



**PERFORMANCE QUALIFICATION PROTOCOL FOR HI-CART CODING MACHINE**

**PERFORMANCE QUALIFICATION  
PROTOCOL  
FOR  
HI- CART CODING MACHINE**

<b>EQUIPMENT ID. No.</b>	
<b>LOCATION</b>	<b>PACKING HALL</b>
<b>DATE OF QUALIFICATION</b>	
<b>SUPERSEDES PROTOCOL No.</b>	<b>NIL</b>



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# PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

## PERFORMANCE QUALIFICATION PROTOCOL FOR HI-CART CODING MACHINE

### 1.0 PROTOCOL 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 provide documented evidence that the Equipment is performing consistently, repeatedly and reproducibly within its established operating range and the results of all test parameters meet the pre-defined acceptance criteria.

**3.0 SCOPE:**

- This Protocol covers all aspects of Performance Qualification for the **Hi-Cart Coding Machine**, installed.
- This Protocol will define the methods and documentation used to qualify the **Hi-Cart Coding Machine** for PQ.



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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.

<b>DEPARTMENTS</b>	<b>RESPONSIBILITIES</b>
<b>Quality Assurance</b>	<ul style="list-style-type: none"><li>• Preparation and Approval of the Performance Qualification Protocol.</li><li>• Protocol Training.</li><li>• Co-ordination with Quality Control, Production and Engineering to carryout Performance Qualification Activity.</li><li>• Monitoring of Performance Qualification.</li></ul>
<b>Production</b>	<ul style="list-style-type: none"><li>• Review Performance Qualification Protocol.</li><li>• To co-ordinate and support Performance Qualification Activity.</li></ul>
<b>Quality Control</b>	<ul style="list-style-type: none"><li>• Analytical Support (Microbiological Testing/Analysis).</li></ul>
<b>Engineering</b>	<ul style="list-style-type: none"><li>• Reviewing of qualification protocol for correctness, completeness and technical excellence.</li><li>• Responsible for trouble shooting (if occurred during execution).</li><li>• Maintenance &amp; preventive maintenance as per schedule.</li></ul>



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**5.0 EQUIPMENT DETAILS:**

<b>Equipment Name</b>	Hi-Cart Coding Machine
<b>Equipment</b>	
<b>Manufacturer's Name</b>	
<b>Location of Installation</b>	Packing Hall

**6.0 SYSTEM 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.

**B. Product in feed occurs:**

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

**C. 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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- D. 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.
- E. 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.
- F. 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.
- G. Rear Side Flaps Closing:** Rear side flaps closing takes place between carton loading on the carton chain and product pushing.
- H. 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.
- I. 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.
- J. 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.
- K. 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.
- L. 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.
- M. 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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**N. 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 REASON FOR QUALIFICATION:**

- New equipment installed.
- After completion of the Operation Qualification of the Equipments, it is imperative to perform the Performance Qualification. The study will establish that the parameters are followed, critical variables are under control and the quality of the output is, as desired.

### **8.0 SITE OF STUDY:**

- Packing Hall.

### **9.0 FREQUENCY OF QUALIFICATION:**

- Once in every Five Year  $\pm 1$  month.
- After any major breakdown or after major modification.
- After Change of Location.

### **10.0 PRE – QUALIFICATION REQUIREMENTS:**

The below mentioned activities should be completed prior to commencing the performance qualification activity:

#### **10.1 Verification of Documents:**

Verification for availability, completeness and approval status of all the required relevant documents shall be done and observations shall be recorded in the performance qualification report.

- SOP for Operation & Cleaning of Hi- Cart Coding Machine.
- SOP for Preventive Maintenance of Hi- Cart Coding Machine.

#### **10.2 Training Record of Validation Team:**

- All the persons involved in the execution of Qualification Protocol must be trained in all aspects of the qualification activity including the test methodology, acceptance criteria and safety precautions to be followed during working at service floor.





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### 11.0 TESTS AND CHECKS:

#### 11.1 Evaluation of Performance:

##### Objective:

To evaluate the documented evidence for speed optimization.

##### 11.1.1 Test & Method:

1. Switch "ON" the equipment & operate as per respective SOP.
2. Run the Equipment at 180 carton/ min (100%), 144 carton/ min (80%) and 110 carton/ min (61%).
3. During running, check the Equipment speed synchronization with carton packing parameters:
  - Flap Folding
  - Damage Carton
  - Printing Quality
4. Check the parameters at each interval for each batch.
5. Three consecutive trials must be tested as described before, in order to demonstrate Consistent performance.

##### 11.1.2 Acceptance Criteria

At different time Interval Equipment should be uniformly pack filled vials into Carton and the rejection should not be more than 2.0%.



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**12.0 CHECKLIST OF ALL TESTS & CHECKS:**

This checklist is provided to ensure that all tests or checks required for this protocol have been executed.

Tests or Checks	Executed (Yes/No)	Remarks
Verification of Documents		
Speed Optimization & Uniformity of Packed vials		

**13.0 REFERENCES:**

- In House

**14.0 DOCUMENTS TO BE ATTACHED:**

- Protocol training record.
- Any other relevant document.

**15.0 NON COMPLIANCE:**

All the Non-compliances of procedure, specifications and sampling, analysis and documentation activities shall be monitored & recorded.

**16.0 DEVIATION FROM PRE-DEFINED SPECIFICATION, IF ANY:**

- In case of any deviation observed during PQ, inform to Head QA for necessary action.
- Document the deviation detail in observed deviation section.
- The Head QA will study the impact of deviation. If deviation is acceptable and it does not have an  
Impact on operation as well as on performance of the machine & prepare final conclusion.

**17.0 CHANGE CONTROL, IF ANY:**

- If any change control is required during PQ, inform to Head QA for necessary action.
- Document the details observed.
- The Head QA will study the impact of change. If change is acceptable and it does not have an  
Impact on operation as well as on performance of the machine & prepare final conclusion.



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**18.0 ABBREVIATIONS:**

HIC	:	Hi- Cart coding
cGMP	:	Current Good Manufacturing Practices
PQ	:	Performance Qualification
QA	:	Quality Assurance
SOP	:	Standard Operating Procedure
HIC	:	Hi-cart coding machine