PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Production	**SOP No.:**
Title: Cleaning and Operation of Pouch Forming Filling and Sealing Machine (Pakona)	**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 & operation of pouch Forming, Filling and sealing machine (Model : PK-90 VL HIGH SPEED)

2.0 SCOPE:

2.1 This procedure is applicable for cleaning & operation of pouch Forming, Filling and sealing machine in production department.

3.0 RESPONSIBILITY:

3.1 Technical Assistant / Trainee Technical Assistant: For Cleaning and operation.

3.2 Officer and Executive-Production Department: For Supervision.

3.3 Officer and Executive-IPQA: For verification.

3.4 Manager – 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 packing cubicle.

5.1.2 Remove “EQUIPMENT STATUS” label and affix “TO BE CLEANED” label on the machine with date and sign of the production officer.

5.1.3 Switch OFF the all utility supply before cleaning.

5.1.4 Clean the control panel with clean and dry lint free cloth.

5.1.5 Clean the top and outer surface of machine with the dry lint free cloth.

5.1.6 Open guard and clean inside surface of machine, hopper and its assembly by dry lint free cloth.

5.1.7 Clean the product deposit area on top and parts on gripper unit by vacuum cleaning followed by dry lint free cloth.

5.1.8 Replace the “TO BE CLEANED” 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 Change over of product with different actives / color / descending potency/ascending potency and if same product processed for more than a week or after maintenance.

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

5.2.2 Remove " EQUIPMENT STATUS " label and affix "TO BE CLEANED " label on the machine with date and sign of the production officer.

5.2.3 Switch off the all utility supply before cleaning.

5.2.4 Remove all the change parts i.e. pouch receiver keys, dosing die, hopper spring, nitrogen ejection nozzle and transfer to washing area into virgin poly bag for cleaning.

5.2.5 Flush the change parts with purified water sufficient to remove the powder. To remove adhered particulate scrub parts with nylon brush using purified water.

5.2.6 Finally rinse the all change parts with 40-50 liters purified water.

5.2.7 Dry the cleaned parts with dry lint free cloth.

5.2.8 Wipe the cleaned parts with lint free cloth using 70% V/V IPA solution followed by mopping with dry lint free cloth.

5.2.9 Clean the control panel with clean and dry lint free cloth.

5.2.10 Use vacuum cleaner on top or parts on gripper unit, product filling stations, hopper and cup filler with assembly followed by cleaning with dry lint free cloth.

5.2.11 Clean thoroughly product discharge route, discharge conveyor, puller roller, mount roll assembly with lint free cloth.

5.2.12 Clean the Serration of sealing jaw- use a wire brush to clean the dirt on the serration.

5.2.13 Clean lower surface of machine and oil if leakage from auto lubrication system.

5.2.14 For cleaning the machine above the human height use the ladder with platform and safety railing.

5.2.15 Clean all SS parts of machine thoroughly with lint free cloth dipped in 70% v/v IPA solution followed by drying with dry lint free cloth.

5.2.16 If machine is idle for 72 hrs. after cleaning, then re-clean by mopping with lint free cloth using 70% V/V IPA solution.

5.2.17 Replace the "TO BE CLEANED" status label by "CLEANED" status label on the machine with date and sign of the production officer.

5.2.18 Record the cleaning activity in equipment usage log as per SOP "Making entries in equipment usage and cleaning log sheet".

5.3 **BASIC SETTINGS OF MACHINE:**

5.3.1 **ROLL MOUNTING AND FORMING ASSEMBLY:**

5.3.1.1 Web roll mounted on the assembly and ensuring centered position at the LHS and RHS bracket. It securely held in position by collar.

5.3.1.2 Insert the roll from RHS side and lever of web adjuster provided at the LHS side should engage with the step provided on the roll mounting shaft.

5.3.2 **WEAVE SETTING:**

5.3.2.1 If two edge of the V formed web are not parallel, it is automatically adjusted by the weaving motor given with foil adjustment sensor.

5.3.3 **SETTING OF TOP HEIGHT OF FORMING PLOUGH**

5.3.3.1 The forming plough must be adjusted in according with web width by loosing the nut using the M16 spanner and re-positioning. The distance from the table top of the machine to the upper edge of the web remain constant at 660 mm. It should not be disturbed.

5.3.4 **FOR PLAIN POUCH**

5.3.4.1 Distance from the machine top plate to the focal point of the folding plough is fixed. To adjust the height loosen the forming plough nut provided and slid the top up/down which necessary. Then run machine and measure after running the machine for one minute and ensure that folding plough mounting nut is firmly tightened.

5.3.5 **PRIMARY SEALING STATION**

5.3.5.1 Sealing jaws located at both side of web are adjusted to correspond to the pouch width and height. The width of the web governs the height adjustment. The quality of sealing is maintained by set temperature, sealing pressure, machine speed.

5.3.6 **VERTICAL SEALING JAW**

5.3.6.1 These are adjusted to correspond to sealing and cutting as per printing design. For this jaws are adjusted in such a way that knife cut the pouch from center of total vertical sealing width.

5.3.7 **SETTING OF SEALING PRESSURE**

5.3.7.1 By rotating the cam follower pin sealing pressure can be increase or decrease. The pressure start to adjusted from zero as otherwise may damage the sealing jaws assembly.

5.3.7.2 Turn the cam follower pin to the lever so that eccentricity is minimum and lever pin center is nearest to the cam face.

5.3.7.3 Inch the machine that sealing jaws nearest to each other and are stationary.

5.3.7.4 Now rotate the cam follower pin to one sealing stationer lever so that one jaw is flush with other and no light passes through it (zero pressure)

5.3.8 **PULLING ROLLER ASSEMBLY**

5.3.8.1 Pulling of pouch shell between 0.1 to 0.5 mm plus of the pouch width.

5.3.8.2 Ensure that eye mark is set as per pouch width.

5.3.8.3 Set puller assembly and cutting knife manually such that the cutting edge is 2 mm right to eye mark.

5.3.8.4 Now engage the hinged roller and run the machine.

5.3.9 **PULLER ROLLER PRESSURE ADJUSTMENT**

5.3.9.1 Two set of roller and if pouch height is less than 325 mm only top puller is used.

5.3.9.2 Knob provided on hinged housing to increase or decrease the pressure.

5.3.9.3 Proper pressure is given to avoid slippage of laminate and that it travel in straight line.

5.3.10 **CUTTING KNIFE**

5.3.10.1 Position of cutting knife is adjusted that cutting edge is half the pouch width from the gripper center at station.

5.3.10.2 The gripper center and pouch transfer key center are same.

5.3.10.3 A scale and arrow are provided to set cutting knife properly.

5.3.10.4 To increase pressure of knife loosen the volt on movable knife holder then tighten the spring and if yet cutting not take place, open lid of cutting block, loose the bolt on the slide and slightly tilt the cutting knife towards the fix blade.

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5.3.11 **POUCH TRANSFER ASSEMBLY**

5.3.11.1 It transfer individual pouch to the gripper unit. Length of the transfer key is adjusted to pouch width.

5.3.11.2 This assembly use the cam for functioning.

5.3.11.3 When high point of this cam reached the transfer key are maximum apart and at low point the key should touch each other so that it can grip pouch.

5.3.11.4 Now loosen the both transfer key holder and clamping plate and inch the machine till follower of transfer key reaches the low pin of cam.

5.3.11.5 Adjust the transfer body toward gripper unit that key center is 2 mm behind gripper's pouch holder position.

5.3.11.6 Tighten the clamping plate and inch machine see there is no jerk in transfer body movement.

5.3.12 **GRIPPER UNIT**

5.3.12.1 Finger shall be that it hold the pouch at least 5 mm of the pouch.

5.3.12.2 Care should be taken that pouch is held in the center and both finger and grip pouch equally on either side i.e. 5 mm.

5.3.12.3 To set gripper run machine with laminate and adjust cutting knife and sealing jaws position and pouch width according to requirement.

5.3.12.4 Now inch the machine that transfer assembly pick the individually cut pouch and move toward the gripper.

5.3.12.5 Now loose bolt which hold finger in gripper finger holder.

5.3.12.6 Slide the finger such that finger will hold 5 mm of the pouch on closing.

5.3.12.7 Tight the bolt and repeat the same with the other fingers.

5.3.13 **VACCUM OPENING**

5.3.13.1 Vacuum suction cup will open initially to pouch.

5.3.13.2 The position of the cup shall be such that they should touch each other exactly in the center of gripper.

5.3.13.3 The movement of the vacuum cup should be smooth and not push each other.

5.3.14 **VOLUMETRIC CUP FILLER**

5.3.14.1 Put the selector switch in RUN position and press the filler push button this rotate the filler shaft and tuning of rotation is done in such a way that when discharge pipe comes underneath the cup filler, the pneumatic cylinder device open the cup closure and product drop from the telescopic cup into the pouch through discharge hopper.

5.3.14.2 By doing as above filling time can be set by doing slight trial and error method.

5.4 **TEMPRATURE SETTING**

5.4.1 Ensure that switch on the Top heater, Bottom heater and Vertical heater before start the operation.
Set the Temp. of Top, Bottom and Vertical heater as per product requirement.

5.4.2 Set the Optimum limit of top and vertical heater should be 100 to 150ºc.and 150 to 200 ºC.

5.4.3

5.5 **OPERATING PROCEDURE**

5.5.1 Before operating the machine check the electrical and pneumatic supply.

5.5.2 Ensure that switch on the PLC count supply, filler OH, Top heater, Bottom heater and Vertical heater.

5.5.3 Feed the product to be into the hopper and maintained for product hopper level.

5.5.4 Web roll mounted properly on the roll mounting assembly.

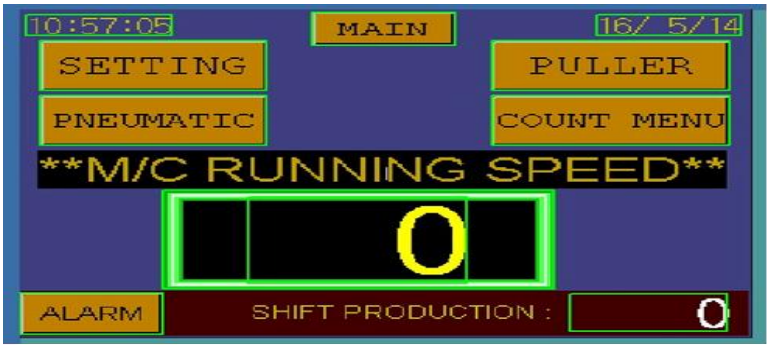
5.5.5 Roll Web passed through the given rollers, folding edge, folding plough and finally through puller rollers.

5.5.6 Put MCB supply ON and the indicator for R-phase, O-phase, B-phase shell glow on control panel

5.5.7 Now put ON the PLC control supply selector switch this will powered up the display unit.

5.5.8 Switch ON the top, bottom and vertical heater selector switch on the control panel this powered up the temperature controller and desired temperature can be set.

5.5.9 Touch the setting in main menu to open the setting menu.



5.5.10 Now select the parameters in setting menu and put value as desired for setting of machine and go through the NEXT button on PLC to select other parameters.

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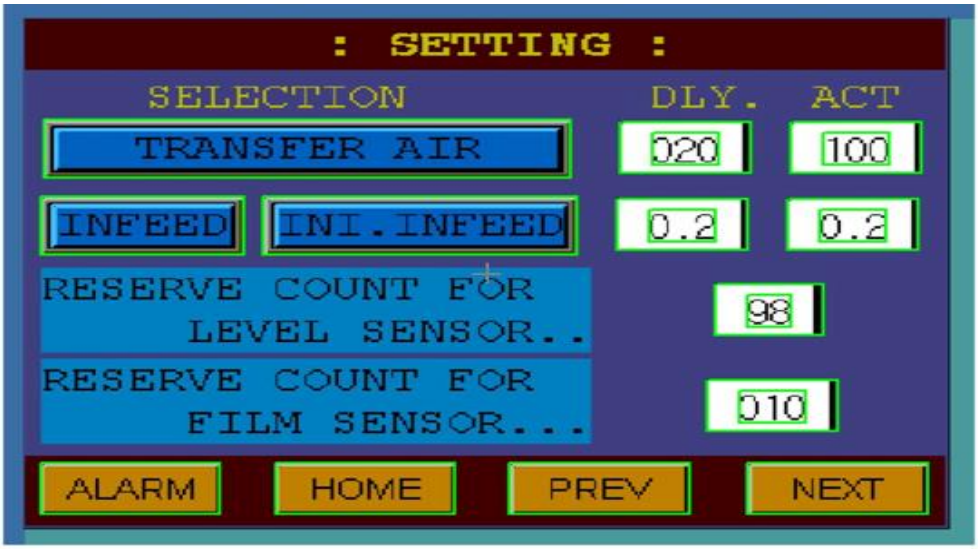
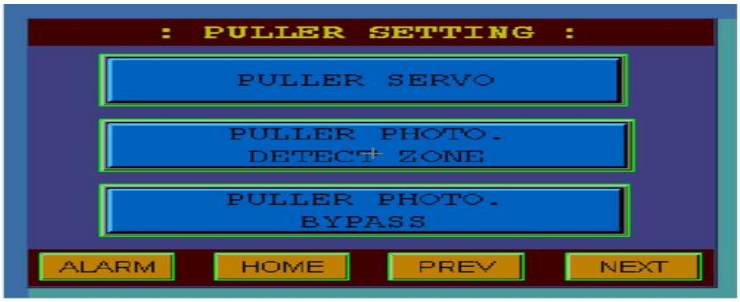
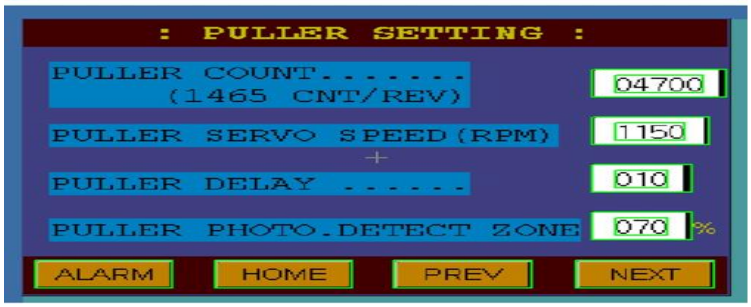
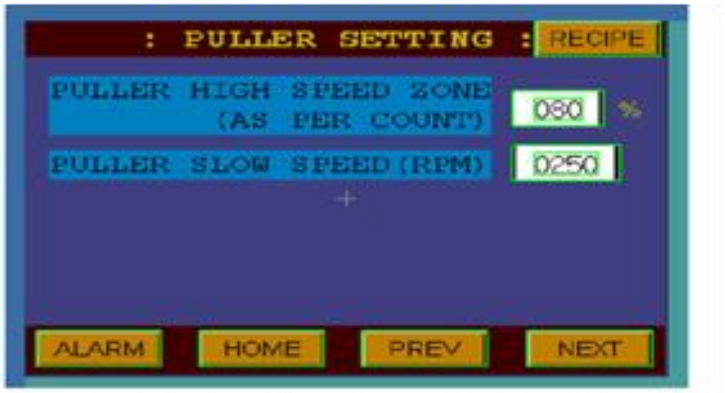


5.5.11 Press puller in main to open puller menu and desired parameter can be set in PLC as per sachet width.







Press pneumatic check in main menu to open Pneumatic

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5.5.12 Press pneumatic check menu in main menu to open the pneumatic check menu and parameter for pneumatic system can be check as required.

5.5.13 Press the count menu check in main menu to open the count menu check and daily production can be check.

5.6 **Challenge Test Procedure For Sensors:**

5.6.1 **For no pouch-no product fill Sensor (Sensor-I):**

5.6.1.1 Run the machine for pouch filling.

5.6.1.2 Machine will pass challenge test if product filling occurs when pouch travel under the ‘no pouch-no product sensor’.

5.6.1.3 Record the observation in Annexure-II "Challenge test for 'No pouch-No product sensor & Product level sensor".

5.6.1.4 Run the machine in 'inch' mode that pouch will be ready for cutting.

5.6.1.5 Now get the pouch cut by pushing the cutter handle manually and withdrawal the pouch from machine.

5.6.1.6 Run the machine in auto mode.

5.6.1.7 Pouch-less finger rotate under the no pouch-no product fill sensor.

5.6.1.8 Machine will pass challenge test if no product filling occurs for this station.

5.6.1.9 Record the observation in Annexure-II "Challenge test for 'No pouch-No product sensor & Product level sensor".

5.6.2 **For Product Level Sensor (Sensor-II):**

5.6.2.1 Fill the hopper with product up-to the product level sensor.

5.6.2.2 Machine will pass challenge test if machine run continuously.

5.6.2.3 Record the observation in Annexure-II "Challenge test for 'No pouch-No product sensor & Product level sensor".

5.6.2.4 Now remove the product from the hopper that product level reached below the level of sensor in hopper.

5.6.2.5 Machine shall pass the challenge test if machine get stop.

5.6.2.6 Record the observation in Annexure-II "Challenge test for 'No pouch-No product sensor & Product level sensor".

6.0 ABBREVIATION (S):

6.1 BPR : Batch Packing Record

6.2 QA : Quality Assurance

6.3 CPM :Cuts Per Minute

6.4 PLC : Programmable logical Control

7.0 REFERENCES (S):

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

7.2 SOP No. : Cleaning of production area.

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8.0 ANNEXURE (S):

Annexure no.	Title of Annexure	Format No.	Mode of Execution
Annexure – I	Cleaning checklist of pouch forming, filling and sealing machine	……	Logbook
Annexure – II	Challenge test for 'No pouch-No product sensor & Product level sensor.	……	Controlled copy

9.0 DISTRIBUTION:

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

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ANNEXURE I

CLEANING CHECKLIST OF POUCH FORMING, FILLING AND SEALING MACHINE (PK-90 VL HIGH SPEED)

Name of the Equipment	**Pouch Forming, Filling and Sealing Machine (Pakona)**		
Equipment ID. No.		**Previous product**	
Batch No.		**Date**	

S.No.	Activity	Activity Performed
1.	Ensure that all the materials of previous batch are removed from the packing cubicle.	
2.	Remove ‘’UNDER PROCESS’’ label and affix ‘’TO BE CLEANED’’ label on the machine with date and sign of production officer.	
3.	Switch OFF the all utility supply before cleaning.	
4.	Remove all the change parts i.e. pouch receiver key, dosing die, hopper spring, nitrogen ejection nozzle and transfer to washing area for through cleaning.	
5.	Flush the change parts with purified water sufficient to remove the powder and adhered particulate scrub with nylon brush using purified water.	
6.	Finally rinse the parts with 40-50 liters purified water and dry the change parts with wipe the change parts with lint free cloth using 70% IPA v/v solution and dry with dry lint free cloth.	
7.	Clean the control panel with clean and dry lint free cloth.	
8.	Use vacuum cleaner on top and parts of gripper unit, product filling station, hopper and its assembly followed by cleaning with dry lint free cloth.	
9.	Clean thoroughly product discharge route, conveyor, puller roller, mount roll assembly with lint free cloth.	
10.	Clean the serration of sealing jaws-use the wire brush to clean the dirt on serration.	
11.	Clean lower surface of machine and oil if leakage from auto lubrication system.	
12.	For cleaning above the human height use the ladder with platform and safety railing.	
13.	Clean all SS parts with lint free cloth dipped in 70% v/v IPA solution followed by drying with dry lint free cloth.	
14.	Replace ‘’TO BE CLEANED’’ with ‘’CLEANED’’ status label on the machine with date and sign of production officer.	
15.	Record all the activity in equipment usage log as per SOP.	

Checked By (Production)
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 NO POUCH-NO PRODUCT & PRODUCT LEVEL SENSOR

FREQUENCY: At start, after every four hours and at end of operation

DATE	TIME	CHALLENGE TEST FOR 'NO POUCH-NO PRODUCT' SENSOR (Sensor-I)		CHALLENGE TEST FOR 'PRODUCT LEVEL SENSOR IN HOPPER' (Sensor-II)		RESULT OK/NOT OK	CHECKED BY (Production)	VERIFIED BY (IPQA)
		*CHALLENGE WITH POUCH (OK NOT OK)	# CHALLENGE WITHOUT POUCH (OK/NOT OK)	* *PRODUCT LEVEL UP-TO THE SENSOR (OK/NOT OK)	# # PRODUCT LEVEL LOWER TO THE SENSOR (OK/NOT OK)			

(Sensor-I) :* Mark ''OK'' in observation if product filling occurs and # mark ''OK'' in observation if product filling not occurs.
(Sensor-II):* * Mark ''OK'' in observation if machine run and # # mark ''OK'' in observation if machine stop.