



STANDARD OPERATING PROCEDURE

Department: Production

SOP No.:

Title: Operation and Cleaning of Automatic Cartoning Machine

Effective Date:

Supersedes: Nil

Review Date:

Issue Date:

Page No.:

1.0 OBJECTIVE:

To lay down a procedure for Operation and Cleaning of Automatic Cartoning Machine (HICART).

2.0 SCOPE :

This procedure is applicable to operation and Cleaning of Automatic Cartoning Machine (HICART).

3.0 RESPONSIBILITY:

Technical Associate : Cleaning and Operation.

Production: Officer /Executive/ Manager

Head Production: To ensure execution & compliance

4.0 PROCEDURE:

4.1 Cleaning Procedure:

4.1.1 Replaced the 'UNDER PROCESS' status label by 'TO BE CLEANED' status label then 'UNDER CLEANED ' while starting the cleaning procedure.

4.1.2 Switch 'OFF' the utility supply before clearing

4.1.3 Remove any packing component stuck in the machine parts. Clean the machine using compressed air to blow the turned packing component.

4.1.4 Use compressed air to remove any remnant of previous product from cartoning machine.

4.1.5 Clear the carton magazine, leaflet magazine and conveyor for the remnant of previous batch/product.

4.1.6 Wet mop the whole machine with lint free cloth soaked in the purified water and cleans the belt.

4.1.7 Clean the clutch brake assembly with lint free cloth.

4.1.8 Clean the machine thoroughly from in and out with lint free cloth soaked in purified water.

4.1.9 Clean the Product conveyor, carton magazine, MMI, utility cables and other parts of machine,



STANDARD OPERATING PROCEDURE

Department: Production

SOP No.:

Title: Operation and Cleaning of Automatic Cartoning Machine

Effective Date:

Supersedes: Nil

Review Date:

Issue Date:

Page No.:

with the help of dry lint free duster.

- 4.1.10 Remove the coding stereo of previous batch from cartoning machine and destroy as per SOP.
- 4.1.11 Visually ensure that machine and area is free from carton, blister and leaflets or its fragments and all the materials of previous batch are removed.
- 4.1.12 Replace the 'TO BE CLEANED' status label by 'CLEANED' status label with date and signature of the production officer.
- 4.1.13 Record the cleaning start time and end time in equipment usage log book and area cleaning as per SOP.

Frequency: Batch changes over / major break down / scheduled maintenance /product change over.

4.2 Machine Setting:

- 4.2.1 Ensure the cleanliness of the machine and area.
- 4.2.2 Remove 'CLEANED' status label and affix 'UNDER PROCESS' status label after line clearance from QA.
- 4.2.3 Switch "ON" the mains and release the emergency switch (if applicable).
- 4.2.4 Open the valve of compressed air.
- 4.2.5 Switch "ON" the PLC and then HMI screen and set the machine in "SET MODE" for initial machine setting.
- 4.2.6 Enter the PLC system and press the "Alarm" to check the any fault. If there is any fault rectify the same before start initial machine setting.
- 4.2.7 If any of the logic sensors are not in proper position then set the position of the sensors accordingly.



STANDARD OPERATING PROCEDURE

| | |
|---|------------------------|
| Department: Production | SOP No.: |
| Title: Operation and Cleaning of Automatic Cartoning Machine | Effective Date: |
| Supersedes: Nil | Review Date: |
| Issue Date: | Page No.: |

4.2.8 The below screen of HMI will display as-

| | | | |
|--|-------------------------------------|-------------|------|
| POSITION | ACG - pampac HICART PLUS | MODE | Date |
| SPEED | | STATUS..... | Time |
| CPM | | | |
| <p>WELCOME TO ACG pam pac</p> <p>ACG world wide</p> <div style="border: 1px solid black; padding: 5px; display: inline-block; margin: 10px auto;">LOG IN</div> <p>ACG world wide</p> | | | |

4.2.9 Press LOG IN and enter the level and pass word as per the authorization.

4.2.10 Press "HOME" the HMI will display as-

| | | | | | |
|------------------------------|-------------------------------------|------------------------------------|---------------------------|----------------------|---------|
| POSITION | ACG - pampac HICART PLUS | MODE..... SET/(INCH) | | | |
| SPEED | | USER:OPERATOR | | | |
| HOME | Functional Keys | Machine Setting | System Setting | Alarm / Event | Monitor |
| Counter | | | Hour Meter | | |
| Good Packs | <input type="text"/> | Total | <input type="text"/> | <input type="text"/> | |
| Rejected Packs | <input type="text"/> | Shift | <input type="text"/> | <input type="text"/> | Reset |
| Reset | | | | | |
| Vacuum | Link Up | Camera | Attach | | |
| <input type="text"/> Carton | <input type="text"/> Convevor | <input type="text"/> Leaflet Front | <input type="text"/> Glue | | |
| <input type="text"/> Leaflet | <input type="text"/> Ext Convevor | <input type="text"/> Leaflet Back | <input type="text"/> Inch | | |
| | <input type="text"/> Line M/C | <input type="text"/> Carton Code | | | |
| | | <input type="text"/> Booklet Code | | | |

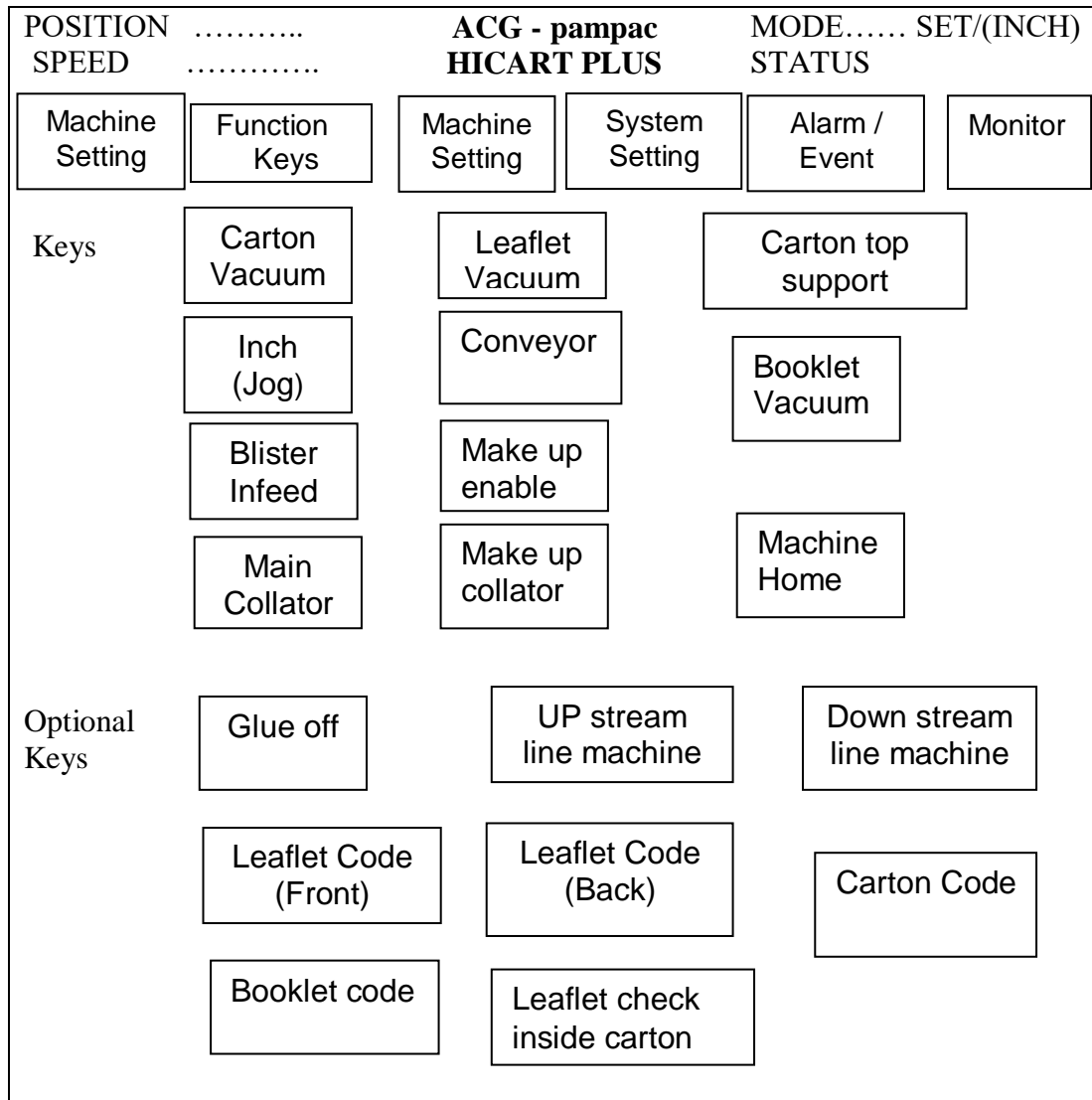


STANDARD OPERATING PROCEDURE

| | |
|---|------------------------|
| Department: Production | SOP No.: |
| Title: Operation and Cleaning of Automatic Cartoning Machine | Effective Date: |
| Supersedes: Nil | Review Date: |
| Issue Date: | Page No.: |

4.2.11 Press and switch “ON” the Carton Vacuum, leaflet vacuum (if required) and Conveyer Inch On during machine setting and set per as given below.

4.2.12 Press “Functional Keys” the HMI will display as-



4.2.13 Product Magazine

- 4.2.13.1 This stores no. of blisters as required.
- 4.2.13.2 Adjust the side support on conveyer belt as per the width of blister.
- 4.2.13.3 Change the collator magazine as per the product.
- 4.2.13.4 Set the number of blister count parameter as per the requirement, from the MMI (in DROP



STANDARD OPERATING PROCEDURE

Department: Production

SOP No.:

Title: Operation and Cleaning of Automatic Cartoning Machine

Effective Date:

Supersedes: Nil

Review Date:

Issue Date:

Page No.:

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.

4.2.13.5 Minimum level of blisters is required in collator magazine, when the levels go below the set level, optical sensor senses the level and stop releasing the blisters then blisters from blister machine are dropped into the magazine.

4.2.14 Product Chain

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

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

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

4.2.15 Product Sensor

4.2.15.1 This unit senses the product present in cell angle. A required number of blisters are available in the product chain.

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

4.2.15.3 Adjust the height of product sensor and blister top support guide with respect to number of blister height.

4.2.16 Carton Magazine

4.2.16.1 The carton feeding system is based on vacuum pickup.

4.2.16.2 Set the carton magazine according to the length and width of the carton.

4.2.16.3 The carton withdrawal is controlled by product / leaflet sensor (if required) and electromagnet. If the product is missing, no carton is released. This is achieved by cutting "Off" the vacuum. If product is present in pocket, carton is sucked from the magazine.

4.2.16.4 The carton is pushed towards the product chain by the carton pusher.

4.2.16.5 The carton is pushed forward in two stages.

- The carton is partially pushed forward.
- Pushed forward until the flaps contact with the outer surface.

4.2.17 Carton Chain and Pusher

4.2.17.1 Folding of backside flap before insertion the product and folding of front side flap after the



STANDARD OPERATING PROCEDURE

| | |
|---|------------------------|
| Department: Production | SOP No.: |
| Title: Operation and Cleaning of Automatic Cartoning Machine | Effective Date: |
| Supersedes: Nil | Review Date: |
| Issue Date: | Page No.: |

insertion product.

- 4.2.17.2 The carton and product are now at the insertion station.
- 4.2.17.3 The loading pusher then pushes the product (with or without enclosure) continuously.
- 4.2.17.4 The carton with product then moves towards stereo roller for coding on flap and then for closing station.
- 4.2.17.5 If product gets stuck, the pusher will not move forward.
- 4.2.17.6 The cartons are closed back and front simultaneously. This takes place in three stages as Bending of tuck-in flap, Pushing in of tuck-in flap, Locking of carton.
- 4.2.17.7 After closing, the carton is conveyed through the carton chain towards the discharge belt and moves towards check weigher after coding in cartonator or moves towards Condot printer (if applicable).

4.2.18 Rejection Sensor

- 4.2.18.1 This sensor senses the metal flat only when required number of blisters is available in the carton.
- 4.2.18.2 Adjust the height of rejection sensor with respect to number of blister height present in carton.
- 4.2.18.3 The height of sensor should be 1.0 mm more than the number of blisters present in carton.
- 4.2.18.4 It will reject the carton having the less or more number of blisters as per the standard.
- 4.2.19 The machine setting parameter of MMI contains different keys as cam for cam setting, pocket setting, counter, timers, blister drop.
- 4.2.20 The blister drop parameter helps for dropping of blisters as per requirement.
- 4.2.21

| | | |
|----------------|---------------------|----------------------|
| POSITION | ACG - pampac | MODE..... SET/(INCH) |
| SPEED | HICART PLUS | STATUS |



STANDARD OPERATING PROCEDURE

Department: Production

SOP No.:

Title: Operation and Cleaning of Automatic Cartoning Machine

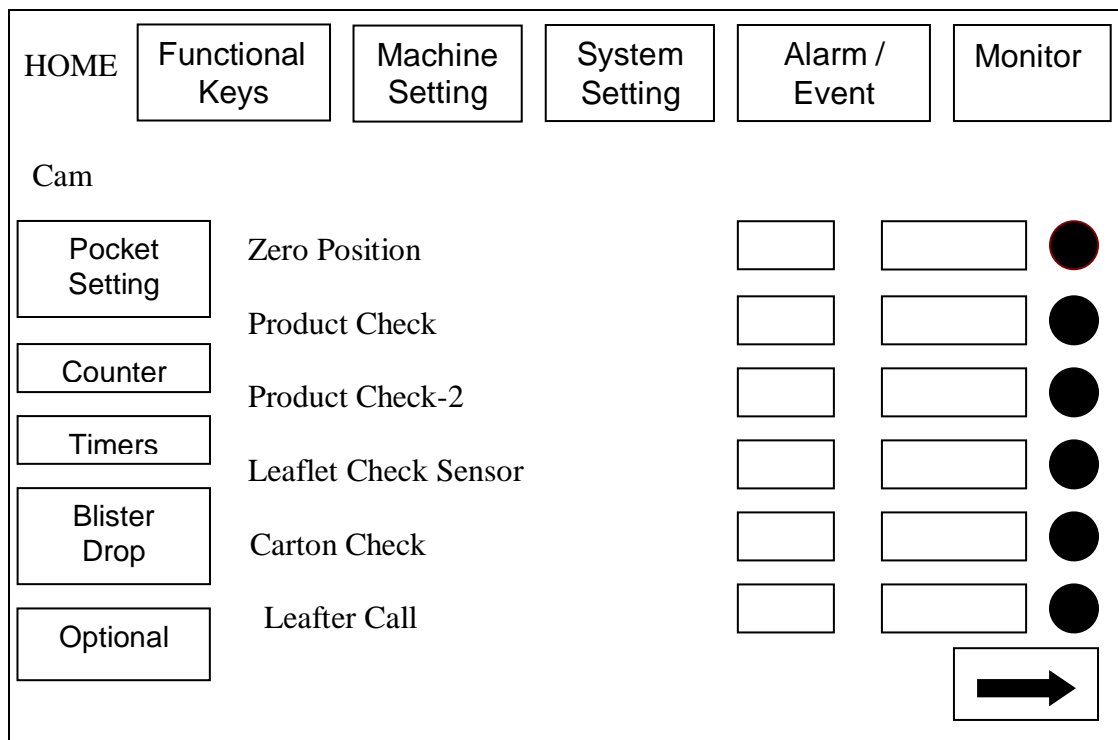
Effective Date:

Supersedes: Nil

Review Date:

Issue Date:

Page No.:



4.3 Operation:

- 4.3.1 After line clearance from QA, put the “UNDER PROCESS” label on the machine.
- 4.3.2 Open the compress air valve, switch ‘ON’ the main supply to machine by pressing the green button.
- 4.3.3 Load carton magazine and leaflet magazine with carton and leaflet respectively.
- 4.3.4 Push ‘ON’ carton vacuum, leaflet vacuum and blister feed on main MMI panel.
- 4.3.5 Check and ensure that the data relevant to cam setting, counter setting, pocket setting and drop box count are fed in the data entry file of MMI panel.
- 4.3.6 After setting machine parameters switch over the machine to ‘RUN MODE’ by turning key to the left and start machine by pressing green ‘Machine Start’ push button and get one carton formed and get print. Attached it in BPR.
- 4.3.7 In case any fault message will come on screen, rectify the same and press ‘RESET’ button.
- 4.3.8 Ensure that all guards shall close and Set speed of machine by rotating knob on panel.
- 4.3.9 Ensure that the blister collator is fitted properly and is touching the conveyer angle while



STANDARD OPERATING PROCEDURE

Department: Production

SOP No.:

Title: Operation and Cleaning of Automatic Cartoning Machine

Effective Date:

Supersedes: Nil

Review Date:

Issue Date:

Page No.:

operating.

- 4.3.10 Ensure that the blister feeding from collator to pocket of conveyer is smooth. If not set the collator for drooping of blister into pocket of conveyer.
- 4.3.11 Ensure that the sensors are sensing the presence of required no. of blister.
- 4.3.12 Ensure that the sensor are sensing the presence of blister, leaflet and carton at respective position.
- 4.3.13 Ensure that leaflets are dispensed in gripper of pocket in which blister are present.
- 4.3.14 Ensure that carton are dispensed in same pocket of conveyer in which leaflet are present both flap are closed properly.
- 4.3.15 Ensure that pusher does't push blister when carton not present in respective section and machine stopped.
- 4.3.16 Continuously run the machine, regular feed carton magazine and leaflet assembly with carton and leaflet respectively.
- 4.3.17 Ensure that batch coding is at proper place of carton flap, if not reset it.
- 4.3.18 Challenge the machine for non-availability of leaflet/blister.
- 4.3.19 Record the operation start time and end time in the Equipment usage log book as per SOP.

4.4 Precaution:

- 4.4.1 Only authorized person should run the machine. In "SET MODE" and "RUN MODE" is protected with password.
- 4.4.2 Do not run productions cycle in "SET MODE" because all the safety interlocks are bypassed in inch mode.
- 4.4.3 For machine operation the compressed air pressure should not be less than 6kg/cm²
- 4.4.4 Do not operate the machine without proper earthing.
- 4.4.5 No product or hardware etc. must fall and entangle in the product chain (i.e. under the product slats) else machine will get locked.

4.5 Shut Down Operation:

- 4.5.1 After completion of process push the red button and stop the machine.
- 4.5.2 Put "OFF" the "CARTON VACUUM" and "LEAFLET VACUUM" (if required) on the screen of HMI.



STANDARD OPERATING PROCEDURE

Department: Production

SOP No.:

Title: Operation and Cleaning of Automatic Cartoning Machine

Effective Date:

Supersedes: Nil

Review Date:

Issue Date:

Page No.:

- 4.5.3 Close the compression air valve.
- 4.5.4 Remove leftover carton, leaflet (if required) and Blister from the magazine or device.
- 4.5.5 Unload the carton & leaflet (if required) on the proper place.
- 4.5.6 Record the operation end time in the Equipment usage log book.
- 4.5.7 Press the red button "OFF" provided on back side of machine in front of electrical panel.

4.6 Change Over Procedure:

- 4.6.1 Set the carton magazine with the ganter scale readings as per carton size.
- 4.6.2 Do the carton transfer setting from carton magazine to carton chain.
- 4.6.3 Check for proper positioning of cartons on carton chain.
- 4.6.4 If required set the carton chain length, width and height.
- 4.6.5 Set the product chain width as per blister size.
- 4.6.6 Set the leaflet (if required) magazine as per leaflet size.
- 4.6.7 Match the timing of the turret with the leaflet (if required) clamp assembly.
- 4.6.8 Set the safety guard so that the carton will properly fix on the carton chain.
- 4.6.9 Set the product pusher as per blister size.
- 4.6.10 Check for proper closing of cartons.
- 4.6.11 Adjust the printing unit as per carton size.
- 4.6.12 Adjust the guide rail of carton transfer belt as per carton size.
- 4.6.13 Set the empty carton reject as per pack size from HMI.

5.0 ANNEXURE (S):

Nil

6.0 REFERENCE (S):

SOP: Preparation, approval, distribution control, revision and Destruction of Standard Operating Procedure (SOP).

SOP: Status Labeling in Production Dept.

SOP: Procedure for Area line clearance.

SOP: Procedure for indent, receipt issue, usage and destruction of rubber stereotypes.



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production

SOP No.:

Title: Operation and Cleaning of Automatic Cartoning Machine

Effective Date:

Supersedes: Nil

Review Date:

Issue Date:

Page No.:

7.0 ABBREVIATION (S) / DEFINITION (S):

SOP: Standard Operating Procedure

IPA: Isopropyl Alcohol

% : Percentage

HMI : Human Machine Interface

v/v : Volume/Volume

Kg /cm² : Kilogram per centimeter square

IPQA : In process Quality Assurance

PLC : Programmable Logic Control

REVISION CARD

| S.No. | REVISION No. | REVISION DATE | DETAILS OF REVISION | REASON (S) FOR REVISION | REFERENCE CHANGE CONTROL No. |
|-------|--------------|---------------|---------------------|-------------------------|------------------------------|
| 1 | 00 | --- | --- | New SOP | --- |