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**1.0 OBJECTIVE:**

To lay down a procedure for Operation and Cleaning of Hi-Cart Cartoning Machine.

**2.0 SCOPE:**

This SOP is applicable for Operation and Cleaning of Hi-Cart Cartoning Machine (Make **Pampac**) used.

**3.0 RESPONSIBILITY:**

Operating Person-Production

**4.0 ACCOUNTABILITY:**

Head Production

**5.0 ABBREVIATIONS:**

BPR      Batch Packing Record

HMI      Human Machine Interface

IPA       Iso Propyl Alcohol

No.       Number

QA       Quality Assurance

SOP      Standard Operating Procedure

**6.0 PROCEDURE:**

**6.1 Precaution:**

**6.1.1** Line Clearance shall be taken by Production (Packing) Officer / Executive & given by QA Officer / Executive prior to startup of the Hi – Cart Machine.

**6.1.2** Do not rush while running the Machine to avoid any accidental injury or Packing of substandard Vial / Cartons / Leaflet.

**6.1.3** Impression of stereo should be taken on respective format and check all the text matter carefully.

**6.1.4** For verification of MRP of particular product refer the MRP mentioned in the SAP at location 1100 in case of Loan License Product (LL) OR 9700 in case of Principle to Principle (P2P) as well as the MRP mentioned in the Process Order & Conversion note.

**6.1.5** A special attention needed to check the letter looking similar like O & 0, I & 1, P & R, O & Q, I& L, C & G, E & F. For reference refer the **Annexure No.-I** titled as "**Identification of Similar Looking Letters**".

**6.1.6 Verification of Functional Unit:**

Operate the machine as per SOP and Check for the following functions of the machine.

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| S. No. | Station | Specification | Verification Procedure |
|---|---|---|---|
| 1. | Product Feeding System | To Transfer the Bottle Into the Product Pocket at Rated Speed | Check the Bottle Dropped without Damage |
| 2. | Prefolded Leaflet transfer system | The Leaflet as per Requirements Transfer Through Turret to Leaflet Clamps Provided on leaflet Chain. | Check the Leaflet Smooth Transfer of Leaflet Without Damage. |
| 3. | Carton Loading System | To Stack /Load the Carton as per Change Part into Carton Magazine & Carton to be Set With the Help of Adjustable Guides | Check Smooth Movement of Stacked Cartons in Carton Magazine for Easy Pickup |
| 4. | Carton Pick Up Transfer System | To Pick Up the Carton From Carton Magazine into Carrier Finger | Carton are Picked and Placed In The Carton Chain Pockets Properly without Damages |
| 5. | Product Pushing System | To Insert the Product into Carton along with Leaflets | Ensure that Smooth Insertion of Product & Leaflets into Carton Without Damage |
| 6. | Carton Closing System | To Close (Lock) the Cartons with the help of Tuck in Pusher & all Guide to be set with the help of Handle and Digital Ganters | Check the Carton are Getting Closed (locked) properly without damage. |
| 7. | Carton rejection System | To Reject the Carton which are Having No Product. | Check the carton and gets rejected as per specification mentioned along side |

**6.1.7 Operating Access Level:** The operating access level and their access authorization is as below:

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| Level | Level Name | Access Authorization |
|---|---|---|
| Level -1 | Operator | Home Screen, Function keys, Optional Keys, Alarm/Events, Monitor, Shift array, PLC Input, PLC Output, ECR Monitor. |
| Level -2 | Supervisor | Home Screen ,Function keys , Optional Keys, Machine Settings, cam, Pockets setting, Counter, timers, Blister Drop, Alarm/Event, Monitor ,Shift array. PLC Input Output, ECR Monitor, |
| Level-3 | Administrator | Set all above, System Setting +Project Setting, Print Information |

### 6.1.8  Detail of Alarm and Interlocking in the Machine:

| S.No. | Description of test | Message displayed on HMI | Result of test |
|---|---|---|---|
| 1. | Emergency switch pressed on HMI | Emergency stop at console | Machine should be stopped immediately. |
| 2. | Push Emergency switch pressed on discharge end | Emergency stop at discharge end | Machine should be stopped immediately. |
| 3. | Emergency switch at pressed at infeed | Emergency stop at machine infeed | Machine should be stopped immediately |
| 4. | Air pressure is less or below the set value | Low air pressure | Machine should be stopped immediately |
| 5. | Carton vacuum key off from HMI | Carton vacuum off | Machine should be stopped immediately |
| 6. | Leaflet vacuum key off from HMI | Leaflet vacuum off | Machine should be stopped immediately |

## 6.2    Operation:

**6.2.1**    Switch "ON" the Control Switch of the Machine.

**6.2.2**    Open the Compressed Air Valve & adjust the Compressed Air Pressure to 6.0 to 6.5 Kg/ cm$^2$.

**6.2.3**    Select login on HMI and enter user and password.

**6.2.4**    Turn the knob on control panel to SET mode to set the machine.

**6.2.5**    Feed the required Unit Cartons in the Carton Magazine.

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**6.2.6** Feed the required Leaflet in the Leaflet Magazine as per applicability.

**6.2.7** Fix the Rubber Stereo in Printing Block with the help of both side adhesive tape.

**6.2.8** Feed screw capped & checked labeled Vials in the M/c hopper.

**6.2.9** Select the function key option in HMI.

**6.2.10** Select the Machine Home, Turn Table, Conveyor, Carton Vacuum, Leaflet Vacuum and Inch in the Display Panel.

**6.2.11** Set the machine as per required pack size and carton coding setting.

**6.2.12** Turn the knob of the Set Mode to the Run Mode and press the "Machine On".

**6.2.13** Check the Batch Coding details on Unit Carton & get it approved from Production Officer & QA officer before running the Machine.

**6.2.14** After cartoning the vials, unit cartons comes out on conveyor belt where Air Jet has been provided to displace empty Carton if it comes.

**6.2.15** Check the individual packed carton for Batch Coding details and any damage.

**6.2.16** Reject and segregate any damaged carton and carton having improper batch coding detail. For reference refer the **Annexure No.-II** tilted as **"Reference examples of rejected cartons due to improper coding".**

**6.2.17** Segregate the rejected carton and keep into lock and key rejection bin.

**6.2.18** After completion of packing destroy the rejected carton and also consider during reconciliation of the same.

**6.2.19** Keep the good Packed Cartons in Shovel for shrink packing.

**6.2.20** Remove the vials and insert from rejected carton and pack into the good carton.

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**Figure- 1:** Hi-Cart Machine

**6.3** **Sensor Detail and Its Functional Role:** The sensor detail and its functional role is mentioned as below:

| S.No. | Sensor | Functional role of sensor |
|---|---|---|
| 1. | Continuous product sensor | This sensor senses the availability of product continuously in the infeed conveyor before star wheel. If gap between vials is more or any vial comes horizontally in the in feed conveyor the machine will be stopped. |
| 2. | Star wheel loading sensor | This sensor senses the overloading of the loading Star Wheel and in case of over loading the machine will be stopped. |
| 3. | Vertical product check | This sensor senses the direction of vial vertical or horizontal in the pocket. If any vial comes in vertical direction the machine will be stopped. |
| 4. | Product check | This sensor senses the availability of product in the product pocket. If product is not available in the pocket then leaflet will not picked up for the particular pocket. |
| 5. | Leaflet low level check | This sensor senses the level of leaflet in the leaflet magazine. If the level of leaflet comes upto low level sensor lever then machine will be stopped. |
| 6. | Leaflet check | This sensor senses the availability of leaflet for particular product. If leaflet is not available then carton will not picked up for the particular product. |
| 7. | Carton low level check | This sensor senses the level of carton in the carton magazine. If |

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| S.No. | Sensor | Functional role of sensor |
|---|---|---|
| | | the level of carton comes upto low level sensor lever then machine will be stopped. |
| 8. | Carton check | This sensor senses the availability of carton for particular product. If carton is not available for any particular product then product will get diverted without insertion. Means the in such case the pusher for this particular pocket will not move & product will remain in the pocket and product will be dropped into the rejection box at discharge end. |
| 9. | Half product insertion check | If product is not inserted completely into carton then machine will be stopped. |
| 10. | Hand wheel sensor | If during machine operation hand wheel comes out from its position then machine will be stopped to avoid any damage. |
| 11. | Arm reference sensor | This sensor gives command to the arm for rotation. |
| 12. | Carton flap home sensor | This sensor gives command to close the flap of carton. |
| 13. | Carton clutch sensor | This sensor senses the overloading of the carton chain clutch and in case of overloading the machine will be stopped. |
| 14. | Empty carton check | This sensor senses the availability of product in the folded carton. Any carton without product will be rejected and dropped into rejection box at discharge end. |
| 15. | Pusher loading sensor | This sensor senses the overloading on the product pusher and in case of over loading the machine will be stopped. |
| 16. | Machine home sensor | This sensor denotes the homing status of machine. |

**6.4    Challenge test:**

   **6.4.1**    Perform the challenge test of below sensor during operation of Hi-Cart machine. Action and observation is also mentioned in the below table.

| S.No. | Sensor | Action during challenge test | Observation |
|---|---|---|---|
| 1. | Vertical product check | Keep one product vertically before sensing | Machine should be stopped immediately |
| 2. | Product check | Manually take out one product from its pocket before sensing | Leaflet should not picked up for this particular pocket |
| 3. | Leaflet low level check | Remove leaflet from magazine up to the low level sensor lever | Machine should be stopped immediately |
| 4. | Leaflet  check | Remove one leaflet manually | Carton should not picked up for |

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| S.No. | Sensor | Action during challenge test | Observation |
|---|---|---|---|
| | | before sensing | the particular pocket |
| 5. | Carton low level check | Remove carton from magazine up to the low level sensor lever | Machine should be stopped immediately |
| 6. | Carton check | Remove carton manually from sucker arm before sensing | Product should get diverted without insertion |
| 7. | Empty carton check | Remove one product before insertion into carton | Carton should get rejected at discharge end |

**6.4.2** **Frequency of Challenge Test:** Perform the challenge test initially before start the machine operation and towards the end of operation.

**6.4.3** Record the challenge test and its observation as per **Annexure No-III** titled as **"Challenge test record during operation of Hi-Cart machine".**

**6.4.4** Give the justification if observation is found **Not OK**.

**6.4.5** Attach the filled annexure in the respective BPR.

**6.4.6** Record the operation details in respective "**Equipment's /Instruments Usage Cleaning Log**" as per **SOP.".**

## 6.5 Cleaning:

**6.5.1** After completion of Packing Operation remove the excess Packing Material from the Packing line and Machine.

**6.5.2** Collect the Rejected Cartons in separate crate or Poly Bag.

**6.5.3** Count the Rejected Cartons and record in the BPR.

**6.5.4** Put the Status Label "TO BE CLEANED" on the Machine.

**6.5.5** Transfer the Finished Goods to the Finished Goods Store.

**6.5.6** Remove the Stereos from the Machine and hand over the Production Officer/Executive for verification and destruction in presence of QA Officer / Executive.

**6.5.7** Run the Machine for cleaning.

**6.5.8** Use Compressed Air to clean the inner side of the Machine.

**6.5.9** Check the Machine and Area for remnant of the Processed Batch.

**6.5.10** Clean the surface of the Machine with the 70% IPA.

**6.5.11** Clean the area by Moping.

**6.5.12** Put the Status Label **"CLEANED"** on the Machine.

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**6.5.13** Record the maintenance/ cleaning details in respective "**Equipment's /Instruments Usage Cleaning Log**" as per **SOP No. HPD/078**.

## 7.0 ANNEXURES:

| ANNEXURE No. | TITLE OF ANNEXURE | FORMAT No. |
|---|---|---|
| Annexure-I | Identification of Similar Looking Letters | |
| Annexure-II | Reference sample of rejected cartons due to improper coding | |
| Annexure-III | Challenge test record during operation of Hi-Cart machine | |

**ENCLOSURES:** SOP Training Record.

## 8.0 DISTRIBUTION:

- Controlled Copy No. 01      Quality Assurance
- Controlled Copy No. 02      Production (I-Block)
- Controlled Copy No. 03      Production (Q-Block, Three Piece Section)
- Master Copy                Quality Assurance

## 9.0 REFERENCES:

- SOP: Product Packing Operation in Parenteral blocks.

## 10.0 REVISION HISTORY:

### CHANGE HISTORY LOG

| Revision No. | Change Control No. | Detail of Changes | Reason for Change | Effective Date | Updated By |
|---|---|---|---|---|---|
| | | | | | |

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**ANNEXURE –I**

**IDENTIFICATION OF SIMILAR LOOKING LETTERS**

| LETTER | SIMILAR LOOKING LETTER |
|---|---|
| C | G |
| E | F |
| I (I) | 1 (One) |
| L | I (I) |
| O (O) | 0(Zero) |
| O (O) | Q (Q) |
| P | R |

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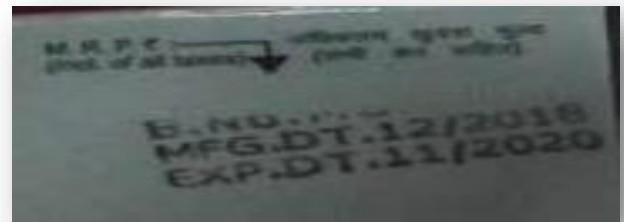| SOP No.: | | Department: | Production | |
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**ANNEXURE –II**
**REFERENCE SAMPLE OF REJECTED CARTONS DUE TO IMPROPER CODING**
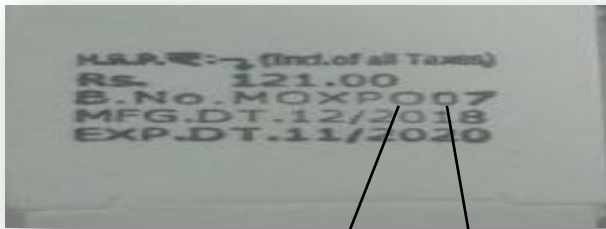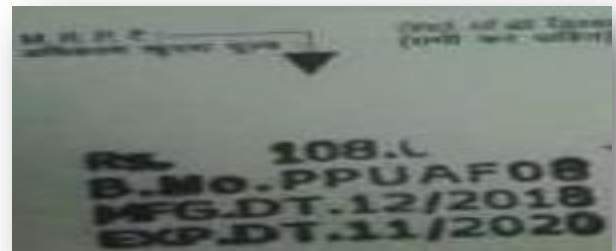


"O"     "Zero"
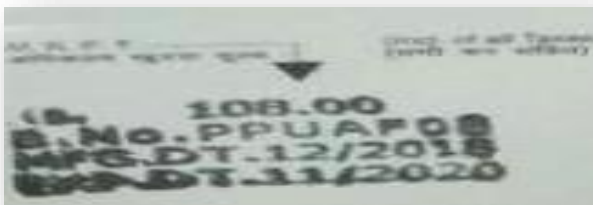
**Differentiation between "O" and "0" (zero)**



**Incomplete printing of batch detail**
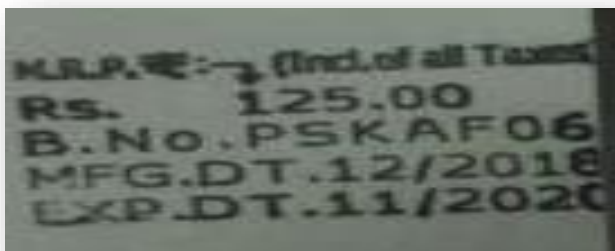


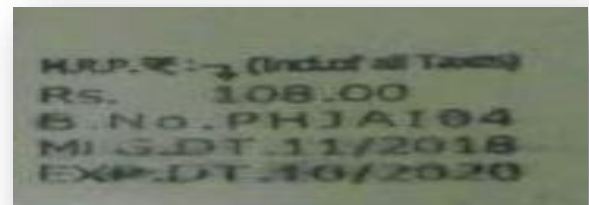**Incomplete printing of batch detail**



**Incomplete printing of batch detail**


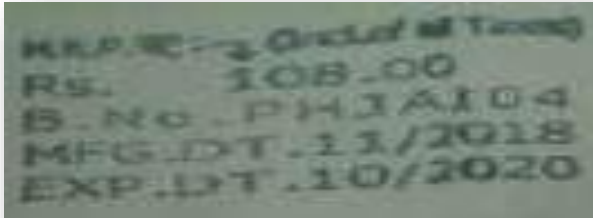
**Excess spreading of ink**



**Rubbing on printed batch detail**

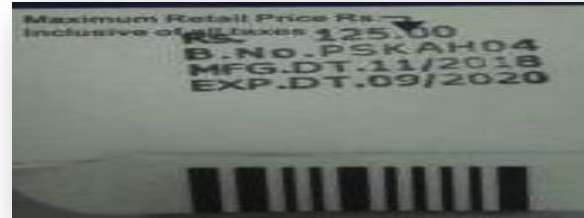| | PHARMA DEVILS | | | |
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**Faded printing of batch detail**



**Printing of batch detail in out of printing zone**

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### ANNEXURE –III
### CHALLENGE TEST RECORD DURING OPERATION OF HI-CART MACHINE

| Date | Product Name | B. No | Time | Challenge Test Observation(OK/Not OK) | | | | | | | Done By (Prod) | Checked By (Prod) | Verified By (IPQA) |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | Vertical product check | Product check | Leaflet low level check | Leaflet check | Carton low level check | Carton check | Empty carton check | | | |
| | | | | | | | | | | | | | |
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➢ **Frequency of Challenge test:** Initially before start the machine operation and towards the end of operation.

➢ Give Justification if observation is found **Not OK**.