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1.0   OBJECTIVE:

To lay down a procedure for cleaning and operation of carton packing machine.

2.0   SCOPE:

This procedure is applicable to the Cleaning and Operation of Carton Packing machine in production.

3.0   RESPONSIBILITY:

Technical Associate : Cleaning and Operation

Officer and Executive : Supervision for cleaning and operation

Officer and Executive IPQA : Line clearance and SOP Compliance

Head Production : SOP Compliance.

4.0   DEFINITION (S):

NA

5.0   PROCEDURE:

5.1   CLEANING

5.1.1   Replace the 'UNDER PROCESS' status label with 'TO BE CLEANED' status label with date and sign of the production officer.

5.1.2   Record the cleaning start time in equipment usage log as per SOP.

5.1.3   Remove secondary packing material, blister and foil pieces, cartons and leaflets of previous product present on the carton packing machine.

5.1.4   Clean the conveyor belt, collator magazine, MMI, utility cables and other parts of machine with the help of clean lint free duster.

5.1.5   Wipe the machine with 70 % v/v IPA.

5.1.6   Replace the 'TO BE CLEANED' status label by 'CLEANED' status label with date and sign of the production officer / QA officer.

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5.1.7   If machine is not used with in 72 hours clean the machine "before use" with lint free duster dipped in 70% v/v IPA solution followed by dry lint free duster and dully sign the 'CLEANED' label again. And record the activity in equipment usage log sheet as per SOP.

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

5.2   MACHINE SETTING:

5.2.1   Switch 'on' the mains and release the emergency switch.

5.2.2   PLC will be light up and following screen shall be displayed:

5.2.3   Keep the machine in 'set mode' by turning the key into 'set mode' given on MMI.

5.2.4   Select the 'login' option from the above window and following screen shall be opened:

5.2.5   There are three 'user levels' which are given with specific rights assignment as under given:

S.No.	Functions	Level-1 (Operator)	Level-II (Supervisor)	Level-III Adminstrator (Production Head)
1.	To make recipe.	N	Y	Y
2.	Create/remove users & change security policy	N	N	Y
3.	View & Switching to a different package memory locations	Y	Y	Y

5.2.6   Select the 'user level' from the above window and enter password and following window will be displayed:

5.2.7   Select the 'function key' from the above window and following window will be displayed then switch 'ON' the carton vacuum, leaflet vacuum, conveyor, blister infeed, guard bypass (Only during machine setting), Inching on (during machine setting).

5.2.8   Select the 'machine Setting' option and in this window we can set standards values against the observed values after running of few cycle of machine in 'inch mode' for given parameters in window:

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5.2.9   Select the 'machine setting' option from the window and following optioned shall be displayed:

5.2.10   Select the 'alarm/event' optioned from the window and this will shows the description of error observed as below given:

5.2.11   Select the 'monitor' option from the window and in this window we can observed the position of different working device e.g. leaflet insertion, carton folding. It must be at zero position.

5.2.12   **Product/Blister Magazine:**

5.2.12.1   This stores various size of blister.

5.2.12.2   Adjust the side support on conveyer belt as per the width of blister.

5.2.12.3   Change the collator magazine as per the product.

5.2.12.4   Set the number of blister count parameter as per the requirement, from the MMI (in DROP COUNT Option). This releases the selected number of blisters in the cell angle one after another and then magazine swings back to match with the next cell angle.

5.2.12.5   For this press EDIT the screen displays.

POSITION	**pam-pac**		SPEED	
MODE			STATUS............	
DATA EDIT				
SET CAM			SPEED	
	SET POCKET			
SET COUNTER			DROP COUNT	
BEGIN	**EDIT**	**MONITOR**	**ALARM**	**EVENT**	**LOG IN**

5.2.12.6   Set the speed of machine by pressing the 'speed' option, number of counts by pressing the 'drop count' option.

5.2.13   **Product/Blister Chain:**

5.2.13.1   The chain has pocket angle (cell angles) mounted on it. The product /blisters carried between these angle.

5.2.13.2   Set the distance between the pocket angle (cell angles) width as per the width of product.

5.2.13.3   The product chain is made in two sections one is fixed and another is adjustable.

5.2.14   **Product Sensor:**

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5.2.14.1   This unit senses the product present in cell angle. This sensor senses the metal flat only when required number of blisters is available in the product chain.

5.2.14.2   If no blister is available or it is less then the required number of blisters, carton will not pickup and product pusher will not operate.

5.2.14.3   Adjust the height of product sensor with respect to number of blister height.

5.2.14.4   Adjust the height of blister top support guide with respect to number of blister height.

5.2.15   **Carton Magazine:**

5.2.15.1   This unit stores the cartons.

5.2.15.2   Set the carton magazine according to the length and width of the carton. The carton withdrawal is controlled by product sensor/leaflet sensor and electromagnet. If the product is missing, no carton is released. This achieved by cutting "off" the vacuum. If product is present in pocket, carton is sucked from the magazine.

5.2.15.3   The carton sucked from the carton magazine, comes down to carton support assembly (with flaps open) and transfer to the carton chain by the pusher.

5.2.16   **Carton Chain and Pusher:**

5.2.16.1   Carton chain holds and carries the carton while it gets opened, filled and closed.

5.2.16.2   Set the width of carton holder in carton chain as per the length and width of carton.

5.2.16.3   Set the height of top support guide as per the height of carton.

5.2.16.4   Set the adjustable side wall as per the width of carton.

5.2.16.5   Set the height of front and rear flap closers as per the height of carton.

5.2.16.6   Set the side wise position of flap opener finger by loosening the clamping screw of finger and the top most position adjustment by sprocket angular position.

5.2.16.7   Check the correct position by rotating the machine by hand wheel. The finger should open.

5.2.16.8   Change the pusher as per the product. (The pushing phase of the pusher tip should be in line with the pusher rod front face else it might damage the chain plates during rotation). Take pusher chain in center of the cell angle pocket by loosening the respective bolt. For checking rotate the entire pusher unit by hand.

5.2.17   **Leaflet Setting:**

5.2.17.1   Set leaflet magazine as per the length and width of leaflet.

5.2.17.2   Match the timing of leaflet transfer to leaflet chain by M 6 leaflet unit drive bolt.

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5.2.17.3   If no blister or less blister come on product chain then no leaflet will not pick-up.

5.2.18   **Rejection Sensor:**

5.2.18.1   This sensor senses the metal flat only when required number of blisters is available in the carton.

5.2.18.2   Adjust the height of rejection sensor with respect to number of blister height present in carton.

5.2.18.3   The height of sensor should be 1.0 mm more then the number of blisters present in carton.

5.2.18.4   It will stop the machine with carton having the less or more number of blisters as per the standard.

5.3   **OPERATION:**

5.3.1   Replace the 'CLEANED' status label with dully filled and signed 'UNDER PROCESS' status label.

5.3.2   Record the operation start time in the equipment usage log sheet as per SOP.

5.3.3   Switch over the machine to 'run mode' by moving the key to the left.

5.3.4   Press the start push button given on HMI.

5.3.5   After completion of batch switch off the machine by pushing the 'OFF' push button given on HMI.

5.3.6   Record the Operation end time in the Equipment usage log sheet as per SOP.

5.3.7   Replace the "Under Process" label with 'To Be Cleaned' label'.

5.4   **Precautions:**

5.4.1   Only authorized person should run the machine in 'inch' mode. Do not run production cycle in 'inch' mode.

5.4.2   All safety interlocks are bypassed in 'inch' mode.

5.4.3   For machine operation the compressed air pressure should not be less than 6 kg/cm^2.

5.4.4   Do not operate the machine with out proper earthing.

5.5   **SETTING OF PHARMA CODE READER FOR CARTON AND LEAFLET:**

5.5.1   **Pharma code setting for carton (Camera 1):**

5.5.1.1   Ensure that 'PACK i 2 CAM' print check system is cleaned.

5.5.1.2   Get the line clearance by Quality Assurance.

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5.5.1.3   Switch 'ON' the mains. Switch 'ON' the console unit by pressing switch on the right side wall of the console unit.

5.5.1.4   "PACK i 2 CAM" screen will be displayed asking for login name and password.

5.5.1.5   System show three types of login levels and they have a specific right assignment.

5.5.1.6   Following tables given below according to user rights.

S.No.	Type of Functions	User Rights Assignment (Y/N)		
		Operator	**Supervisor**	**Manager**
1.	**To create new 'user' & 'password'**	**N**	**N**	**Y**
2.	**To prepare Recipe**	**N**	**Y**	**Y**
3.	**To set the eject count**	**N**	**Y**	**Y**

5.5.1.7   Then system will go in learn 'MODE'. When carton pass image will displayed on the screen.

5.5.1.8   To adjust the image position set the gap sensor position (horizontal can be adjusted)

5.5.1.9   To start fresh job it will display learn mode as waiting for carton.

5.5.1.10   Check camera, flash, trigger position, adjust proper light, no wrinkle or sag on label.

5.5.1.11   Then screen will display 'PLEASE SET IMAGE AND PRESS OK BOTTON' if image is 'ok' then press 'OK' (Rotate image by clicking on the rotate button to set angle (0,90,180, and 270)) Then press 'OK'.

5.5.1.12   The screen will display "Please give the area of reference".

5.5.1.13   Then supervisor gives AREA (ROI) & press OK button.

5.5.1.14   Select the pharmacode option green indicator of pharmacode will glow. Pop up window will be displayed.

5.5.1.15   Feed the pharmacode value directly or else to find value click on the bar code indicator.Choose thin and thick bar so that same combination of bar is produced. This will give pharmacode value in value indicator. Select the direction arrow, value will change.

5.5.1.16   Select appropriate direction and click OK and press 'CLOSE' to return main screen.

5.5.1.17   Give ROI on pharmacode. In right centre in preview window mage of pharmacode will be displayed. This bar code should be always vertical, if it is horizontal use rotate button and set the vertical by giving proper angle. Pharmacode value is displayed in left bottom.

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5.5.1.18   Press test button to check the pharmacode value if pharmacode value is wrong then it shows 'Pharma value is hard to analyze'. Give proper ROI or press direct button". If Pharma value is scanned successfully. Than it shows 'Pharma value is scanned successfully'. Press 'OK' button to exit Pharma setting.

5.5.1.19   For ejector system of cam 1, label / product must be have zero value.

5.5.2   **Pharmacode setting for Leaflet (Camera 2):**

5.5.2.1   In option window click on the Pharmacode option, green indicator of Pharmacode will glow. Pop up window will be displayed.

5.5.2.2   Set the Pharmacode same as Cam 1 as per point 5.5.1.1 to 5.5.1.19.

5.5.2.3   Set Mini, Rotation, Band values.

5.6   **Enter Job Name:**

5.6.1   Click on text box 'JOB NAME'. Keypad will appear ENTER job name with the help of keypad. After click 'OK' keypad will appear again

5.6.2   Enter new job name and press 'OK' to return main menu.

5.6.3   Click on 'ECS' option and window will open with avg. time value.

5.6.4   Now pass approx six carton in front of camera and some value will be displayed.

5.6.5   Now click on load option and then select 'OK'.

5.7   **LOAD FROM PREVIOUS JOB:-**

5.7.1   Click 'load button' and give job name and click 'OK' button to return main screen.

5.7.2   Press 'start' button to run the job.

5.8   **SELECTION OF MACHINE EJECTION CONTROL:-**

5.8.1   Enter no. of blister between camera and blister gap sensor.

5.8.2   Click 'OK' to return main menu.

5.9   **CHALLENGE TEST FOR PHARMACODE READER FOR CARTON:**

5.9.1   After setting of pharmacode reader, production,QA officer shall take a single good carton of product, which has to be printed.

5.9.2   Pass that carton through machine, it should pass through the machine.

5.9.3   Now mark one or two extra lines in pharmacode.

5.9.4   Now again pass this carton with extra line through machine.

5.9.5   The machine shall reject this carton by ejector mechanism in to rejection box.

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FREQUENCY :Challenge test shall be performed at start after every four hours and at end of operation.

5.10 **CHALLENGE TEST FOR PHARMACODE READER FOR LEAFLET:**

5.10.1 After setting of pharmacode reader, production,QA officer shall take a single good leaflet of product.

5.10.2 Pass that leaflet through machine, it should pass through the machine.

5.10.3 Now mark one or two extra lines in pharmacode.

5.10.4 Now again pass this leaflet with extra line through machine.

5.10.5 The machine shall reject leaflet by ejector mechanism in to rejection box.

Record the observation in Annexure-I.

6.0 **ABBREVIATION (S):**

SOP : Standard Operating Procedure

MMI : Man-Machine Interface

PLC : Programmable Logical control

No. : Number

SOP : Standard Operating Procedure

v/v : Volume / Volume

% : Percentage

ROI : Region Of Interest

OCR : Optical Character Recognition.

7.0 **REFERENCES:**

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

SOP No. Restricted use (password protected) of system

8.0 **ANNEXURE (S):**

Annexure-I: Challenge test for camera inspection system (Propix Technology) for carton and leaflet.

Annexure-II: Cleaning checklist of Autocartonator (HI-CART).

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9.0   DISTRIBUTION:

Master Copy: Quality Assurance

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ANNEXURE I
CHALLENGE TEST FOR PROPIX CAMERA SYSTEM (PACK i 2) FOR SCANNING OF CARTON & LEAFLET

DATE	TIME	Pharmacode value		# For leaflet Pharmacode reader (Camera 1)	# For carton Pharmacode reader (Camera 2)	CHECKED BY (Production)	VERIFIED BY (QA)
		Reference	***Observed**				

*   Record the pharmacode value displayed on the HMI .

\# Record OK if faulty leaflet rejected by camera system and record 'not Ok' if faulty leaflet not rejected by camera system.

\#   Record OK if faulty carton rejected by camera system and record 'not Ok' if faulty carton not rejected   by camera system.

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ANNEXURE II

Cleaning and Operation of Autocartonator machine (Model: HI-CART) with Propix camera inspection system for pharma code scanning of carton and leaflet (PACK i 2)

Name of the Equipment		AUTOCARTONATOR (HI-CART) machine	
Equipment I.D. No.		Previous	
Batch No.		Date	

S. No.	Activity	Activity Performed
1.	Replace the 'UNDER PROCESS' status label with 'TO BE CLEANED' status label with date and sign of the production officer.	
2.	Record the cleaning start time in equipment usage log as per SOP No.: PG/178.	
3.	Remove secondary packing material, blister and foil pieces, cartons and leaflets of previous product present on the carton packing machine.	
4.	Clean the conveyor belt, collator magazine, MMI, utility cables and other parts of machine with the help of clean lint free duster.	
5.	Wipe the machine with 70 % V/V IPA.	
6.	Replace the 'TO BE CLEANED' status label by 'CLEANED' status label with date and sign of the production officer / QA officer.	
7.	If machine is not used with in 72 hours clean the machine "before use" with lint free duster dipped in 70% v/v IPA solution followed by dry lint free duster and dully sign the 'CLEANED' label again.	
8.	Record the activity in equipment usage log sheet as per SOP.	
9.	Record the cleaning activity in equipment usage log sheet as per SOP.	

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

Checked By (Prod.)
Sign/date

Verified By (QA)
Sign/date