



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Cleaning and Operation of Strip Pack Machine with Pin Hole Detector and NFD System	Effective Date:
Supersedes: Nil	Review Date:
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Vernacular SOP: No

1.0 OBJECTIVE:

- 1.1 To lay down a procedure for Cleaning and Operation of Strip Pack Machine with Pinhole Detector and NFD system.

2.0 SCOPE:

- 2.1 This procedure is applicable to the Cleaning and Operation of Strip Pack Machine with Pinhole Detector and NFD System in Production Department.

3.0 RESPONSIBILITY:

- 3.1 Technical Associate: Cleaning and Operation
3.2 Officer/ Executive Production: Supervision for Cleaning and Operation
3.3 IPQA: Verification / Line clearance and SOP compliance
3.4 Head Production: SOP Compliance

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 Strip pack cubicle.
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 Clean the machine with vacuum cleaner followed by clean dry lint free duster.
5.1.4 Clean the channel chute, product filling disc/nylon brush (If applicability), hopper, vibration plate, pin hole detector, NFD and brush with a dry lint free duster.
5.1.5 Clean the sealing rollers with brass brush to remove all the adhered material on the rollers clean with the help of thinner.
5.1.6 Wipe the Batch coding unit with duster dipped into thinner to remove the spread ink.



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- 5.1.7 Wear hand gloves to remove the spread ink.
- 5.1.8 Clean the conveyor belt with dry lint free duster.
- 5.1.9 Clean the area as per SOP (“Cleaning of Production Area”).
- 5.1.10 Replace the ‘UNDER CLEANING’ status label by ‘CLEANED’ status label with date and sign of the production officer.
- 5.1.11 Record the cleaning end time in equipment usage log sheet 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 actives / color / ascending and descending potency, if same product is processed for more than a week or after maintenance.**
- 5.2.1 Follow the step no. 5.1.1 to 5.1.3
- 5.2.2 Ensure that the power supply is put ‘off’.
- 5.2.3 Clean the machine and area with vacuum cleaner.
- 5.2.4 Dismantle the feed hopper (If applicability), product filling disc/nylon brush (If applicability), bowl dish (If applicability), vibrator unit (If applicability), feeding channels.
- 5.2.5 **Dismantling procedure for filling disc**
- 5.2.5.1 Rotate the screw given at center of filling disc in clockwise direction this will uplift the disc.
- 5.2.5.2 Now remove the remaining disc plates by unscrewing the given screw.
- 5.2.6 Transfer the dismantled change parts for washing e.g. feed hopper, channel, SS bowl (If applicability) to the washing area in virgin poly bag.
- 5.2.7 Flush the dismantled parts with purified water sufficient to remove the powder.
- 5.2.8 Scrub the dismantled parts with a nylon scrubber to remove the adhered particulate using purified water.
- 5.2.9 Finally rinse all the cleaned parts with the 10-20 liters of purified water.
- 5.2.10 Clean the parts with a dry lint free cloth.
- 5.2.11 Wipe the cleaned parts with 70% v/v IPA solution.
- 5.2.12 Clean the pressure sealing rollers with brass brush to remove all the adhered material clean with the help of thinner.
- 5.2.13 Clean the vibrator unit, nylon brush with dry lint free duster.



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- 5.2.14 Clean the product filling disc with lint free duster moist with 70% v/v IPA solution.
- 5.2.15 Wipe the batch-coding unit with lint free duster dipped in thinner to remove the spread ink and then clean with dry lint free cloth.
- 5.2.16 Keep cleaned parts in the storage cabinet of change parts for strip Pack machine in packing spare parts room.
- 5.2.17 Clean the surrounding area of the machine.
- 5.2.18 Clean the inner and outer surface of the machine, control panel and utility lines with a dry lint free cloth.
- 5.2.19 Wipe the machine surface with lint free cloth using 70% v/v IPA solution.
- 5.2.20 Clean the machine conveyor belt with a clean dry lint free duster.
- 5.2.21 Clean the area as per SOP (“Cleaning of Production Area”).
- 5.2.22 Replace the ‘UNDER CLEANING’ status label by “CLEANED” status label with date and sign of the production officer as per SOP (“Status labeling”).
- 5.2.23 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”).

5.3 OPERATING PROCEDURE:

5.3.1 Machine Setting:

Caution: Ensure that the main switch is in ‘OFF’ position.

5.3.1.1 Mounting of sealing roller:

5.3.1.1.1 Mount the sealing roller on the shaft then tighten the grub screw.

5.3.1.1.2 Ensure that the centerline of the rollers is exactly above the centerline of draw of brushes.

5.3.1.1.3 Regulate the right sealing roller by means of stud and nuts to affect the parallel position of right sealing roller.

5.3.1.2 Adjustment of sealing pressure:

5.3.1.2.1 Check the cavity alignment of the sealing rollers.

5.3.1.2.2 Tighten the pressure-setting stud for the sealing pressure until passing of packing material is knurled.

5.3.1.2.3 Tighten the stud for equalization of pressure gradually until the packing leaves the sealing roller in a correctly position all over the web.



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5.3.1.3 **Adjustment of cutting device:**

- 5.3.1.3.1 Ensure that both the cam for the cutting device is functioning properly.
- 5.3.1.3.2 Push the cutter assembly downward to impart scissors action of the moving blade of cutter assembly.
- 5.3.1.3.3 Adjust the point of cutting assembly by loosening the screws and turning the hand wheel.
- 5.3.1.3.4 Change the cutting length by means of change gears and adjusting the screws on cam disc.

5.3.1.4 **Adjustment of dropping of tablets:**

- 5.3.1.4.1 If the dropping of tablet is early, rotate the back gear with pin ring in clockwise direction slowly so that the correct is achieved. If the dropping is late, do the reverse.
- 5.3.1.4.2 For product filling disc if the dropping of tablet is early, rotate the two screws one in clockwise direction and other in anticlockwise direction. If the dropping is late, do the reverse.

5.3.1.5 **Setting of printing unit:**

- 5.3.1.5.1 Take the required quantity of ink and fix on the stereo drum.
- 5.3.1.5.2 Properly wet the ink roller with adequate quantity of ink and thinner for proper printing on foil.
- 5.3.1.5.3 Adjust the pressure between stereo drum and the foil roller with the help of two side screws. The printing should be clear and legible.
- 5.3.1.5.4 Adjust the pressure between ink roller and the stereo drum with the help of two side screws. The printing should be clear and legible.
- 5.3.1.5.5 Printing should be monitored by operator for proper printing. Ink and thinner should be applied on ink roller as per requirement during running of batch.

5.3.2 **Operation:**

- 5.3.2.1 After line clearance from IPQA. Put the 'EQUIPMENT STATUS' label on the machine.
- 5.3.2.2 Switch 'ON' the main switch from electrical panel.
- 5.3.2.3 Set the temperature of sealing heater as per BPR.
- 5.3.2.4 Set the machine speed as per BPR.
- 5.3.2.5 Take out the strips with tablets from the machine and check for the following:
 - Knurling is proper to ensure smooth pressure.



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- Dropping of the tablets is in the center of the pockets to avoid cutting of pockets.
- Cutting of the strips to the required size in the knurling portion to avoid cut pockets.
- See the overprinting details as per the BPR. Also check for no smudging of ink.
- Ensure leak test as mentioned in the BPR.

5.3.2.6 Switch 'OFF' the main switch from electrical panel.

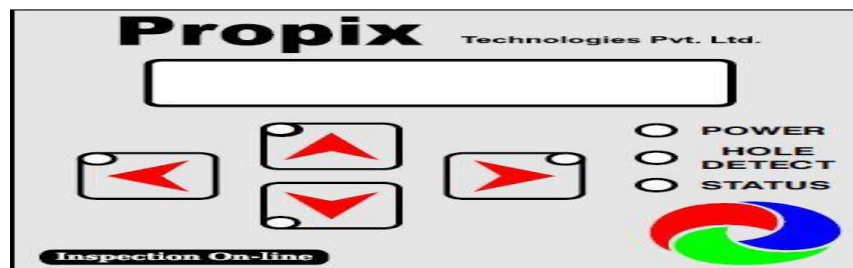
5.3.2.7 Affix 'UNDER CLEANING' label on the machine at end of batch.

5.4 PIN HOLE DETECTOR:

5.4.1 Pin hole detector for detection of point hole, micro fissures and micro pores which may occur on aluminum Strip Packs during their cold-forming or lamination process and usually impossible to be seen by human eyes.

5.4.2 LCD screen is provided on front panel of system along with keypad for viewing counter verification and various system statuses.

5.4.2.1 KEYPAD OF PIN HOLE DETECTOR



5.4.2.2 Indicators of Display unit are as:

Panel2 indicators are i.e.

1. Power On/Red indication and
2. Hole Detect/Yellow Indication.
3. Status- Green

5.4.2.3 ABCD symbols give reference as given below.

A means Accuracy as per below flow chart setting

B means Bad count as per below flow chart setting

C means Rejection que as per below flow chart setting

D means Sys. Setting as per below flow chart setting



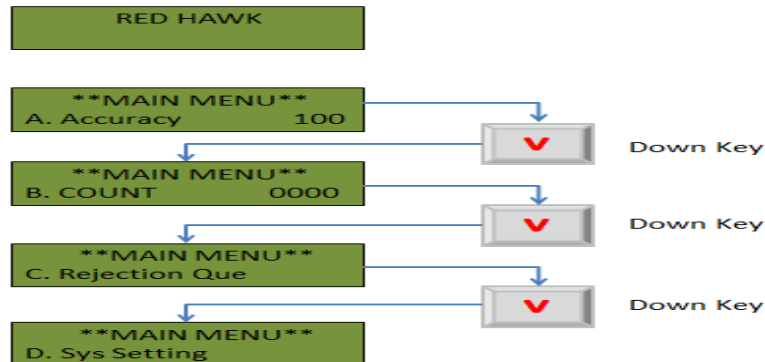
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5.4.2.4 The screen shows as follows:



5.4.3 Sensitivity of the system can be adjusted according to the requirement for detecting micron holes at suppressed speed and resolution.

5.4.4 On display unit sensitivity selection option is provided which can be used for setting number of different selections. Here we select up to 200 Microns.

5.4.5 The foil is guided between the transmitter and the receiver of detection unit. The foil is illuminated by infrared light while being transmitted. Highly sensitive sensor element registers if the infrared light beam penetrates a crack.

5.4.6 The detection unit positioned as, that slanting to the direction of the foil transfer in such a way that the centre of the foil match with the centre line of detection unit.

5.4.7 Distance between receiver and transmitter must not be greater than 50mm for proper detection.

5.4.8 **Flow Chart of Pin hole detector (working Diagrams) as follows**

5.4.8.1 For the change of Accuracy as per product



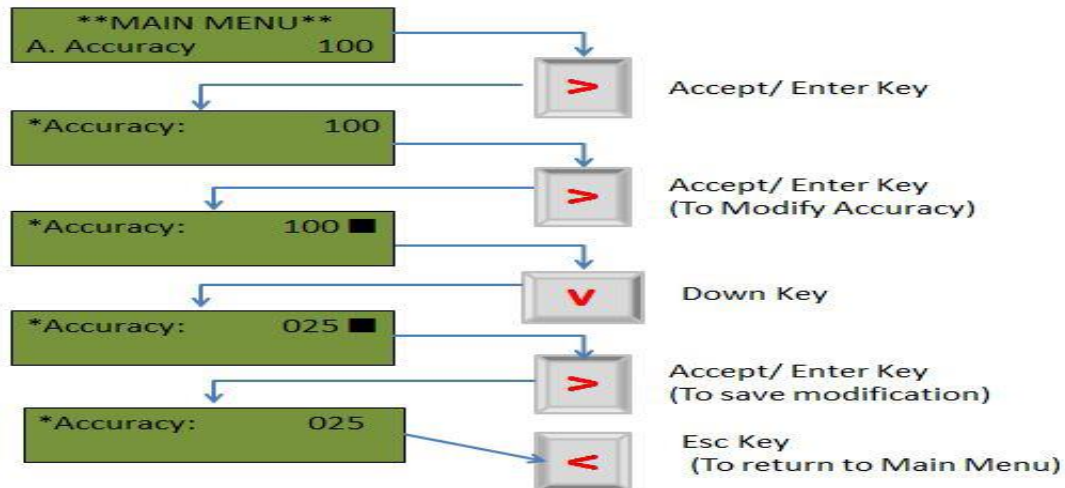
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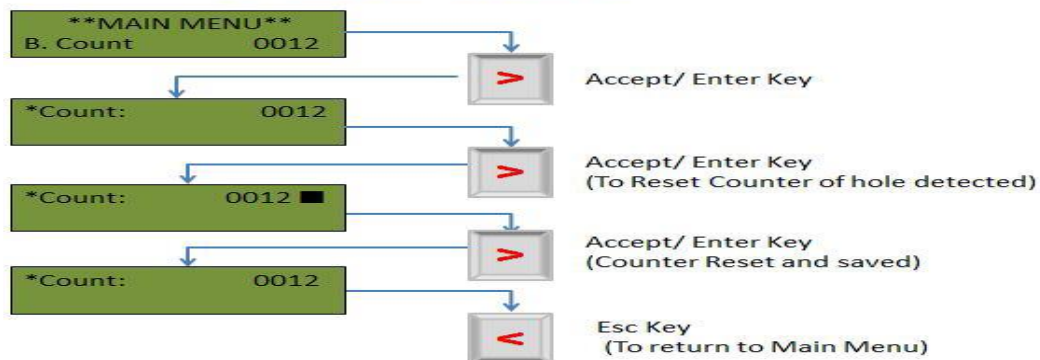
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To Change Accuracy



5.4.8.2 For to clear count of product:

To Clear Count



5.4.8.3 To change output signal timing:



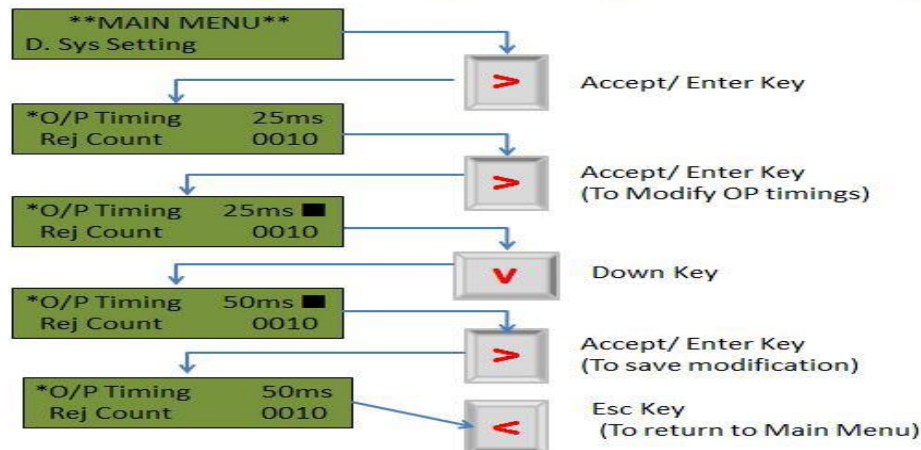
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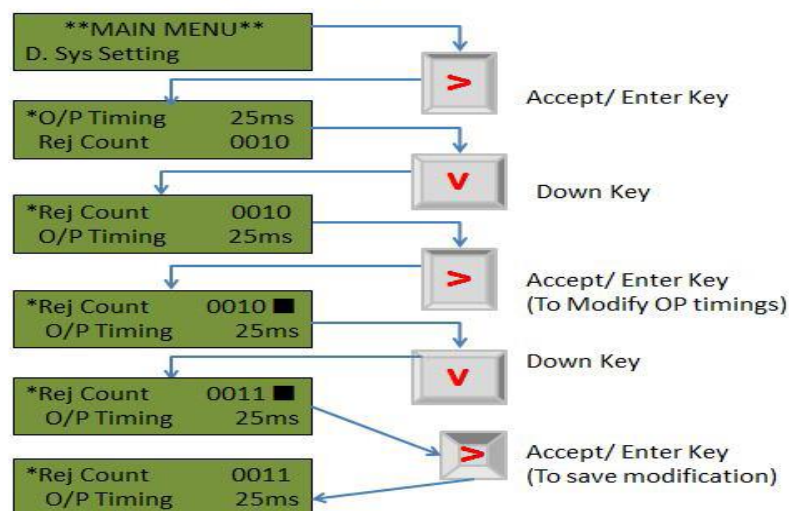
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To Change Output Signal Timings



5.4.8.4 To change rejection station count:

To Change Rejection Station Count



5.5 Challenge test for Pin Hole Detector

5.5.1 Challenge test for good strip

5.5.1.1 Pass the good foil through the pinhole device.

5.5.1.2 The good strip must be pass through the pin hole device.

5.5.1.3 Record the observation in the Annexure II (Challenge test for pin hole detector,



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5.5.2 Challenge test for rejected strip

5.5.2.1 Puncture the foil (aluminum printed as well as plain foil) at any point deliberately of diameter 0.3 mm to 1.0 mm by a fine needle.

5.5.2.2 Mark the puncture area.

5.5.2.3 When the marked foil contact with receiver unit and signaled as beep.

5.5.2.4 After a beep sound it must be rejected according to count setting of machine.

5.5.2.5 Rejected strip (marked strips) reject automatically.

5.5.2.6 Rejected strips recorded in Annexure II (Challenge test for pin hole detector)

Frequency: At the start, end and after every 4 hours of the operation.

5.6 **OPERATION of NFD system:**

5.6.1 **Sensor roller assembly setting:**

5.6.1.1 Use of this assembly is to sense the presence or absence of tablet/capsule in the strip pocket.

5.6.1.2 It contain Sensing roller which directly come in contact with the strip, Sensing strip which is always in contact with the sensor and up down movement of the strip is sensed by the sensor, Spring which keeps the sensing strip in its position, Left and right movement adjustment screw, forward and backward movement adjustment screw and Locking pin which locks the assembly in right position.

5.6.1.3 Set the assembly in such a way so that when empty pocket is present in front of sensing roller, distance between sensor and sensing strip should be zero and when filled pocket is present in front of sensing roller, distance between sensor and sensing strip should be 10 mm.

5.6.1.4 One assembly is to be set for each column which is filled in one dropping.

5.6.2 **Support assembly setting:**

5.6.2.1 Use of this assembly is to support the tablet/capsule when it is getting sensed by the sensing roller assembly.

5.6.2.2 It contain Support assembly bracket which is movable up to 90 degree to remove the support rod, Support rings which are to be adjusted to support the tablets while sensing.

5.6.2.3 Set the support rings so that their position is in line with each knurling of the combined strip sample before the slitters. These rings can be moved on the support rod to left or right by making internal screw loose.



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5.6.3 **Rejection assembly setting:**

- 5.6.3.1 Use of this assembly is to guide the bad strips into rejection bin and good strips to conveyor belt.
- 5.6.3.2 It contains the Flapper which is a metallic plate to guide the strips. Set the flapper according to the number of strips getting cut in one stroke below the cutter. Ideally one flapper for one strip.
- 5.6.3.3 Flapper assembly can be moved up and down and flappers can be moved forward and backward according to the strip length and strip position.

5.6.4 **Foil joint sensor setting:**

- 5.6.4.1 Two sensors are provided on each side i.e. one at plain foil side and one at printed foil side, to sense the joint in the foil roll.
- 5.6.4.2 Set the sensors in such a way that it can easily sense the joint on the roll by moving the sensor forward and backward.

5.6.5 **NFD parameter setting:**

- 5.6.5.1 Switch ON the machine by using the ON/OFF switch present on the side wall of the machine.
- 5.6.5.2 Start the compressed air supply to the machine.
- 5.6.5.3 After switching ON the HMI displays the main screen. It shows the Current Date, Current Time, Encoder position, Speed of the machine in cuts/min, No. of good strips, No. of empty strips, No. of partial strips and MENU option.
- 5.6.5.4 Press the MENU option on the screen, next screen appears which displays VIEW and EDIT option.
- 5.6.5.5 By pressing EDIT option next screen appears which requires password. By entering proper password the system goes to edit mode and new screen appears with Main Menu.
- 5.6.5.6 Press the **Parameter** option on the screen, a new screen appears which is having following values
 - a) No. of Toes: Press the No. of Toes option and enter the number of toes present on the cam disc by using the numerical keyboard on the screen.
 - b) No. of Track: Press the No. of Track option and enter the number of strips per cutting operation by using the numerical keyboard on the screen.
 - c) Sensor Count: Press the Sensor Count option and enter the number of tablets/capsules to be sense by sensor in each row by using the numerical keyboard on the screen.



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d) Column per Track: Press the Column per Track option and enter the number of columns per strip/track by using the numerical keyboard on the screen.

e) Sensor Delay: Press the Sensor Delay option and enter the time taken to sense the tablet for sensor by using the numerical keyboard on the screen. Ideally for small tablets value should be 1 and for large tablets value should be 0.

f) No. of strips from sensing roller to flapper: Press the No. of strips from sensing roller to flapper option and enter the number of strips present between sensing roller and flapper by using the numerical keyboard on the screen.

g) By pressing EXIT option, main menu screen appears.

h) By pressing NEXT option, new screen appears which contains value SENSOR COUNT. Enter the number of tablets to be sensed by each sensor per strip by using the numerical key board present on screen. Numbering of the sensors starts from the machine wall.

i) After entering SENSOR COUNT, press NEXT option, a new screen appears which contains the value FLAPPER SELECTION. Enter the number of the flapper to be used for each strip and if flapper is not in use then select the NOT USED option. Numbering of the flapper starts from the machine wall.

j) By pressing EXIT option, main menu screen appears.

5.6.5.7 Press the **CLOCK CAM** option on the screen, a new screen appears which is having following values

a) NFD Clock: Take the sensing roller position at the end of the strip and press the SET option on the screen.

b) Flap: Take the strip position between the cutter and flap and then press the SET option on the screen.

c) By pressing NEXT option, new screen appears which contains values LOAD DEFAULT, CAM SIZE INCREASE and CAM SIZE DECREASE. Press LOAD DEFAULT option to load the tablet cam values automatically.

d) By pressing back option, main menu screen appears.

5.6.5.8 Press the **SENSOR STATUS** option on the screen, a new screen appears which is having following values

a) Screen shows the number of tablets which is getting sensed by each sensor during the operation.

b) By pressing the screen once, main menu screen appears.

5.6.5.9 Press the **TAB HOLD CAM** option on the screen, a new screen appears which is having following values



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- a) Clock Setting: Stop the machine at last tablet drop of the strip from feeding channel. This is to done by operating the machine in inch mode.
- b) At this position press SET CLOCK option on screen. It will set the start and end cam for tablet hold.
- c) CLOCK ADJUST: Use SHIFT UP and SHIFT DOWN options to adjust the start and end cam manually for fine setting.
- d) By pressing EXIT option, main menu screen appears.

5.6.5.10 Press the **PRINTING REJECTION** option on the screen, a new screen appears which is having following values

- a) Printing Rejection ON/OFF: Press this option to keep this provision ON or OFF.
- b) Reject Count: Press the Reject Count option and enter the number of strips to be rejected by using the numerical keyboard on the screen.
- c) Reject Length: Press the Reject Length option and enter the number of strips from printing station to feeding by using the numerical keyboard on the screen.
- d) Time: Press the Time option and enter the machine stoppage time in seconds after which the printing rejection should operate by using the numerical keyboard on the screen.
- e) By pressing EXIT option, main menu screen appears.
- f) This provision is used to reject the printing rejection strips after each stoppage of the machine of defined time.

5.6.5.11 Press the **SEALING REJECTION** option on the screen, a new screen appears which is having following values

- a) Sealing Rejection ON/OFF: Press this option to keep this provision ON or OFF.
- b) Reject Count: Press the Reject Count option and enter the number of strips to be rejected by using the numerical keyboard on the screen.
- c) Reject Length: Press the Reject Length option and enter the number of strips from sealing roller to flapper by using the numerical keyboard on the screen.
- d) Time: Press the Time option and enter the machine stoppage time in seconds after which the sealing rejection should operate by using the numerical keyboard on the screen.
- e) By pressing EXIT option, main menu screen appears.



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f) This provision is used to reject the sealing rejection strips after each stoppage of the machine of defined time.

5.6.5.12 Press the **LH JOINT REJECTION** option on the screen, a new screen appears which is having following values.

- a) LH Joint Rejection ON/OFF: - Press this option to keep this provision ON or OFF.
- b) Reject Count: - Press the Reject Count option and enter the number of strips to be rejected by using the numerical keyboard on the screen.
- c) Reject Length: - Press the Reject Length option and enter the number of strips from LH joint sensor to feeding by using the numerical keyboard on the screen.
- d) Time: - Press the Time option and enter the time delay for sensor to avoid the fluctuations during sensing due to wrinkles or printed matter on the foil. Single value indicates 10 milliseconds.
- e) Joint Sensor Teach: - Press this option to open the new screen which contains the procedure to teach the sensor.
- f) By pressing EXIT option, main menu screen appears.
- g) This provision is used to reject the joint in the foil at the left side of the machine.

5.6.5.13 Press the **RH JOINT REJECTION** option on the screen, a new screen appears which is having following values

- a) RH Joint Rejection ON/OFF: - Press this option to keep this provision ON or OFF.
- b) Reject Count: - Press the Reject Count option and enter the number of strips to be rejected by using the numerical keyboard on the screen.
- c) Reject Length: - Press the Reject Length option and enter the number of strips from RH joint sensor to feeding by using the numerical keyboard on the screen.
- d) Time: - Press the Time option and enter the time delay for sensor to avoid the fluctuations during sensing due to wrinkles or printed matter on the foil. Single value indicates 10 milliseconds.
- e) Joint Sensor Teach: - Press this option to open the new screen which contains the procedure to teach the sensor.
- f) By pressing EXIT option, main menu screen appears.
- g) This provision is used to reject the joint in the foil at the right side of the machine.



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5.6.5.14 Press '→' present on screen, sub menu screen appears which shows the Current Date, Current Time, Encoder position, Speed of the machine in cuts/min, No. of good strips, No. of empty strips, No. of partial strips.

- a) It also shows the BUZZER ON/OFF option by which the buzzer sound can be turned on and off.
- b) PRODUCTION COUNTER RESET option by which the total count can be reset back to zero.
- c) NFD AUTO, NFD REJECT and MANUAL ACCEPT by which NFD runs in auto mode, all the strips are rejected and all the strips are accepted respectively.
- d) Press '←' option to return back to main menu screen.

5.6.5.15 By pressing EXIT option, main screen appears on display.

5.6.6 Press the MENU option on the screen, next screen appears which displays VIEW and EDIT option.

5.6.7 By pressing VIEW option Main menu screen appears and all the parameters such as EDIT mode can be viewed. When any parameter required to change in VIEW mode then password is required and when correct password is given the system directly goes to EDIT mode.

5.7 Alarms:

5.7.1 Buzzer sound with a flash light turns on when a empty pocket is detected by the sensor.

5.7.2 If the compressed air supply to the machine is low then the main screen shows the message 'LOW AIR PRESSURE' with continues sound of the buzzer.

5.7.3 Give the required air pressure to the machine rectify the problem and reset the alarm by pressing the screen.

5.7.4 If LH joint is detected, it shows the alarm 'LH JOINT DETECTED', press the screen once to acknowledge the alarm

5.7.5 If RH joint is detected, it shows the alarm 'RH JOINT DETECTED', press the screen once to acknowledge the alarm

5.7.6 If printing rejection is observed, it shows the alarm 'PRINTING REJECTION DETECTED', press the screen once to acknowledge the alarm.

5.7.7 If sealing rejection is observed, it shows the alarm 'SEALING REJECTION DETECTED', press the screen once to acknowledge the alarm.

5.8 Challenge test for NFD:



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5.8.1 Stop the tablet/capsule in one column and allow the empty pocket to run in front of the sensing roller and check whether the corresponding strip is rejected. Repeat the same procedure for all the columns and check that all the strips are rejected.

5.8.2 Challenge test is to be performed at the start, end and after every 4 hours of the operation.

6.0 ABBREVIATION (S):

6.1 IPA : Iso Propyl Alcohol

6.2 QA : Quality Assurance

6.3 SOP : Standard Operating Procedure

6.4 No. : Number

6.5 SS : Stainless Steel

6.6 BPR : Batch Packing Record.

6.7 v/v : Volume /Volume

6.8 NFD : Non-filled Detection

6.9 HMI : Human Machine Interface

7.0 REFERENCE(S):

7.1 SOP: Making entries in equipment usage and Cleaning log sheet.

7.2 SOP: Cleaning of Production Area

7.3 SOP: Status Labeling

8.0 ANNEXURE(S):

Annexure no.	Title of Annexure	Format no.	Mode of Execution
Annexure - I	Cleaning Checklist of Strip Pack machine		Logbook
Annexure - II	Challenge Test for Pin Hole Detector		Controlled Copy
Annexure – III	Challenge Test for NFD System		Controlled Copy

9.0 DISTRIBUTION:



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Title: Cleaning and Operation of Strip Pack Machine with Pin Hole Detector and NFD System	Effective Date:
Supersedes: Nil	Review Date:
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- 9.1 **Master Copy** : Quality Assurance
- 9.2 **Controlled Copy (S)** : Production Department (01), 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



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ANNEXURE I

CLEANING CHECKLIST OF STRIP PACK MACHINE

Name of the Equipment		STRIP PACK MACHINE	
Equipment ID No.		Previous product	
Batch No.		Date	
S.No.	Activity	Activity Performed	
1.	Affix the dully filled 'TO BE CLEANED' status label on equipment with date and signature of the production officer as per SOP.		
2.	Clean the machine and area with vacuum cleaner.		
3.	Dismantle the feed hopper (If applicability), product filling disc/nylon brush (If applicability), bowl dish (If applicability), vibrator unit (If applicability), feeding channels.		
4.	Dismantling procedure for filling disc		
4.1.	Rotate the screw given at center of filling disc in clockwise direction this will uplift the disc.		
4.2.	Now remove the remaining disc plates by unscrewing the given screw.		
5.	Transfer the dismantled change parts for washing e.g. feed hopper, channel, S.S bowl (If applicability) to the washing area in virgin poly bag.		
6.	Flush the dismantled parts with purified water sufficient to remove the powder		
7.	Scrub the dismantled parts with a nylon scrubber to remove the adhered particulate using purified water.		
8.	Finally rinse the cleaned parts with the 10-20 liters of purified water.		
9.	Clean the change parts with a dry lint free cloth.		
10.	Wipe the cleaned dismantled parts with 70% v/v IPA solution.		
11.	Clean the pressure sealing rollers with brass brush to remove adhered particulate clean with the help of thinner.		



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S.No.	Activity	Activity Performed
12.	Clean the conveyor belt with a dry lint free duster.	
13.	Clean the vibrator unit, nylon brush with dry lint free duster.	
14.	Clean the product filling disc with lint free duster moist with 70% v/v IPA solution.	
15.	Wipe the batch-coding unit with lint free duster dipped in thinner to remove the spread ink and then clean with dry lint free cloth.	
16.	Keep cleaned parts in the storage cabinet of change parts for strip Pack machine in packing spare parts room.	
17.	Clean the inner and outer surface of the machine, control panel and utility lines with a dry lint free cloth.	
18.	Wipe the machine surface with lint free cloth using 70% v/v IPA solution.	
19.	Clean the machine conveyor belt with a clean dry lint free duster.	
20.	If machine is idle for more than 72 hours, wipe the machine body and all the parts with 70 % V/V IPA solution using lint free cloth, it shall be counter signed on previous "CLEANED" status label by production and IPQA officer with date	
21.	Keep all these cleaned parts in the storage cabinet of change parts for strip Pack machine in packing spare parts room.	

Checked By (Prod.)
Sign/Date

Verified By (QA)
Sign/Date

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



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ANNEXURE II

CHALLENGE TEST FOR PIN HOLE DETECTOR

FREQUENCY: AT START, END AND AFTER EVERY 4 HOUR OF THE OPERATION

PRODUCT NAME:

BATCH NO.:

S.No.	DATE	TIME	OBSERVATIONS		CHECKED BY (Production)	Verified By (IPQA)	REMARKS
			# GOOD STRIPS	*MARKED STRIPS			

GOOD STRIPS: Mark as "OK" in observation and must be pass.

* MARKED STRIPS: Mark as "OK" in observation must be rejected.



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ANNEXURE III

CHALLENGE TEST FOR NFD SYSTEM

FREQUENCY: AT START, END AND AFTER EVERY 4 HOUR OF THE OPERATION

PRODUCT NAME:

BATCH No.:

S.No.	DATE	TIME	OBSERVATIONS		CHECKED BY (Production)	Verified By (IPQA)	REMARKS
			# GOOD STRIPS	*EMPTY STRIPS			

GOOD STRIPS : Mark "OK" in observation and must be pass.

* EMPTY STRIPS : Mark "OK" in observation must be rejected.