



**PERFORMANCE QUALIFICATION PROTOCOL FOR CARTON PACKING MACHINE**

**PERFORMANCE QUALIFICATION  
PROTOCOL  
FOR  
CARTON PACKING MACHINE**

<b>EQUIPMENT ID. No.</b>	
<b>LOCATION</b>	<b>Packing Area</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 CARTON PACKING MACHINE

### 1.0 PROTOCOL APPROVAL:

#### PREPARED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

#### REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OPERATING MANAGER (QUALITY ASSURANCE)			
HEAD (ENGINEERING)			
HEAD (PRODUCTION)			

#### APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			



## **PERFORMANCE QUALIFICATION PROTOCOL FOR CARTON PACKING MACHINE**

### **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 **Carton Packing Machine**, installed in Packing Area.
- This Protocol will define the methods and documentation used to qualify the **Carton Packing 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.

DEPARTMENTS	RESPONSIBILITIES
<b>Quality Assurance</b>	<ul style="list-style-type: none"><li>• Preparation Review &amp; Authorization of the Performance Qualification Protocol.</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>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>



**PERFORMANCE QUALIFICATION PROTOCOL FOR CARTON PACKING MACHINE**

**5.0 EQUIPMENT DETAILS:**

<b>Equipment Name</b>	Carton Packing Machine
<b>Equipment ID.</b>	
<b>Manufacturer's Name</b>	ACG-Pampac
<b>Supplier's Name</b>	ACG-Pampac
<b>Model</b>	HICART PLUS
<b>Serial Number</b>	
<b>Location of Installation</b>	Packing Area

**6.0 SYSTEM DESCRIPTION:**

HI Cart plus is Continuous Motion cartooning Packing machine, Suitable for automatic Cartoning of Product Like Ampoule Bottle Tubes and blister . the Type of Machine meets the Need of The high Volume Production , Giving an Output of up to 180 Carton /minutes Depending upon Application .the Machine Performed following Function .

- Receive unit Product From Up stream machine on Product Chain .
- Storing of pre Broken Carton in flat from in the Carton Magazine .
- Picking Up The carton 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 Main Functional Areas:**

**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 adjusted Product Pockets



## **PERFORMANCE QUALIFICATION PROTOCOL FOR CARTON PACKING MACHINE**

Individual Product Pocket can be adapted to the Product Size with an adjustment of Chain . Length of the Chain Extension is depends on application , Upstream integration and Room Layout

### **Product Chain Extension :**

The product chain Extension is additional extension for the Product Chain the Extension Provides Additional Space Between Transfer and Cartooning Machine for Customer Specific use ei. For Manual Product Insertion Into the Product Chain.

### **B. Carton Chain:**

The Carton Chain Transport open Carton from carton Landing to Carton Closing. Following Process take Place on the Carton Chain:

- 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.

The Individual Chain Pocket can be adapted to the Carton Size with an Adjustment of Chain .

**Note:** Range of Carton Depending on Chain Configuration selected while order Finalization. Machine will be based on the Customer Need Defined during order Finalizations.

### **C. Carton Loading Magazine :**

The carton Magazine Hold Various Size of Carton .Magazine Parts can be adjusted Easily to Accommodation Various Sizes of Carton With the Help of Numeric scales . For each Type each size/ Type of Carton , Values Can be This Conveyor is Drive Intermittently, Though Unidirectional Bearing and Pneumatic Cylinder . A Pressure plate with a dead Weight put Constant Pressure on the Carton Stack . two Plunger Cylinder hold the Cartons During Carton Pick up. Two Cylinder are Provided, one another on the Bottom.



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**D. Carton Pick up & Transfer System:** The carton are Picked up with pickup arms from the carton Magazine and Then Place it the Carton holder . Pick and Place is done by Vacuum , which is Generated either by air venture or Vacuum pump . Suction cups Mounted at the end of Sucker arm do Main pick up Function .these are Rubber Cups, flexible Enough with Cushioning Action makes Carton Pick up easy up arms driven Through the Main Motor and shaft, Oscillating Movement for pick up arms generated through Linkage in Connection with main Shaft. , Carton Vacuum Can be enabled or disabled from Main Screen of HMI.

An Integrated Carton Pre Breaking system Is provided along with the Carton Pick up System . this unit open /from Carton Before Placing it on the Carton Chain Various Gears along with belt drive Rotates Rotary Pick unit . this Unit rotate Continuously . Sucker arms are mounted on Bracket, which in Turn Mounted on Rotary Pickup unit Through Small Gears.

There are Three Vacuum & air Control Valve used in the Unit. Two Valve are Connected to the Vacuum Lines of the Sucker and one to the Pre- Breaker.

In Run Mode , Whenever the Product is not Present in any Pocket of the Product Chain or the Leaflet is not Released for some Pocket , the Signal is Sent to the Vacuum & air control Valve by a Sensor.

Then the Valve for the Corresponding Sucker Operates , the Vacuum Is Vacuum is Not off and carton is Picked for the product Pocket in which the Product or Leaflet is not Present.

The Valve for the Pre Breakers Operation is Mode .the Position of the Sucker arm for which the vacuum in the Pre Breaker is to be Made on and off are Set.

Thus the operation the Position comes, making the Vacuum in the Pre Breaker On at the start of Pre Pre Braking and Cutting it OFF at the end of Pre Breaking .

Carton pre Breaking unit is Provided to Pre Break the Carton Before Placing Them on the Carton Chain .

**E. Carton Positioning :** The Carton Position unit Consist of a Carton To ward the product Chain From Rear side of the Machine.

The Carton is pushed Forward in the Forward :

- The Carton Partially pushed Forward
- The Carton Pushed Forward Unit Flaps come in the Contact with the Outer surface of the Cell angle along with Their Full Length.

The side Flap Opener Opens the Side Flaps of the carton for Smooth Insertion of the Product from Product Chain Side.





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**F. Rear Side Flaps Closing :** The Side Flap Closing Takes Places Between Carton Loading on the Carton Chain and product Pushing . Stationary Guide Close Left Side Flap and Folding Finger closes the Right Side Flap , Folding Finger is Moveable and Driven Through the Same Drives of Carton Positioning.

**G. Product Pushing system :** The Product Pushing system is Provided to Push the Carton. It Consist of Product Pusher That Push the Product and Leaflet into the Carton . Pushing Takes Places when Product and Carton Comes to the Insertion point.

Folded Leaflet Gets Release by the Leaflet Clamp at this Station and then Inserted into the Carton with the product.

Pusher assembly Consist of a Pusher With rod and pre Pusher . if Product gets Stuck in Between , due to some Reason , It Operates the Overload Safety switch that Stop the Machine .

**H. Carton Closing :** After Slide Flaps Closing Carton system to Main Flap Closing station . front and Rear Flap Closing Takes Place Simultaneously in 3 step.

Flap Position for Closing is done by Creasing guide and guide Rod. These are arranged to blend locking flap with main flap.

**Pre- closing:** Pre closing and completed closing is done by tuck in closers. In pre closing , tuck in closer pushes the locking flap to lock the carton.

**Complete closing :** Pre closing and completed closing is done by tuck in closers. In pre closing , tuck in closer pushes the locking flap over the side flap to lock the carton

### **I. Carton Discharge**

The closed carton from the carton chain are transferred to the discharge belt. Discharge belt continuously carry these carton to the next point which may be either Collection bin or Line conveyor.

Discharge belt assembly includes two flat belts , driven through the main drive. Speed of both the belts is synchronized and slightly higher than the carton chain speed.

### **J. Empty Carton Rejection System**

This system is provided to detect and reject the empty carton from the discharge conveyor. A sensor is provided to detect the presence of the product in the carton .If the product is not available in carton



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, the sensor gives signal to the control system, and it operates an ejection lever, which is operated by a pneumatic cylinder. The rejected carton will then be collected in a separate bin.

### **K. Printing Station**

This station has batch code embossing provision. A metallic roller holds embossing letters for coding on the carton flap. The carton flap is passed through the metallic roller and pressure roller to get the impressions of letters on the carton flap.

### **L. Pre- folded Leaflet Transfer System**

This attachment is provided to transfer the folded leaflet into the carton.

Pre folded leaflets are stored in magazine. The leaflets are picked up by the sucker arm and then transferred to the transfer belts. Belts carry this leaflet up to leaflet clamps with rotary turret. Then clamps along with chain carry these leaflets to the pusher station for insertion in the carton.



## **PERFORMANCE QUALIFICATION PROTOCOL FOR CARTON PACKING MACHINE**

### **7.0 REASON FOR QUALIFICATION:**

- New equipment installed in **Packing Area**.
- 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 Area LVP Line.

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

- Once in every 5 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 carton Packing Machine.
- SOP for Preventive Maintenance of carton Packing 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.



## **PERFORMANCE QUALIFICATION PROTOCOL FOR CARTON PACKING MACHINE**

### **11.0 TESTS AND CHECKS:**

#### **11.1 Evaluation of Performance:**

##### **Objective:**

To evaluate the Performance of Carton Packing Machine by Using Three Commercial batch.

##### **11.1.1 Test & Method:**

1. Switch "ON" the equipment & operate as per respective SOP.
2. Run the Equipment at 160 carton/ min 120 carton/ min and 40 carton/ min
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 bottle into Carton and the rejection should not be more than 2.0%.



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

Tests or Checks	Executed (Yes/No)	Remark	Verified by Quality Assurance
Verification of Documents			
Evaluation of Performance by Using Three batch			
Uniformity of Product for Rejection			

**13.0 REFERENCES:**

- In House

**14.0 DOCUMENTS TO BE ATTACHED:**

- 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:**

cGMP	:	Current Good Manufacturing Practices
CPM	:	Carton Packing Machine
PQ	:	Performance Qualification
QA	:	Quality Assurance
SOP	:	Standard Operating Procedure
PPQ	:	Performance Qualification Protocol