



# PHARMA DEVILS

PRODUCTION DEPARTMENT

## STANDARD OPERATING PROCEDURE

<b>Department:</b> Production	<b>SOP No.:</b>
<b>Title:</b> Cleaning and Operation of Blister Pack Machine, <b>Make:</b> Elmach	<b>Effective Date:</b>
<b>Supersedes:</b> Nil	<b>Review Date:</b>
<b>Issue Date:</b>	<b>Page No.:</b>

**Vernacular SOP:** No

### 1.0 OBJECTIVE:

1.1 To lay down a procedure for Cleaning and Operation of Blister Pack Machine; Elmach packages.

### 2.0 SCOPE:

2.1 This procedure is applicable for Cleaning & Operation of Blister Pack Machine in Production Department.

### 3.0 RESPONSIBILITY:

3.1 Technical Associate: For cleaning and operation Blister Pack Machine EPI- 500XT.

3.2 Officer and Executive: Production Department- For supervision of Cleaning and Operation of Blister Pack Machine EPI- 500 XT.

3.3 IPQA: Verification of Cleaning and Operation of Blister Pack Machine EPI-500 XT.

3.4 Head of Department: For compliance of SOP of Cleaning and Operation of Blister Pack Machine EPI-500 XT.

### 4.0 DEFINITION (S):

4.1 NA

### 5.0 PROCEDURE:

#### 5.1 TYPE A CLEANING:

**Change over from one batch to next batch of the same product and potency.**

5.1.1 Ensure that all the materials of previous batch are removed from the blister packing cubicle.

5.1.2 Remove 'EQUIPMENT STATUS' label and affix "UNDER CLEANING" label on the machine with date and sign of the production officer.

5.1.3 Clean the machine with dry lint free cloth and then by vacuum cleaning.

5.1.4 Clean the channel, feeding assembly, hopper, hopper lid and guide track with a dry lint free cloth.

5.1.5 Clean the punch tool and forming unit and perforation unit with lint free duster.

5.1.6 Clean the inner and outer surface of the machine, control panel and utility lines with a lint free duster.



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- 5.1.7 Clean the sealing unit with a brass brush by applying silicon compound.
- 5.1.8 Replace the “UNDER CLEANING” status label by “CLEANED” status label on the machine with date and sign of the production officer.
- 5.1.9 Record the cleaning activity in equipment usage log as per SOP (“Making entries in equipment usage and cleaning log sheet”).

### 5.2 TYPE B CLEANING:

**This is a cleaning procedure for Changeover of product with different activities /color/descending potency/ascending potency / same product processed for more than a week or after maintenance of contact parts.**

- 5.2.1 Replaced the “EQUIPMENT STATUS” status label by “UNDER CLEANING” status label with date and sign of the production officer.
- 5.2.2 Ensure that the power supply and compressed air supply are put “OFF”.
- 5.2.3 Dismantle the hopper, hopper lid, feed channel and transfer to washing area in virgin poly bag for cleaning.
- 5.2.4 Clean the machine and area with vacuum cleaning.
- 5.2.5 Scrub the dismantled parts with a nylon scrubber using purified water.
- 5.2.6 Finally rinse the cleaned parts with 10-20 liters of purified water.
- 5.2.7 Dry the cleaned parts with a dry lint free cloth.
- 5.2.8 Wipe the dismantled parts with 70% v/v IPA solution.
- 5.2.9 Cover the dismantled parts with poly bag and transferred to packing spare cabinet.
- 5.2.10 Remove the punching tool and guide track, forming plate and clean with dry lint free cloth.
- 5.2.11 Remove the sealing unit and clean with a brass brush by applying silicon compound.
- 5.2.12 Transfer the guide track and sealing and forming unit to packing spare cabinet.
- 5.2.13 Clean the inner and outer surface of the machine, control panel and utility lines with a dry duster.
- 5.2.14 Wipe the machine with 70% v/v IPA solution.
- 5.2.15 Reassemble the cleaned hopper, channel assembly and hopper lid.
- 5.2.16 Replace “UNDER CLEANING” status label by “CLEANED” status label with date and sign of the production officer.
- 5.2.17 After cleaning if machine is idle for more than 72 hrs. re-clean the machine with dry lint free cloth followed by wiping with 70% v/v IPA solution before using the machine.



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5.2.18 Record the cleaning operation time in equipment usage log sheet and check the cleaning activity as per Annexure- I (“Cleaning and operation of blister pack machine, **Make:** Elmach packages, **Model:** EPI-500 XT” PG/263/F1/00).

5.2.19 Clean the area as per SOP (“Cleaning of Production Area”).

### 5.3 **Machine Setting:**

#### 5.3.1 **Loading The Change Parts:**

##### 5.3.1.1 **Procedure for fixing forming plate:**

5.3.1.1.1 Switch “OFF” the machine.

5.3.1.1.2 Alu: Slide in the die-set in the guides provided on the moving plate. Fasten plug mount plate with thrust plate and plug guide plate with the top plate.

5.3.1.1.3 To access mounting holes of thrust plate, pockets are provided in the top plate.

5.3.1.1.4 PVC: Slide in the die set in the guides provided on the moving plate. Fasten the blow head to the top plate and connect air.

##### 5.3.1.2 **Procedure for fixing Counter Sealing Plate:**

5.3.1.2.1 Counter Sealing Die is to be placed on dowel pins provided on the moving plate of the sealing Station and is to be fastened.

##### 5.3.1.3 **EMBOSSING/PERFORATION:**

5.3.1.3.1 Letter-holding/slotted plate is mounted on the moving plate and hammer and blade holding plate is mounted on the top plate

##### 5.3.1.4 **PUNCH:**

5.3.1.4.1 An assembled punch is to be placed on the station and fastened properly. Pneumatic cylinder is provided with the machine, cylinder is to be mounted on the lower plate and piston is to be engaged with the moving bracket.

##### 5.3.1.5 **Feeding station:**

5.3.1.5.1 It consists of hopper, vibrator, tablet level sealing proxy, feeding channel.

5.3.1.5.2 Speed of all the vibrators is controlled independently by the potentiometer provided in the operator panel.



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### 5.3.2 Equipment Setting:

**It consists of two sets of reel support, reel fastening screw, reel adjusting screw, all activities are controlled by PLC.**

- 5.3.2.1 Switch "ON" the machine.
- 5.3.2.2 Remove Base film Clamp from the quill by unscrew the socket set screw.
- 5.3.2.3 Insert the new Real.
- 5.3.2.4 Position the Real along the quill, in correct location as per Real setting gauge.
- 5.3.2.5 Tighten screw to clamp Real.
- 5.3.2.6 Thread the base film all the way up-to the punching station.
- 5.3.2.7 Engage the index roller.
- 5.3.2.8 Switch 'OFF' all functions on the "Switches" screen of the MMI.
- 5.3.2.9 Then, put the forming air (only for thermo-formable base film) and set the forming temperature and wait until the temperature is reached.
- 5.3.2.10 Set the speed of machine as per requirement.
- 5.3.2.11 Form the few meters of web. Once the web is punched, thread the trim section.
- 5.3.2.12 Switch Sealing "ON" and set the required temperature values for upper & lower preheating plates. Verify that this temperature is reached.
- 5.3.2.13 Thread the Lidding Foil and bring the Front End of the Lidding Foil under the sealing station and pull it until it extends a little beyond the sealing station. Fasten to the Base Film using Adhesive tape.
- 5.3.2.14 Put the correct values into all the required parameters in all the "SET PARAMETER" screen on the MMI.
- 5.3.2.15 If base is Aluminum foil, selection of corresponding option will automatically 'SWITCH "OFF' the platen heaters. For Alu-Alu Base Film, also keep the upper platen open.
- 5.3.2.16 Check the index setting by actual measurement of advance over 10 repeats, and this must match with the value per advance from the identification chart, /pack layout.
- 5.3.2.17 Check that forming & Punching Station positions of the Station match the Pack Layout.
- 5.3.2.18 If there is any mismatch (sealing crushing, packs punched of set), verify firstly that the stations are in correct position as per the identification chart and then correct the advance until the formed web matches in all stations.



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5.3.2.19 Verify the sealing quality, run the machine for some cycles to ensure that sealing is perfect.

### 5.4 OPERATION

5.4.1 After the line clearance from IPQA, put the "EQUIPMENT STATUS" label on the machine.

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

5.4.3 Switch "ON" the 'MAIN ISOLATOR SWITCH' from electrical panel.

5.4.4 Switch on the heater and adjust thermostat to provide the heating condition predetermined for the particular product as per mentioned in the BPR.

5.4.5 Fix printed lidding and base foil rolls on the machine as specified in BPR.

5.4.6 Record the temperature of sealing units in the BPR.

5.4.7 Fix the ink cartridge at the overprinting kit of the machine with the requisite height.

5.4.8 Affix the approved stereo.

5.4.9 Check the sealing performance, overprinting and cutting of strips and adjust if required.

5.4.10 Affix the specimen of the overprinted matter approved by the production officer and IPQA officer to BPR.

5.4.11 Cross check the containers of the product to be blistered are having approved status label.

5.4.12 Load the product to be blistered in to the hopper, cover with lid and start the machine to run the machine through the PLC as follows.

### 5.5 PLC operation:

5.5.1 Switch "ON" the mains switch.

5.5.2 MMI shows main screen

ELMACH PACKAGES SET PWD IND CONTL
--------------------------------------

5.5.3 Press CONTL.

5.5.4 MMI shows MODE: (Select AUTO or MANUAL).

5.5.5 Select enter frequently to go at required options.

5.5.6 Press the scrolling key frequently to go for next option.

5.5.7 CYCLE: (Select CONTINUOUS)



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- 5.5.8 BASE FOIL: (Select the type)
- 5.5.9 EMBOSSING: (Select YES or NO)
- 5.5.10 MMI shows MODE: (Select AUTO or MANUAL)
- 5.5.11 PRINTING :( Select YES or NO)
- 5.5.12 PRC: (Select YES or NO)
- 5.5.13 MACHINE SPEED: (Select the speed)
- 5.5.14 PRODUCT COUNT
- 5.5.15 PRODUCT COUNT RESET
- 5.5.16 INDEX: (feed the index according to foil width)
- 5.5.17 PRC ON COUNT: (Select YES or NO)
- 5.5.18 PRC OFF COUNT: (Select YES or NO)
- 5.5.19 After the operation, affix 'UNDER CLEANING' label on the machine and record all the observations in the equipment usage log sheet as per SOP ("Making entries in equipment usage and cleaning log sheet").

### 5.6 **Precaution:**

- 5.6.1 Any tablet or blister that would have come in contact with the sealing roller shall be removed and discarded.
- 5.6.2 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.

### 6.0 **ABBREVIATION (S):**

- 6.1 BPR : Batch Packing Record
- 6.2 QA : Quality Assurance
- 6.3 CPM : Cuts Per Minute
- 6.4 PRO. : Product
- 6.5 PLC : Programmable logical Control
- 6.6 VIB : Vibrator
- 6.7 PERFO : Perforation
- 6.8 NFD : Non Fill Detector



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### 7.0 REFERENCES (S):

- 7.1 SOP: Making Entries in Equipment Usage and Cleaning log sheet.
- 7.2 SOP: Cleaning of Production area.

### 8.0 ANNEXURE (S):

Annexure no.	Title of Annexure	Format No.	Mode of Execution
Annexure-I	Cleaning and operation of Blister Pack Machine, <b>Make:</b> Elmach packages, <b>Model:</b> EPI-500 XT.		Logbook

### 9.0 DISTRIBUTION:

- 9.1 **Master Copy** : Quality Assurance
- 9.2 **Controlled Copy (S):** Production Department (01)
- 9.3 **Reference Copy (S) :** Production Department (01)

### 10.0 REVISION HISTORY:

S.No.	VERSION No.	CHANGE CONTROL No.	REASON(S) FOR REVISION	DETAIL OF REVISION	EFFECTIVE DATE
1.	00		New SOP	NA	



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### ANNEXURE I

#### Cleaning and operation of Blister Pack Machine, Make: Elmach packages, Model: EPI-500 XT

Name of the Equipment		BLISTER PACK MACHINE (ELMACH PACKAGES)	
Equipment ID No.		Previous product	
Batch No.		Date	
S.No.	Activity		Activity Performed
1.	Replaced the "UNDER PROCESS" status label by "TO BE CLEANED" status label with date and sign of the production officer.		
2.	Ensure that the power supply and compressed air supply are put "OFF".		
3.	Dismantle the hopper, hopper lid, feed channel and transfer to washing area in virgin poly bag for cleaning.		
4.	Clean the machine and area with vacuum cleaner.		
5.	Scrub the dismantled parts with a nylon scrubber using purified water.		
6.	Finally rinse the cleaned parts with 10-20 liters of purified water.		
7.	Dry the cleaned parts with a dry lint free cloth.		
8.	Wipe the dismantled parts with 70% v/v IPA solution.		
9.	Cover the dismantled parts with poly bag and transferred to packing spare cabinet.		
10.	Remove the punching tool and guide track, forming plate and clean with dry lint free cloth.		
11.	Transfer the guide track and sealing and forming unit to packing spare cabinet.		
12.	Clean the inner and outer surface of the machine, control panel and utility lines with a dry duster.		
13.	Wipe the machine with 70% v/v IPA solution.		
14.	Replace "TO BE CLEANED" status label by "CLEANED" status label with date and sign of the production officer.		
15.	After cleaning if machine is idle for more than 72 hrs., re-clean the machine with dry lint		





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S.No.	Activity	Activity Performed
	free cloth followed by wiping with 70% v/v IPA solution before using the machine.	
16.	Record the cleaning operation time in equipment usage log sheet and check the cleaning activity as per Annexure- I.	
17.	Clean the area as per SOP.	

**Checked By ( Prod. )**  
Sign/date

**Verified By ( QA )**  
Sign/date

**Note :** Put '√' mark if activity performed and put 'X' if activity not performed.