



**PERFORMANCE QUALIFICATION PROTOCOL
FOR
CARTON PACKING MACHINE**

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EQUIPMENT ID. No.	
LOCATION	Packing Area, Catch Cover
DATE OF QUALIFICATION	
SUPERSEDES PROTOCOL No.	NIL



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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)			



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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 **Carton Packing Machine**, installed in Packing Area, Catch Cover.
- 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
Quality Assurance	<ul style="list-style-type: none">• Preparation Review & Approval of the Performance Qualification Protocol.• Co-ordination with Quality Control, Production and Engineering to carryout Performance Qualification Activity.• Monitoring of Performance Qualification.
Production	<ul style="list-style-type: none">• Review Performance Qualification Protocol.• To co-ordinate and support Performance Qualification Activity.
Engineering	<ul style="list-style-type: none">• Reviewing of qualification protocol for correctness, completeness and technical excellence.• Responsible for trouble shooting (if occurred during execution).• Maintenance & preventive maintenance as per schedule.



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5.0 EQUIPMENT DETAILS:

Equipment Name	Carton Packing Machine
Equipment ID.	
Model	VP120
Sr.No.	
Manufacturer's Name	ACG-Pampac
Supplier's Name	ACG-Pampac
Location of Installation	Packing Area, Catch Cover

6.0 SYSTEM DESCRIPTION:

The carton Packing machine, Model VP 120 is Continuously Operating Machine. Particularly Suited for Semi Automatic Packing of Variety of Good.

The machine consists of following parts:

A. Carton Chain: Carton chain transports the Carton from one Work Station to the Next Station.

Following Process have taken Place on the Carton belt.

- Transfer And final Erection of The Carton,
- Folding of Side flap – Bottom Side,
- Folding of the Main Flap- Bottom
- Printing / Embossing of the Flap
- Insertion of the Leaflet
- Product Loading(Manually
- Folding of the Side Flaps- Top
- Folding of the main Flaps- Top Side

B. Carton Loading Magazine : The carton Blanks Loaded Vertically in the Magazine on Conveyor belt. 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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- C. Carton Pick up :** 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.
- D. Carton Transfer:** The Sucker arms pick up the Carton and place in the Carton holder , A Carton Assembly Includes Top Carton Holder , Bottom Carton and Bottom Support Plate . top and Bottom holder hold the Carton whereas Support plate Supports Like Carton From Bottom during Transfer Carton Holder Assembly is Mounted on Rods with Sliding hub ,the Carton Holder Transfer the Carton from Magazine to a Carton Chain. Carton Holder Parts are Adjustable According to the Carton Length, Height and Width to Accommodate Various Size.
- E. Bottom Side Flaps Closing :** When the Carton Travels on the Chain , a Satisfactory and a Movable Finger Open Upper side Flaps this Facilities easy Product Loading Simultaneously, the Satisfactory and Movable Finger Close the Bottom Side Flap.
- F. Bottom Main Flaps Closing :** The Closing of Bottom Main flap is done in the Three Stages . First tuck- in Folded. In Second Stage tuck-in flap Is positioned in the Carton and about to Close and Finally Tuck-in Flap is Closed in the Third Round.
- G. Top Side flap Closing :** After the Feeding into Carton , the Stationary and Movable Finger Close the Top Side Flap. .
- H. Top Main Flap Closing :** The Closing of Top Main Flap is Done in Three Stages tuck in Flap is Folded. In Second Stage Tuck in Flap is Positioned in the Carton and About to close and Finally tuck-in Flap is Totally closed in the third Round.
- I. Printing Unit:** The Station Use to Give the Batch Code Printing Provision on Top flap is Passed Through the Stereo Roller and Pressure Roller to Get the Stereo Roller and Carton Flap is Passed Through Roller and Pressure Roller to get the Implementation of Stereo on the Carton Flap . This Provision Can be Done on top Flap
- J. Pre- Folded Leaf let Transfer System .**
- K. Area for Manual Product Feeding:**
- L. Half Filled Product Inspection:**
- M. Empty Carton Rejection System**



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N. Carton Discharge:

O. Head Wheel:

7.0 REASON FOR QUALIFICATION:

- New equipment installed in **Packing Area Catch Cover**.
- 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 Catch Cover.

9.0 FREQUENCY OF QUALIFICATION:

- Once in every 5 Year ± 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.



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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 120 carton/ min (100%), 80 carton/ min (80%) and 40 carton/ min(60%).
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:

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