 This procedure is applicable to the Cleaning and Operation of De-foiling machine in Production Area.

3.0 RESPONSIBILITY:

3.1 Technical Associate: Cleaning and operation of De-foiling machine of strip pack

3.2 Officer/ Executive Production: Supervision of Cleaning and operation of machine

3.3 Head Production: SOP Compliance

3.4 IPQA: Line Clearance

4.0 DEFINITION (S):

4.1 NA

5.0 PROCEDURE:

5.1 CLEANING

5.1.1 This is a cleaning procedure applicable for cleaning after completion of every batch/or any maintenance activity.

5.1.2 Affix dully filled “UNDER CLEANING” status label on equipment with date and signature of the Production Officer as per SOP (Status labeling).

5.1.3 Record the cleaning start time in equipment usage log as per SOP (Making entries in equipment usage and cleaning log sheet).

5.1.4 Ensure that the De-foiling Machine is switched ‘‘OFF’’.

5.1.5 Dismantle the tablet scrap plate, tablet discharge chute and scrap collection discharge chute and place in a polythene bag and take it to washing area in a trolley.

5.1.6 Clean the dismantled parts with purified water and dry the dismantled parts using a lint free duster and finally clean with 70% v/v IPA solution.

5.1.7 Clean the all body of machine with 70% v/v IPA solution with the help of lint free duster.

5.1.8 Fix the dismantled parts to the de-blistering Machine.

5.1.9 Replace “UNDER CLEANING” status label with “CLEANED’ label.

5.1.10 Record the cleaning activity in equipment usage log as per SOP (Making entries in equipment usage and cleaning log sheet).

5.1.11 The cleaned equipment is idle for 72 hours, after this period Wipe all the parts of equipment with 70% v/v IPA solution before use. And should be a counter sign on previous “CLEANED” label by production & QA officer with date as per SOP (Status labeling).

5.2 OPERATING PROCEDURE:

5.2.1 Equipment setting:

5.2.1.1 Switch ‘‘OFF’’ the main from electric panel.

5.2.1.2 Set the feeding plate of the machine.

5.2.1.3 Set the Slater according to the strip size.

5.2.1.4 Set the scrap pin to down position for collection of waste foil.

5.2.2 Operation:

5.2.2.1 After the line clearance from QA, remove CLEANED label and put the EQUIPMENT STATUS label on the machine.

5.2.2.2 Enter start time of the batch in equipment usage log as per SOP (Making entries in equipment usage and cleaning log sheet).

5.2.2.3 Switch ‘‘ON’’ the main from electric panel.

5.2.2.4 Strip packs are fed in to machine manually through the inlet of de-foiling machine.

5.2.2.5 The strip pack pass through the Slater and center roller collect the strip Insert the strips to be de-foiled from the one side in the direction of increasing order of width of rollers so that at the end maximum pressure should be applied to expel the tablets.

5.2.2.6 The expelled product will fall in to the tray.

5.2.2.7 Enter the completion time of De-foiling machine in equipment usage log sheet.

5.2.2.8 Switch ‘‘OFF’’ the main from electric panel.

5.2.2.9 Affix UNDER CLEANING label on the machine at end of batch.

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6.0 ABBREVIATION(S):

6.1 IPA : Iso Propyl Alcohol

6.2 V/V : Volume / Volume

6.3 Q.A. : Quality Assurance

6.4 SOP : Standard Operating Procedure

6.5 % : Percentage

6.6 mm : Millimeter

7.0 REFERENCE (S):

7.1 SOP: Cleaning of production area.

7.2 SOP: Making entries in equipment usage and cleaning log sheet.

7.3 SOP: Status Labeling

8.0 ANNEXURE (S):

8.1 Nil

9.0 DISTRIBUTION:

9.1 **Master Copy :** Quality Assurance

9.2 **Controlled Copy (S):** Production Department (02), Quality Assurance (01)

9.3 **Reference Copy (S) :** Production Department (01)

10.0 REVISION HISTORY:

S.No.	Version No.	Change Control No.	Reason (s) for Revision	Details of revision	Effective Date
1.	00	NA	New SOP	NA	NA