



## Cleaning and Operation of Alu-Alu Blister Pack Machine

### 1.0 OBJECTIVE:

To lay down a procedure for cleaning and operation of Alu-Alu Blister pack machine.

### 2.0 SCOPE:

This procedure is applicable for cleaning & operation of alu-alu blister pack machine in production department.

### 3.0 RESPONSIBILITY:

Technical Associate- For cleaning and operation.

Officer and Executive–Production Department- For supervision

Manager-Production Department- For compliance of SOP.

### 4.0 DEFINITION (S):

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 “UNDER PROCESS” label and affix “TO BE CLEANED” 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 cleaner.

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

5.1.5 Replace the “TO BE CLEANED” status label by “CLEANED” status label on the machine with date and sign of the production officer.

5.1.6 Record the cleaning activity in equipment usage log as per SOP.

#### 5.2 TYPE B CLEANING:

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

5.2.1 Replaced the “UNDER PROCESS” status label by “TO BE CLEANED” 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, channel assembly, vibrating plate and guide track and transfer to washing area for cleaning.



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- 5.2.4 Clean the machine and area with vacuum cleaner.
  - 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 Remove the punching tool from the machine and clean with dry lint free cloth.
  - 5.2.10 Place a crate below the forming unit and loosen upper bolt.
  - 5.2.11 Clean them with dry lint free duster and cover with polybag and transfer to the packing spare cabinet.
  - 5.2.12 Clean the sealing unit with a brass brush by applying silicon compound.
  - 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 Transfer the guide track, feeding channel to the packing spare cabinet.
  - 5.2.17 Replace “TO BE CLEANED” status label by “CLEANED” status label with date and sign of the production officer.
  - 5.2.18 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.
  - 5.2.19 Record the cleaning operation time in equipment usage log sheet and check the cleaning activity as per Annexure- I .
  - 5.2.20 Clean the area as per SOP.
- 5.3 OPERATING PROCEDURE:**
- 5.3.1 Ensure the area and equipment is clean. Affix “UNDER PROCESS” label duly filled and signed on the machine and record all the observations in equipment usage and cleaning log sheet as per SOP.
- 5.4.1 Equipment setting**
- 5.4.1.1 It consists of two sets of reel support, reel fastening screw, reel adjusting screw, all activities are controlled by PLC.
- 5.4.2 Procedure for fixing forming plate**
- 5.4.2.1 Switch “OFF” the machine.
  - 5.4.2.2 Unscrew the centering bolt and fix the forming plate.
  - 5.4.2.3 Tighten the forming plate with screw in the star knob bolt till the almost reaches the face of the plate.
- 5.4.3 Procedure for fixing Counter Sealing Plate**
- 5.4.3.1 Switch “OFF” the machine.
  - 5.4.3.2 Counter sealing machine is directly mounted on the sealing station shaft.
  - 5.4.3.3 Clamped/tight with a close tolerance hub.



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### 5.4.4 Capsule feeding station

- 5.4.4.1 It consist of hopper, vibrator, tablet level sealing proxy, feeding channel
- 5.4.4.2 Speed of all the vibrators is controlled independently by the potentiometer provided in the operator panel.
- 5.4.4.3 Switch “ON” the machine.

### 5.4.4 Loading of Film and foil (Aluminium Foil)

- 5.4.4.1 Remove Base film Clamp from the quill by unscrew the socket set screw.
- 5.4.4.2 Insert the new Real.
- 5.4.4.3 Position the Real along the quill, in correct location as per Real setting gauge.
- 5.4.4.4 Tighten screw to clamp Real.

### 5.4.5 Machine Setting

- 5.4.5.1 Thread the base film all the way upto the punching station.
- 5.4.5.2 Engage the index roller.
- 5.4.5.3 Switch “OFF” all functions on the “Switches” screen of the MMI.  
Then, put the Forming Air (only for Thermo-formable Base Film) and set the forming temperature and wait until the temperature is reached.
- 5.4.5.4 Set the speed of machine as per the identification chart.
- 5.4.5.5 Form the few meters of web. Once the web is punched , thread the trim section.
- 5.4.5.6 Switch Sealing “ON” and set the required temperature values for upper & lower preheating plates. Verify that this temperature is reached.
- 5.4.5.7 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.
- 5.4.5.8 Put the correct values into all the required parameters in all the “SET PERAMETER” screen on the MMI.  
If base is Aluminium foil, selection of corresponding option will automatically “SWITCH “OFF” the platen heaters. For Alu-Alu Base Film, also keep the upper platen open.
- 5.4.5.9 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. Check that the positions of the Sealing & Punching Station match the Pack Layout.
- 5.4..5.10 If there is any mismatch (sealing crushing, packs punched of set), verify firstly that the station are in correct position as per the identification chart, and then correct the advance until the formed web matches in all stations.
- 5.4.5.11 Verify the sealing quality, Run the machine for some cycles to insure that sealing is perfect.



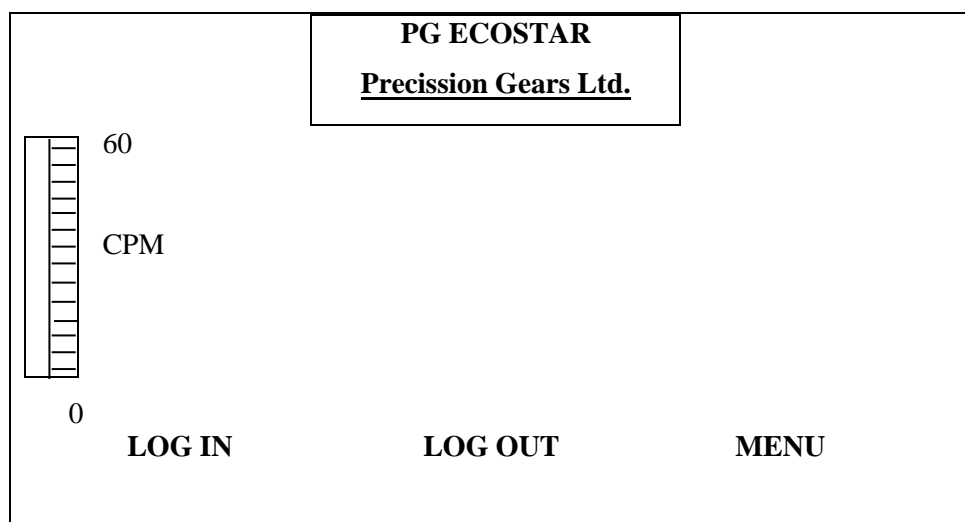
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### 5.5 OPERATION:

- 5.5.1 After the line clearance from Q.A., put the “UNDER PROCESS” label on the machine.
- 5.5.2 Enter start time of the machine in the equipment usage log sheet as per SOP.
- 5.5.3 Switch “ON” the “MAIN ISOLATOR SWITCH” from electrical panel.
- 5.5.4 Switch on the heater and adjust thermostat to provide the heating condition predetermined for the particular product as per mentioned in the BPR.
- 5.5.5 Fix printed Aluminium foil and plain aluminium foil rolls on the machine as per BPR.
- 5.5.6 Record the temperature of sealing units in the BPR
- 5.5.7 Fix the ink cartridge at the overprinting kit of the machine with the requisite height.
- 5.5.8 Affix the approved stereo.
- 5.5.9 Check the sealing performance, overprinting and cutting of strips and adjust if required.
- 5.5.10 Affix the specimen of the overprinted matter approved by the production officer and QA officer to BPR.
- 5.5.11 Cross check the containers of the product to be blistered are having approved status label.
- 5.5.12 Cross check the weight of the product to be blistered and record the weight on the BPR.
- 5.5.13 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.

### 5.6 Operation of PLC as per following instructions

- 5.6.1 Switch “ON” the mains switch.
- 5.6.2 MMI shows main screen



- 5.6.3 Press “LOG IN” & enter the password.



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5.6.4 Then press “MENU”. The MMI shows following options

<b>HELP</b>	<b>ALARM</b>
<b>RECIPE</b>	<b>PLC</b>
<b>PROD.DATA</b>	<b>SWITCHES</b>
<b>MAIN</b>	

5.6.5 Press “SWITCHES”, the MMI shows

<b>RUN/JOG</b>	<b>SEAL ON/OFF</b>	<b>FEEDER ON/OFF</b>
<b>VIB-I ON/OFF</b>	<b>PADDLE-I ON/OFF</b>	<b>SINGLING ON/OFF</b>
<b>FORM.AIR ON/OFF</b>	<b>PERFO. ON/OFF</b>	<b>SWEEP ON/OFF</b>
<b>MENU</b>	<b>MAIN</b>	<b>NEXT</b>

5.6.6 Check the status of machine as per requirement to run the machine switch on all the options as per requirement. And for other options go to “NEXT”. The MMI will show

<b>NFD Active/By-Pass</b>	<b>SPLICE Active /By-Pass</b>	<b>GUARD Active/By-Pass</b>
<b>PRINTER ON/OFF</b>	<b>NFD IR / S.LD PIN</b>	<b>PRC ON / OFF</b>
<b>MAIN</b>		

Activate all the options as per requirement.

5.6.7 After activation of all required options come to the main menu. And start the machine from the control panel.

5.7 Setting and operating of camera: Set and operate the camera on Alu-Alu as per product refer SOP.



## Cleaning and Operation of Alu-Alu Blister Pack Machine

### 6.0 ABBREVIATION (S)

BPR : Batch Packing Record  
QA : Quality Assurance  
CPM :Cuts Per Minute  
PRO. : Product  
PLC : Programmable logical Control  
VIB : Vibrator  
PERFO.: Perforation  
NFD : Non Fill Detector

### 7.0 REFERENCES (S):

SOP No. : Making entries in equipment usage and cleaning log sheet.  
SOP No. : Cleaning of production area.  
SOP No. : Cleaning and Operation of Camera on Blister /Alu- Alu Machine

### 8.0 ANNEXURE (S):

Annexure – I : Cleaning checklist of blister pack machine (Alu-Alu)

### 9.0 DISTRIBUTION:

- 9.1 **Master Copy** : Quality Assurance  
9.2 **Controlled copy (S)** : Production department, Quality Assurance  
9.3 **Reference copy (S)** : Production department



**Cleaning and Operation of Alu-Alu Blister Pack Machine**

**ANNEXURE I**

<b>Name of the Equipment</b>		<b>BLISTER PACK MACHINE (ALU-ALU)</b>	
<b>Equipment I.D. No.</b>		<b>Previous product</b>	
<b>Batch No.</b>		<b>Date</b>	
<b>S. No.</b>	<b>Activity</b>		<b>Activity Performed</b>
1.	Dismantle the hopper, hopper lid, feed channel, assembly, vibrating plate and guide track. Put all the dismantled parts in a virgin poly bag and affixed "TO BE CLEANED" label and transfer the poly bag to washing area for cleaning.		
2.	Scrub the dismantled parts with a nylon scrubber using purified water.		
3.	Finally rinse the cleaned parts with 10-20 liters of purified water.		
4.	Dry the cleaned parts with a dry lint free cloth.		
5.	Keep all the dried parts on a cleaned stainless steel pallet and cover it with a virgin polythene bag with a status label as "CLEANED" with date and signature of the production officer and transfer them to respective packing cubicle.		
6.	Wipe the dismantled parts with 70% v/v IPA solution.		
7.	Remove the punching tool from the machine and clean with dry lint free cloth.		
8.	Place a crate below the forming unit and loosen upper bolt.		
9.	Clean them with dry lint free duster and cover with polybag and transfer to the packing spare cabinet.		
10.	Clean the sealing unit with a brass brush by applying silicon compound.		
11.	Clean the inner and outer surface of the machine, control panel and utility lines with a dry duster.		
12.	Wipe the machine with 70% v/v IPA solution.		

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

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

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

