



**OPERATIONAL QUALIFICATION
PROTOCOL CUM REPORT
FOR
HI- CART CODING MACHINE**

EQUIPMENT ID. No.	
LOCATION	PACKING HALL
DATE OF QUALIFICATION	
SUPERSEDE PROTOCOL No.	NIL



OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR HI-CART CODING MACHINE

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PHARMA DEVILS
QUALITY ASSURANCE DEPARTMENT

OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR HI-CART CODING MACHINE

1.0 PROTOCOL PRE – APPROVAL:

INITIATED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			
HEAD (ENGINEERING)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			



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2.0 OBJECTIVE:

- To verify that the equipment operates in accordance with the design requirements as defined by set Acceptance Criteria and complies with relevant cGMP Requirements.
- To verify the Operational features of Hi-Cart Coding Machine and to ensure that it produces desired Quality & rated output according to manufactures specifications.

3.0 SCOPE:

- The scope of this operational qualification protocol cum report is limited to qualification of **Hi-Cart Coding Machine (Make:.....)** installed in the Packing hall.
- This Protocol cum Report will define the methods and documentation used to perform OQ activity of Hi-Cart Coding Machine.
- Successful completion of this Protocol will verify that Hi-Cart Coding Machine meet all acceptance criteria and ready for Performance Qualification.



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4.0 RESPONSIBILITY:

The Validation Group, comprising of a representative from each of the following departments shall be responsible for the overall compliance of this Protocol cum Report:

DEPARTMENTS	RESPONSIBILITIES
Quality Assurance	<ul style="list-style-type: none">• Preparation, Review, Approval and compilation of the operational Qualification Protocol cum Report.• Co-ordination with Production and Engineering to carryout Operational Qualification.• Monitoring of Operation Process.• Post Approval of Qualification Protocol cum Report after Execution.
Production	<ul style="list-style-type: none">• Review of Operational Qualification Protocol cum Report.• To Co-ordinate and support for execution of Operational Qualification study as per Protocol.• Post Approval of Operational Qualification Protocol after Execution.
Engineering	<ul style="list-style-type: none">• Review of Operational Qualification.• To co-ordinate and support Operational Qualification Activity.• Calibration of Process Instruments.• Post Approval of Qualification Protocol cum Report after Execution.



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5.0 EQUIPMENT DETAILS:

Equipment Name	Hi-Cart Coding Machine
Equipment ID.	
Manufacturer's Name	
Supplier's Name	
Location of Installation	Packing Hall

6.0 EQUIPEMENT DESCRIPTION:

HICART PLUS is continuous motion cartooning machine, suitable for automatic cartooning of products like Ampoules, Bottles, tubes and blisters. The machine meets the need of high volume production, giving an output of upto 180 cartons/minute depending upon application. The machine performs the following functions:

- Receive unit product from upstream machine on product chain
- Storing of pre-broken cartons in flat form in the carton magazine
- Picking up the cartons from carton magazine with rotary pick up system
- Opening/erecting the carton
- Rear side flaps folding before product pushing
- Loading product
- Both side carton closing(front & rear sides)
- Discharge either to a bin or to downstream machine

The machine consists of following parts:

A. Product Chain: Product chain transports the product from receipt area to the pushing area. Product in feed occurs:

- On a pair of roller- supported, double transport chains,
- Guided in plastic plates,
- With adjustable product pockets.

B. Carton Chain: The carton chain transports open cartons from carton landing to carton closing.

Following Processes take place :

- Transfer and final erection of the cartons , Insertion of the product and leaflet
- Folding of the side flaps-front and rear sides, Printing/embossing of the flap, carton closing



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- C. Carton Loading Magazine:** The carton magazine holds various size of cartons. Magazine parts can be adjusted easily to accommodate various size of cartons with the help of numeric values. For each size/ type of carton, values can be noted down from numeric scales in the setting chart.
- D. Carton Pick-up & Transfer System:** The carton pick-up and transfer system picks up the folded carton with sucker arms from the carton magazine and then places it in the carton belt of the machine. Cartons are picked up by vacuum which is generated by vacuum pump/vacuum venturi. Suction cups mounted at the end of sucker arms for picking up. There are three vacuum & air control valves used in the unit. Two valves are connected to the vacuum lines of the two suckers and one of the pre-breaker.
- E. Carton Positioning:** The carton positioning unit consists of a carton pusher that pushes the carton towards the product chain from rear side of the machine.
- F. Rear Side Flaps Closing:** Rear side flaps closing takes place between carton loading on the carton chain and product pushing.
- G. Product pushing System:** The product pushing system is provided to push the product in to carton. It consists of product pushers that pushes the product and leaflet into the carton Pushing take place when the product and carton comes to the insertion point.
- H. Carton Closing:** After side flaps closing, carton comes to Main flaps closing system. Front and Rear flaps closing takes place simultaneously in 3 steps:
- Flap positioning:** Position for closing is done by creasing guide and guide rod. These are arranged to bend locking flap with main flap.
- Pre-closing & Complete Closing:** Pre-closing and complete closing is done by tuck in closers.
- I. Carton Discharge:** The closed cartons from the carton chain are transferred to the discharge belt. Discharge belt carry these cartons to the collector or line conveyor.
- J. Empty Carton Rejection System:** This System is provided to detect and reject the empty cartons from the discharge conveyor. A sensor is provided to detect the presence of product in the carton.
- K. Embossing/Printing Station:** This station has batch code embossing. A metallic roller folds embossing letters for coding. Carton flap is passed through the metallic roller and pressure roller to get the impressions of letters.
- L. Pre-Folded Leaflet Transfer System:** It transfer the folded leaflet into carton from magazine. The leaflet are picked by the sucker arm and then transferred to the transfer belts. Belts carries these leaflet upto the clamps, carry these leaflets to pusher station for insertion to carton.



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M. Bottle Transfer System: It is used for on-line transfer of bottles from upstream machine or turntable to product chain of carton packing. It contains major parts: Turn table, Transfer conveyor and Star wheel. The star wheel transfer the bottle to individual pockets. It picks one standing, bottle at a time from conveyor and drops them in the product chain and transfer to cartooning machine.

7.0 PRE - QUALIFICATION REQUIREMENTS:

7.1 Verification of documents:

The results of any tests should meet the limits and acceptance criteria specified in the test documents. Any deviations or issues should be rectified and documented prior to OQ commencing.

S.No.	Document Name	Document / SOP No.	Completed (Yes/No)	Checked By (Engineering) Sign/Date	Verified By (Quality Assurance) Sign/Date
1	DQ Protocol cum Report				
2	IQ Protocol cum Report				
3	Draft SOP for Operation & Cleaning of Hi-Cart Coding Machine				
4	Draft SOP for Preventive Maintenance of Hi-Cart Coding Machine				

Checked By
Production
Sign/Date:

Verified By
Quality Assurance
Sign/Date:.....

Inference:

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Reviewed By
Manager QA
Sign/Date:



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8.0 CRITICAL VARIABLES TO BE MET:

8.1 Operational and Functional Checks:

Operate the machine as per Manufacturer's Manual/SOP and Check for the following functions of the Equipment.

Component/ System	Procedure	Acceptance criteria	Observation	Observed By (Engineering) Sign/Date
Product Feeding System	Check the bottle dropped without any damage	Bottles should be transfer into the product pocket at rated speed without any damage		
Prefolded Leaflet transfer system	Check the transfer of leaflet without any damage	Folded leaflets will be picked and transfer through turret to leaflets clamps provided on leaflet unit		
Carton Magazine	Check smooth movement of stacked cartoons in carton magazine for easy pickup	Carton movement should be smooth in magazine		
Carton pickup and transfer system	To pick up the cartons from carton magazine and transferred into carton chain pockets.	Cartons will be pick and place in the carton chain pockets properly without damages		
Product Pushing system	To insert the product into carton along with leaflets	Ensure that smooth insertion of product & leaflets into cartons without damage		



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Component/ System	Procedure	Acceptance criteria	Observation	Observed By (Engineering) Sign/Date
Carton Closing System	Check the cartons are getting closed properly without damage	Cartons will be close with the help of tuck in pushers and all guides		
Carton Rejection system	Check the cartons gets rejected	Cartons without products should be rejected		
Main Power ON/OFF	Switch ON the POWER Button	Power will ON		
	Switch OFF the POWER Button	Power will OFF		
Speed Regulator (Potentiometer)	Rotate the potentiometer clockwise	Speed will increase		
	Rotate the potentiometer anticlockwise	Speed will decrease		
Run/Set Mode Key	Turn the key to left side for run mode and right side for set mode	Indication will appear on HMI screen and machine will operate in respective mode		
Main FRL Pressure Regulator	Rotate the regulator clockwise	Pressure will increase		
	Rotate the regulator anticlockwise	Pressure will decrease		
Access Level & Passwords				
Operator Level (1)	Enter the password for operator level	Functional keys will appear		



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Component/ System	Procedure	Acceptance criteria	Observation	Observed By (Engineering) Sign/Date
Supervisor Level (2)	Enter the password for Supervisor level	Functional keys, bits and counter will appear		
Administrator Level	Enter the password for Administrator level	Functional keys, bits, System settings, rejection status and counter will appear		
Speed Verification with HMI				
HMI verification	Set the machine speed on HMI, Run the machine for one minute and check the carton	Physically checked carton should be matched with display set speed.		
Sensor Verification				
Vertical Bottle Check	Keep the bottle vertical before sensing	Machine will stop immediately		
Product check	Take out the product manually before sensing	Leaflet will not picked up for the particular pocket		
Leaflet check	Remove leaflet manually before sensing	Carton will not picked up for the particular pocket		
Empty carton check	Remove product before insertion into carton	Carton will get rejected at discharge end		
Carton low level check	If the carton found below the low level sensor	Machine will stop after set time display alarm		



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Component/ System	Procedure	Acceptance criteria	Observation	Observed By (Engineering) Sign/Date
Leaflet low level check	If the carton found below the low level sensor	Machine will stop after set time display alarm		

Checked By
Production
Sign/Date:

Verified By
Quality Assurance
Sign/Date:

Inference:

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Reviewed By
Manager QA
Sign/Date:



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8.2 Alarms & Safety Interlocks Verification:

Item	Procedure	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Carton vacuum off	Cut off the vacuum for carton	Machine will not start in run mode		
Carton top support open	Open the carton top support	Machine should stop immediately and will not start		
Air Pressure Low	Low the air pressure below 3 bar	Machine will stop immediately & will not start		
Low level carton in magazine	Lower the level of carton in magazine	Machine will stop as per set time		
Low level leaflets in magazine	Lower the level of leaflets in magazine	Machine will stop as per set time		
Empty carton detection	Put the carton without product	Carton without product will gets rejected at discharge end		
Machine Gaurds open	-	Machine will stop immediately		
Product sensor	-	Leaflet will not be picked up		
Leaflet sensor	-	Carton will not be picked up		
Carton not sensed	-	Product pusher will get diverted		

Checked By
Production
Sign/Date:

Verified By
Quality Assurance
Sign/Date:

Inference:

.....
.....

Reviewed By
Manager QA
Sign/Date:



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8.3 Power Failure Verification:

Item	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Main Power Shut Down	Equipment stops in a safe and secure condition.		
Main Power Restored	Equipment can be restarted with no problems or adverse conditions.		

**Checked By
Production
Sign/Date:**

**Verified By
Quality Assurance
Sign/Date:**

Inference:

.....
.....

**Reviewed By
Manager QA
Sign/Date:**



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9.0 REFERENCES:

- Vendor Documents
- Operation and Maintenance Manual

10.0 DOCUMENTS TO BE ATTACHED:

- Any other Relevant Documents.

11.0 DEVIATION FROM PREDEFINED SPECIFICATION IF, ANY:

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12.0 CHANGE CONTROL, IF ANY:

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13.0 REVIEW (INCLUSIVE OF FOLLOW UP ACTION, IF ANY):

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14.0 CONCLUSION:

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15.0 RECOMMENDATION:

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16.0 ABBREVIATIONS:

- No. : Number
- WHO : World Health Organization
- cGMP : Current Good Manufacturing Practices
- DQ : Design Qualification
- IQ : Installation Qualification
- OQ : Operational Qualification
- SOP : Standard Operating Procedure
- MOC : Material of Construction
- SS : Stain less Steel
- ID : Inner Diameter



OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR HI-CART CODING MACHINE

17.0 POST APPROVAL:

INITIATED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			
HEAD (ENGINEERING)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			