STANDARD OPERATING PROCEDURE	
Department: Production	**SOP No.:**
Title: Cleaning and Operation of Blister Packing Machine (Elmac EPI-2500)	**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 Blister Packing Machine (ELMAC EPI-2500).

2.0 SCOPE:

2.1 This procedure is applicable for the Cleaning and Operation of Blister Packing Machine (ELMAC-EPI-2500) in Production Department.

3.0 RESPONSIBILITY:

3.1 Technical Associate : Operation and cleaning.

3.2 Officer and Executive : Supervision for cleaning and operation

3.3 Officer and Executive IPQA : Line clearance and SOP Compliance

3.4 Head Production : SOP Compliance

4.0 DEFINITION (S):

4.1 NA

5.0 PROCEDURE:

5.1 **CLEANING Type A:**

CHANGE OVER FROM ONE BATCH TO NEXT BATCH OF THE SAME PRODUCT AND SAME POTENCY.

5.1.1 Ensure that all the materials of previous batch are removed from the area.

5.1.2 Affix the 'UNDER CLEANING' status label on machine.

5.1.3 Turn off the power supply of the machine.

5.1.4 Record the cleaning start time in equipment usage log book.

5.1.5 Switch off the utility supply of the machine.

5.1.6 Clean the machine with clean dry lint free cloth.

5.1.7 Clean the hopper, vibration plate, and feeding channel/roller, guide track and feeder box/feeding channel with a dry lint free cloth.

5.1.8 Wipe the batch-coding unit with duster dipped in cleaning aid to remove the spread ink and then clean with dry lint free duster. Dispose the ink by pouring ink in double polybag.

5.1.9 Clean the sealing roller with cleaning aid.

5.1.10 Clean the conveyor belt with a dry lint free cloth.

5.1.11 Replace the 'UNDER CLEANING' status label by 'CLEANED' status label with date and signature of the production officer.

5.1.12 Record the cleaning end time in equipment usage log book.

5.2 **TYPE B:**

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

5.2.1 Ensure that all the materials of previous batch are removed from the area.

5.2.2 Affix the 'UNDER CLEANING' status label on machine.

5.2.3 Record the cleaning start time in equipment usage log book.

5.2.4 Ensure that the power supply, chilled water supply and compressed air supply are put off.

5.2.5 Dismantle the hopper, hopper view glass, hopper lid, feed chute, feeding channel/roller assembly, feeder box brushes/feeder channel (whichever applicable).

5.2.6 Put the dismantled part in poly bag with affixed 'UNDER CLEANING' status label and transfer it to the wash area.

5.2.7 Remove the forming roller by unscrew the centering bolt and collect the water from roller in polybag and dispose the water in wash area.

5.2.8 Remove the punching tool, embossing tool (as per applicability), perforation tool (as per applicability) from the machine and clean with dry lint free cloth.

5.2.9 Scrub the dismantled parts like hopper, vibration plate, feeding channel with a nylon scrubber using purified water.

5.2.10 Clean the dismantled parts with purified water and dry the cleaned parts with a dry lint free cloth.

5.2.11 Dismantle the sealing roller (ensure the temperature of roller shall be cooled down) and clean with dry lint free cloth.

5.2.12 Shrink wraps the cleaned change parts then transfer to designated area and put cleaned status label.

5.2.13 Clean the pressure sealing roller with brass brush and cleaning aids.

5.2.14 Wipe the batch coding unit with lint free duster dipped in cleaning aid to remove the spread ink and then clean with dry lint free duster (If used), otherwise clean batch coding unit with dry lint free duster.

5.2.15 Clean the inner and outer surface of the machine, control panel and utility lines with a dry cloth and clean area beneath the machine.

5.2.16 Wipe the SS parts of machine and production aids with 70 % v/v IPA solution.

5.2.17 Wipe the acrylic guard with wet lint free cloth dipped in purified water followed by dry lint free cloth.

5.2.18 Wipe the rejection box with wet lint free cloth dipped in purified water followed by dry lint free cloth.

5.2.19 Clean the conveyor belt with a dry lint free cloth.

5.2.20 Replace the 'UNDER CLEANING' status label by "CLEANED" Status label.

5.2.21 Record the cleaning end time in equipment usage log book.

5.2.22 If the machine remains idle for more than 72 hours after cleaning then clean the machine with lint free cloth followed by wiping with 70% v/v IPA solution before using the machine.

5.3 **Machine Setting:**

5.3.1 **Roll Mounting of Base-Film and Aluminium Foil.**

5.3.1.1 The aluminium foil/PVC film roll is clamped on the core shaft. The roll after mounting can be shifted axially for centering of web.

5.3.1.2 The tension of the web can be adjusted by means of the brake provided on the core shaft. Slight tension to prevent inertial rotation of the reels.

5.3.2 **Setting of Blister Forming Roller.**

5.3.2.1 Blisters are formed on the PVC film web continuously by vacuum. Blister-forming roller consists of two sections, the vacuum suction chamber on the outer surface of the roller and the cooling chamber which is mounted on a stainless steel shaft secured by means of a centering bolt. Unscrew the centering bolt and remove of the centering bolt. Withdraw the roller from the shaft carefully and on clearing the shaft end, slightly tilt the roller downwards so that residual water will be drained out

5.3.2.2 Clean the roller and its outer surface. Mount the roller carefully; balance the roller in both axes till the free movement for entry.

5.3.2.3 Turn on the chilled water supply and check for any water leakage, if observed the turn off chilled water supply and remount the forming roller on shaft with proper setting.

Note: The blister forming roller must be removed from the machine during B-type Cleaning. The blister forming roller must be cleaned only with water. Allow water to drain from the roller completely.

5.3.3 **Setting of Contact Heaters.**

5.3.3.1 Contact Heater Temperature is to be set as per batch record parameter.

5.3.3.2 The contact heater stroke length is set so that there is slight contact with the forming roller.

5.3.3.3 If the contact heater is not rotating while in contact with the forming roller and with the base film, the air-gap is to be reduced between the contact heater and forming roller.

5.3.4 **Setting of Hopper Level Sensor.**

5.3.4.1 Sensor is mounted at product hopper. The sensor has three LEDs, Yellow / Green. When sensor is powered with supply the Green LED turns on. Yellow light glows when tablet level in the hopper is above the minimum cut-off distance taught in the sensor.

5.3.5 **Setting of Guide-Track.**

5.3.5.1 The Guide-track supports the blister formed PVC web between the blister forming roller and support sealing roller. It is supported by two brackets and can be raised or lowered to adjust its level with the blister-forming roller and the support- sealing roller.

5.3.6 **Setting of Feeding Unit.**

5.3.6.1 The Feeding Unit is consists of Vibrator with Hopper, Dispensing Unit with In feed Roller, In feed Motor. The dispensing unit can be tilted at any angle and also shifted 'in' or 'out' for web centering. The dispensing unit houses the back sieve plate, feeding channel and in feed roller. The vibrator in the dispensing unit discharges the tablets/capsules from the hopper. The photocell and light source housed in the unit cut off the vibrator when the level is attained behind the infeed roller.

5.3.6.2 The feeding level is continuously monitored by the photo level control. Set the dispensing unit vertically till it reaches its lowest limit. Level the Guide Track with the web level adjusting screws. Shift the dispensing unit 'in' and 'out' till the channel grooves are centralized with the blisters. In this position, lift the channels slightly and tighten the clamp. Observe the flooding levels of the tablets/Capsules and adjust the level of the Photocell.

5.3.7 **Setting of Support Sealing Roller.**

5.3.7.1 To remove support sealing roller from the shaft, lift the pressure sealing roller assembly to have an adequate clearance, utmost care must be taken to prevent damage to its surface.

5.3.7.2 Keep the sealing roller in the out position when the sealing is not required and do not allow the pressure sealing roller assembly to run idle on the support sealing roller.

5.3.7.3 Fix the aluminum pressure plate on the guide-track only when the machine runs with the foil to prevent damage to the surface of the support-sealing roller.

5.3.7.4 Air nozzles available for cooling of support sealing roller.

5.3.8 **Setting of Pressure Sealing Roller.**

5.3.8.1 The Pressure Sealing Roller consists of mainly a specially knurled roller having cartridge heaters. The assembly is mounted on the machine just above the support-sealing roller. This unit should be mounted on the machine only after the support-sealing roller has been fitted.

5.3.8.2 Disconnect the supply plug of the assembly and Lift the Pressure Roller after loosening the clamp. Re-tighten the clamp firmly.

5.3.8.3 Increase the pressure to attain satisfactory contact between the pressure sealing roller and the support-sealing roller.

5.3.9 **Setting of Punching Tool.**

5.3.9.1 The unit is used for punching and ejecting the blister packs from the main web and shearing the waste-trim.

5.3.9.2 The tool consists mainly two parts, the upper punch holder plate with spring-loaded shear and punches with ejector plates and the lower die-holder plates with die and bottom fixed shear. Both parts slide into each other over hardened guide pillars and brushes with sleeve bearings.

5.3.9.3 The connecting rod reaches the innermost limit of rotation. Lift the punch and locate the mounting holes on the unit with the mounting pillars.

5.3.9.4 Screw nuts on the pillars in a diagonal fashion such that all the nuts are securely fastened to the face of the punch tool.

5.3.9.5 Insert the crank pin through the connecting rod and the connection bracket and lock it in place.

5.3.10 **Setting of Embossing Tool (If Applicable).**

5.3.10.1 The unit is used for embossing the batch details as per batch record.

5.3.10.2 The tool consists of holder plates with metallic letter dies and hammer.

5.3.10.3 The connecting rod reaches the innermost limit of rotation and exerts the pressure on holder for the impression of metallic letters on blisters.

5.3.11 **Setting of Index Ratchet.**

5.3.11.1 Indexing Ratchet is a plate fixed to the indexing mechanism at a right angle to the blister-formed web. For every forward stroke of the mechanism, the ratchet is locked against the blister and pushes the web into the punching tool. During the reverse stroke of the crank, the ratchet slides back over the blisters.

5.3.12 **Setting of Batch Code Printing Unit (If Applicable).**

5.3.12.1 The printing drum, transfer roller and inking roller have suitable ratios with one another and are inter-linked. The unit is driven synchronously from the main machine. The foil runs between the printing drum and the pressure idler roller. The pressure idler roller is moved up against the printing drum and can be adjusted from both ends to achieve satisfactory impression. The printing drum is divided into equal parts along the length by a centerline marking. The divisions are used as a reference for inserting the stereos for printing.

5.3.12.2 Before mounting the BCP unit on the machine, fix the stereos on the printing drum. Roll the drum with slight pressure on a flat surface. Re-fix the stereo drum in the BCP unit. The ink can be increased when desired when running the unit on the machine. Rotate BCP unit by rotating gear shaft in clockwise direction for free movement of the unit.

5.3.12.3 At the end of every working day, always drain out ink or whenever necessary. Clean the roller with an ink cleaning aid.

5.3.13 **Setting of Print Registration Control.**

5.3.13.1 It used for print registration control of the packs aluminium foil with “Print Mark”

5.3.13.2 To Teach Print Mark Sensor, refer below procedure.

5.3.13.2.1 Bring "Print Mark" of Lid foil below sensor light beam as shown below.

5.3.13.3 Press "TEACH BUTTON" for more than 3 Seconds & both LEDs of sensor will start "Flashing" in RED Color.

5.3.13.4 While both LEDs are flashing, Press & immediately Release "TEACH Button".

5.3.13.5 Both LEDs will become steady & sensor light beam goes OFF for a moment.

5.3.13.6 Again Both LEDs will start flashing in "RED".

5.3.13.7 Now move "Print Mark" away from light beam & just press & release "TEACH Button" immediately.

5.3.13.8 Sensor light beam goes OFF for a moment, also both LEDs turns OFF.

5.3.13.9 Sensor Supply LED turns into "GREEN" & light beam turns "ON". This completes the Print Mark Sensor Teaching procedure.

5.3.13.10 Verification of Print Mark Sensor done by bring "Print Mark" below sensor light beam, Output LED turns into Orange color.

5.4 **Machine Change Over Setting.**

5.4.1 After line clearance of area from QA, Get the change part as per product.

5.4.2 Ensure that main power is switch 'off' (If required then "ON" the power as per requirement of the machine for setting of change part).

5.4.3 Assemble the Blister forming roller to the forming station.

5.4.4 Assemble the hopper, bowl dish and feeding chute.

5.4.5 Fix the guide track in feeding zone.

5.4.6 Assemble the sealing rollers to sealing station.

5.4.7 Fix the printing unit (if required).

5.4.8 Fix the embossing tool (If required) to the embossing assembly.

5.4.9 Assemble the punch tool on machine and ensure the proper alignment of punching index roller with punch tool.

5.4.10 Open the valve of compressed air and chilled water supply to machine.

5.4.11 Set the heating temperature of forming roller and sealing roller as per BPR.

5.4.12 When machine setting is done then start the machine for idle run.

5.5 **OPERATING PROCEDURE:**

5.5.1 After line clearance of area from QA put the 'under process' label on machine.

5.5.2 Transfer the packing material to the cubicle.

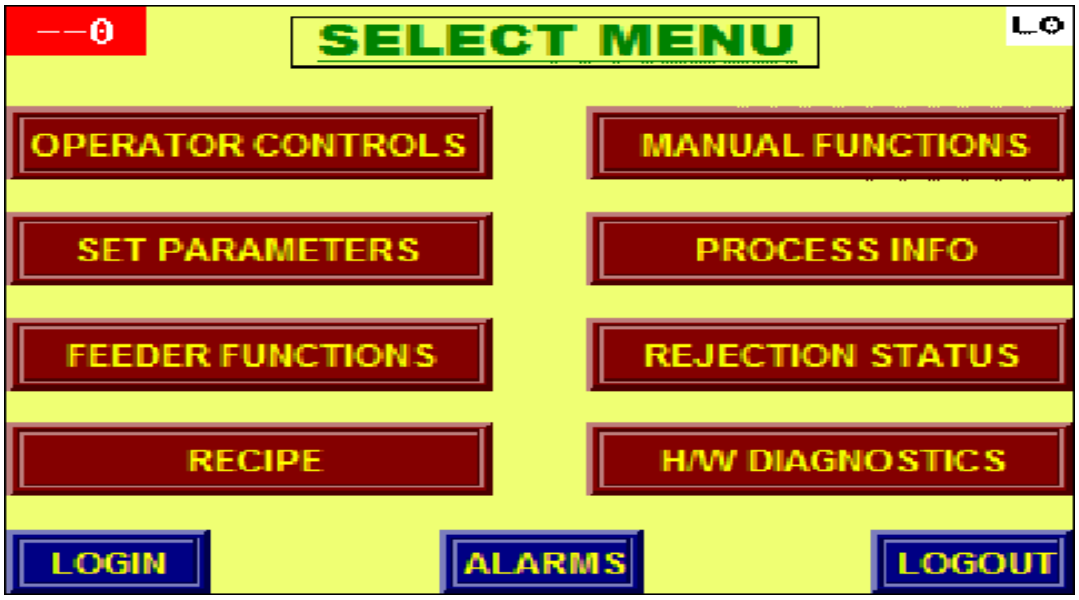
5.5.3 Check the dispensed material as per details given in respective batch packing record

5.5.4 Check the material code no, material description, A.R. No., before mounting the each roll of PVC/PVDC and Aluminium Foil.

5.5.5 Transfer the Tablets/Capsules from quarantine area to cubicle as per batch record.

5.5.6 Switch on the main power supply button.

5.5.7 Turn ''ON'' the start/stop button which will activate the machine for operation and wait for few seconds, HMI will display as follow:

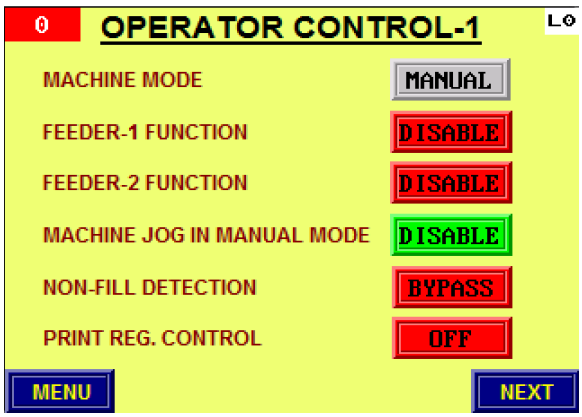


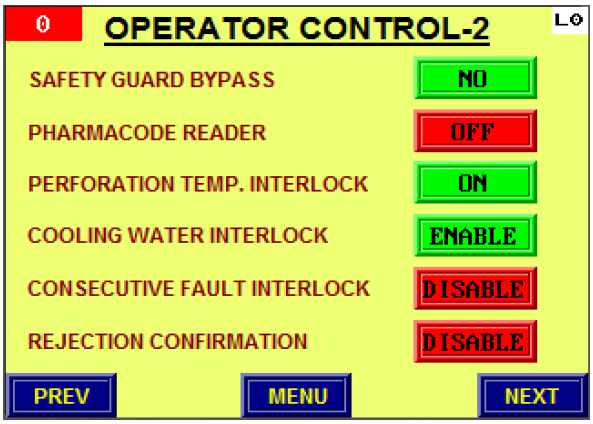
This screen is the main routing point for access to various sets of Screens namely,

Touch key	Description
OPERATOR CONTROLS	Operator can select Machine cycle features.
SET PARAMETERS	All relevant parameters can be accessed.
MANUAL FUNCTIONS	Manual functions for all Solenoids, motors etc. can be performed in this screen.
H/W DIAGNOSTICS	Display 'Hardware Diagnostics' screen
PROCESS INFO	Actual machine process values are displayed here.

FEEDER FUNCTIONS	Display 'Feeder Function' screen.
REJECTION STATUS	Displays 'Rejection Status Screen' screen.

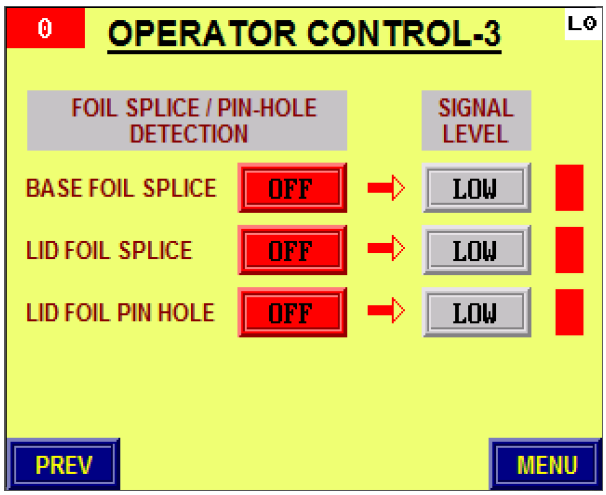
5.5.8 Operator control parameters are described as following:

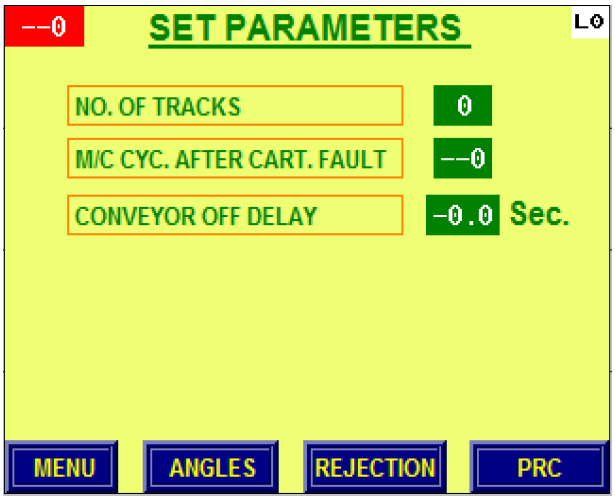




Parameter	Description
MACHINE SPEED	Set the desired machine speed via Up/Down Key.
MACHINE MODE	Set the desired Machine Operating Mode
FEEDER-1 FUNCTION	Select Feeder -1 Function
FEEDER-2 FUNCTION	Select Feeder-2 Function
MACHINE JOG IN MANUAL MODE	Select Machine Jog in Manual Mode
NON-FILL DETECTION	Feature for Rejection of Empty or Half-empty packs
PRINT REG. CONTROL	Print Reg. Control can be made ON/OFF with this Key
SAFETY GUARD BYPASS	Select Status of Safety Guards during Machine operation.
PHARMACODE READER	Select Pharmacode reader feature.
PERFORATION REJECTION	Select perforation rejection feature.
COOLING WATER INTERLOCK	Cooling Water Level detection feature
CONSICUTIVE FAULT INTERLOCK	Consecutive wrongly filled Blister detection feature
REJECTION CONFIRMATION	Select Rejection Confirmation

STANDARD OPERATING PROCEDURE	
Department: Production	**SOP No.:**
Title: Cleaning and Operation of Blister Packing Machine (Elmac EPI-2500)	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**





Parameter	Description
BASE FOIL SPLICE DETECTION	Base Foil Splice feature to detect Joints in Base foil
BASE FOIL SPLICE SIGNAL LEVEL	Select signal level when Spliced foil appears below Base foil Splice Sensor
LID FOIL SPLICE DETECTION	Lid Foil Splice feature to detect Joints in Lid foil
LID FOIL SPLICE SIGNAL LEVEL	Select signal level when Spliced foil appears below Lid foil Splice Sensor
LID FOIL PIN HOLE DETECTION	Lid Foil Pin Hole Detection feature to detect Pin hole
LID FOIL PIN HOLE DETECTION SIGNAL	Select signal level when Pin hole appears below Lid foil
NO. OF TRACKS	Set Number of Tracks for the Change part in use.
M/C CYC. AFTER CART. FAULT	Set no. of machine cycles to run before the machine stops due to down-stream Cartonater fault
CONVEYOR OFF DELAY	Set Off-delay for Conveyor Motor after the end of Dry/Auto run.

5.5.9 Switch ‘on’ the heater and set the temperature of Forming and Sealing heater as per mentioned in BPR.

5.5.10 Record the forming and sealing condition in BPR.

5.5.11 Check the formed web for cutting, embossing (if applicable), perforation, overprinting (if applicable),and set if required.

5.5.12 Affix specimen of embossed/overprinting matter checked by production and QA.

5.5.13 Load the container into hopper serially.

5.5.14 Perform the startup activity and Challenge test as per Batch Record and then run the batch.

5.5.15 Affix ‘UNDER CLEANING’ label’ on machine after completion of batch.

STANDARD OPERATING PROCEDURE	
Department: Production	**SOP No.:**
Title: Cleaning and Operation of Blister Packing Machine (Elmac EPI-2500)	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

5.6 **Precaution:**

5.6.1 **If machine stopped during operation:** At the time of machine stoppage the blisters with product under the sealing roller should be cross marked with marker pen and to be rejected by machine.

5.6.2 **Procedure of marking of blisters:** For marking of blisters after stoppage, run the machine and marked the identified blister on the web (at lidding foil side) for proper identification and the same blisters to be reject by the machine.

5.6.3 **Machine stoppage during roll change: When the machine stopped during roll** change, any breaks and shift change over it must be ensured that no product is retained in web. After the machine is restarted, a few empty blisters should run initially to ensure the overprinting details.

5.6.4 During break and at the end of working shift the product left in hopper or vibratory bowl and channel should be removed, any blister lying on the packing line should also be removed.

5.6.5 Empty blister which are generated during the setting of machine then kept them segregated before start of the packing activity.

6.0 ABBREVIATION (S):

6.1 SOP - Standard Operating Procedure

6.2 HMI - Human Machine Interface

6.3 IPA – Isopropyl alcohol

6.4 v/v- Volume by Volume

7.0 RERERENCE (S):

7.1 SOP No.: Making entries in equipment usage and cleaning log sheet.

7.2 SOP No.: cleaning of production area.

8.0 ANNEXURE (S):

Annexure no.	Title of Annexure	Format No.	Mode of Execution
Annexure-I	Cleaning checklist of Blister Packing Machine (ELMAC EPI-2500)		Logbook

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 (02)

STANDARD OPERATING PROCEDURE	
Department: Production	**SOP No.:**
Title: Cleaning and Operation of Blister Packing Machine (Elmac EPI-2500)	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

10.0 REVISION HISTORY:

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

PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Production	**SOP No.:**
Title: Cleaning and Operation of Blister Packing Machine (Elmac EPI-2500)	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

ANNEXURE I

Cleaning checklist of Blister Packing Machine (ELMAC EPI-2500)

Name of the Equipment: Blister Packing Machine (EPI-2500)			
Equipment ID No.:		**Date:**	
Previous Product Name:		**Previous Batch No.:**	

S. No.	Activity	Activity Performed
1	Affix the 'TO BE CLEANED' status label on Blister Packing Machine.	
2	Ensure that the power, chilled water and compressed air supply are put off.	
3	Dismantle the hopper, hopper view glass, hopper lid, feed chute, feeding channel/roller assembly, linear vibrating plate and guide track, nylon brush, wiper brush.	
4	Dismantle the feeder box and brushes/feeder channel (whichever applicable).	
5	Put the dismantled part of machine in poly bag with affixed 'TO BE CLEANED' status label and transfer it to the washing area.	
6	Scrub the dismantled parts with a nylon scrubber using purified water. **NOTE:** 2% Sodium Lauryl Sulphate (SLS) solution shell be used for scrubbing with nylon brush if API is Efavirenz before final rinsing of equipment/parts.	
7	Clean the dismantled parts with purified water.	
8	Dry the cleaned parts with a dry lint free cloth.	
9	Wipe the cleaned dismantled parts with 70% v/v IPA solution.	
10	Shrink wrap the cleaned change parts and put 'CLEANED' status label and transfer to designated area for change part.	
11	Remove the punching tool, embossing tool, perforation tool from the machine and clean with dry lint free cloth.	
12	Remove the metallic letter from embossing letter holder and return the metallic letter after cleaning with dry lint free cloth (if metallic letter used).	
13	Dismantle the forming roller and sealing roller and clean with dry lint free cloth.	
14	Clean the sealing unit with brass brush using cleaning aids.	

STANDARD OPERATING PROCEDURE	
Department: Production	**SOP No.:**
Title: Cleaning and Operation of Blister Packing Machine (Elmac EPI-2500)	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

15	Wipe the batch-coding unit with lint free Cloth dipped in cleaning aid to remove the spread ink and then clean with dry lint free Cloth (If used), otherwise clean batch-coding unit with dry lint free Cloth.	
16	Clean the conveyor belt with lint free cloth.	
17	Wipe the SS parts of machine with 70 % v/v IPA solution and acrylic guard with wet lint free cloth followed by dry lint free cloth.	
18	Clean the inner and outer surface of the machine, control panel and utility lines with a dry cloth.	
19	Clean the area, beneath of the equipment and other utensil of the area.	
20	Reassemble the cleaned parts of machine like acrylic glass in hopper, hopper, hopper lid, nylon brush, wiper brush and feeder box etc.	
21	Transfer the guide track; feeding chute to designated area for change part.	
22	Replace the ‘TO BE CLEANED’ status label by “CLEANED “status label.	

Checked By (Prod.)
Sign/Date

Verified By (QA)
Sign/Date

Note: Put ‘√’ mark if activity performed and put “X” if activity not performed.