



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Cleaning and Operation of HI Cart machine (ACG Pam Pack, Model, HI Cart 5)	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

1.0 OBJECTIVE:

To lay down a procedure for Cleaning and Operation of HI CART machine.

2.0 SCOPE:

This procedure is applicable to Cleaning and Operation of HI CART machine in Tablet Production department.

3.0 RESPONSIBILITY:

Technical Associate: For cleaning and Operation.

Officer/ Executive Production/IPQA: For Supervision

Head Production: SOP Compliance.

IPQA: Line clearance and online process confirmation.

4.0 DEFINITION(S):

NA

5.0 PROCEDURE:

5.1 Cleaning:

- 5.1.1 Remove 'UNDER.PROCESS' label and affix 'TO BE CLEANED' label on the machine with date and sign of production officer.
- 5.1.2 Switch 'OFF' the utility supply before cleaning.
- 5.1.3 Remove any packing component stuck in the machine/machine parts. Clean the machine using compress air jet to blow the tornd packing component.
- 5.1.4 Clean the carton and leaflets magazine and conveyor for the remnant of previous of previous batch/pack.
- 5.1.5 Clean the formed carton conveyor and its surrounding.
- 5.1.6 Clean the rejection chute, rejection tray, machine cover and guards.
- 5.1.7 Physically examine the machine thoroughly and ensure that the machine is free from carton, blister and leaflets. Or its fragments.
- 5.1.8 Clean the exterior with duster.
- 5.1.9 Clean the control panel with clean and dry lint free duster.
- 5.1.10 Remove the coding detail of previous batch from condot printer.



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

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

5.1.13 Clean the surrounding area as per SOP.

5.2 OPERATING PROCEDURE:

5.2.1 Open the compress air valve, switch 'ON' the main supply to machine by pressing the green button.

5.2.2 Load carton magazine and leaflet magazine with carton and leaflets respectively.

5.2.3 Push 'ON' carton vacuum literature vacuum and blister feed on main MMI panel.

5.2.4 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.

5.2.5 In case any fault message will come on screen, rectify the same and press 'RESET'

5.2.6 Keep the mode key on 'RUN' position. Press machine 'ON' switch and get one carton formed and print. Attach it in BPR.

5.2.8 Ensure that the blister collator is fitted properly and is touching the conveyor angle while operating.

5.2.9 Ensure the following.

5.2.10 Blister feeding from collator to pocket of conveyor is smooth. If not set the collator for dropping of blister into pocket of conveyor.

5.2.11 Sensor are sensing the presence of req. no. of blister.

5.2.12 Sensor are sensing presence of blister, leaflets and cartons at respective position.

5.2.13 Leaflets are dispensed in gripper of pocket in which blister are present.

5.2.14 Carton dispensed in same pocket of conveyor in which leaflet are present both flap are close properly.

5.2.15 Pusher doesn't push blister when carton not present in corresponding section and machine stopped.

5.2.16 Continuously run the machine. Regular feed carton magazine and leaflet assembly with carton and leaflets respectively.

5.2.17 Ensure that batch coding is at proper place of carton flap, if not re-set it.

5.2.18 Challenge the machine for non-availability of literature/blister.

5.3 Shut Down:

5.3.1 Stop the machine and main drive when all the packs on the conveyor are discharged out.

5.3.2 Switch 'OFF' the drive and the machine. Switch 'OFF' main supply and compressed air valve.



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5.3.3 Empty carton magazine and leaflets holder. Keep the leftover material in original shipper.

5.3.4 Record the wastage of printed packing material in respective BPR. Destroy it after get checked by IPQA officer.

5.3.5 Record the output in BPR. Make entries in equipment usage log as per SOP.

6.0 ABBREVIATION (S):

SOP: Standard Operating Procedure.

MMI: Man Machine Interface

No.: Number

7.0 REFERENCE(S):

SOP: Status labeling

SOP: Equipment usage log.

8.0 ANNEXURE (S):

NA

9.0 DISTRIBUTION:

Master Copy: Quality Assurance

Controlled Copy (s): Production Department, Quality Assurance

Reference Copy (s): Production Department