



**INSTALLATION QUALIFICATION PROTOCOL CUM REPORT
FOR
CARTON PACKING MACHINE**

**INSTALLATION QUALIFICATION
PROTOCOL CUM REPORT
FOR
CARTON PACKING MACHINE**

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



**INSTALLATION QUALIFICATION PROTOCOL CUM REPORT
FOR
CARTON PACKING MACHINE**

PROTOCOL CONTENTS

S.No.	TITLE	PAGE No.
1.0	Pre-Approval	3
2.0	Objective	4
3.0	Scope	4
4.0	Responsibility	5
5.0	Equipment Details	6
6.0	System Description	6-8
7.0	Pre-Qualification Requirements	8
8.0	Critical Variables to be Met	9-15
9.0	References	16
10.0	Documents to be Attached	16
11.0	Deviation from Pre-Defined Specification, If Any	16
12.0	Change Control, If Any	16
13.0	Review (Inclusive of follow up action, If Any)	16
14.0	Conclusion	17
15.0	Recommendation	17
16.0	Abbreviations	18
17.0	Post Approval	19



**INSTALLATION QUALIFICATION PROTOCOL CUM REPORT
FOR
CARTON PACKING MACHINE**

1.0 PROTOCOL PRE – 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)			



**INSTALLATION QUALIFICATION PROTOCOL CUM REPORT
FOR
CARTON PACKING MACHINE**

2.0 OBJECTIVE:

- To provide documented evidence for the Installation Qualification of Hi-Cart Coding Machine in Packing Area Catch Cover.
- To confirm that the equipment and its components are installed as per the Specifications mentioned in the design qualification document and other requirements given by supplier.

3.0 SCOPE:

- The scope of this installation qualification protocol cum report is limited to qualification of Carton Packing Machine (Make: ACG Pampac) to be installed in the Packing Area Catch Cover.
- This document provides all the relevant information related to specification, installation checks and acceptance criteria to be required to perform installation qualification activity of Carton Packing area Machine.



**INSTALLATION QUALIFICATION PROTOCOL CUM REPORT
FOR
CARTON PACKING MACHINE**

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 and Compilation of the Installation Qualification Protocol cum Report.• Co-ordination with Production and Engineering to carryout Installation Qualification.• Monitoring of Installation Qualification Activity.• Post Approval of Qualification Protocol cum Report after Execution.
Production	<ul style="list-style-type: none">• Review & Pre Approval of Installation Qualification Protocol cum Report.• To Co-ordinate and support for Execution of Qualification study as per Protocol.• Post Approval of Installation Qualification Protocol Cum Report after Execution.
Engineering	<ul style="list-style-type: none">• Review & Pre Approval of Installation Qualification Protocol cum Report.• Co-ordination, Execution and technical support in Installation Qualification Activity.• Calibration of Process Instruments.• Responsible for Trouble Shooting (if occurs during execution).• Post Approval of Installation Qualification Protocol Cum report after Execution.



**INSTALLATION QUALIFICATION PROTOCOL CUM REPORT
FOR
CARTON PACKING MACHINE**

5.0 EQUIPMENT DETAILS:

Equipment Name	Carton Packing Machine
Equipment ID.	
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.

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.



**INSTALLATION QUALIFICATION PROTOCOL CUM REPORT
FOR
CARTON PACKING MACHINE**

- 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**
- N. Carton Discharge:**
- O. Head Wheel:**



**INSTALLATION QUALIFICATION PROTOCOL CUM REPORT
FOR
CARTON PACKING MACHINE**

7.0 PRE – QUALIFICATION REQUIREMENTS:

7.1 Verification of Documents:

- Executed and approved design qualification document.
- Electrical circuits diagram.
- Technical specification of equipment.

7.1.1 Procedure:

- Verify the above mentioned documents for availability, completeness and approval status.
- If any deviation is observed the same has to be recorded giving reasons for deviation and approved. Deviation should be approved by Authorized person.
- Approved Drawings and supporting documents would form a part of the IQ Protocol cum Report.

7.1.2 Acceptance Criteria:

- All the documents should be available, complete and approved by Respective Authorities.



**INSTALLATION QUALIFICATION PROTOCOL CUM REPORT
FOR
CARTON PACKING MACHINE**

8.0 CRITICAL VARIABLES TO BE MET:

8.1 Installation Qualification Checklist:

INSTALLATION CHECKS	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
Grouting and Mounting	Should be properly grouted and mounted.		
Leveling	Should be properly balanced and leveled.		
Edges of parts	Metal parts should be properly ground without any sharp edges.		
Welding of Joints	Welding of joints should be without any welding burrs.		
Place of Installation	Packing Area, Catch Covers		
Room Condition	RH: NMT 55 % TEMP: NMT 25 °C		
Illumination	NLT 300 Lux		
Working space around the Equipment.	Should be sufficient for easy operation, cleaning, sanitation and maintenance.		

Checked By
Production
Sign/Date:

Verified By
Quality Assurance
Sign/Date:

Inference:

.....
.....
.....

Reviewed By
Manager QA
Sign/Date:



**INSTALLATION QUALIFICATION PROTOCOL CUM REPORT
FOR
CARTON PACKING MACHINE**

8.2 Installation Checks for Technical Specification:

CRITICAL VARIABLES		ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
Equipment Name		Carton Packing Machine		
Type		Continuous ,Motion Vertical Carton Packing Machine		
Model		VP120		
S.No.				
Output		Upto 120 cartons/min Depending Upon The Product		
Machine Weight (Net)		1600 Kg.		
Machine Weight (Gross)		2400 Kg.		
Carton Size	Length	60 mm		
	Width	20 mm		
	Height	15 mm		
Leaflet size (pre Folded)	Length	110 mm-170 mm		
	Width	20-35 mm		
Leaflet Paper		45 to 60 GSM		
Noise Level		80 db (approx)		
Recommended Temperature Range		18 – 30 ° C		
Recommended Humidity		45- 60 %		
Main Motor				
Make		Rotomotive (90 L-4)		



PHARMA DEVILS
QUALITY ASSURANCE DEPARTMENT

**INSTALLATION QUALIFICATION PROTOCOL CUM REPORT
FOR
CARTON PACKING MACHINE**

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
Model	Rating : 3 Phase ,415 V, 50 Hz, 1.5 Kw,1400 RPM, 3.5 A		
HMI			
Make	Weintek Labs.		
Model	MT 8071 IE		
Power Supply			
Make	Omron		
Model	MT 8071 IE		
PLC			
Make	Mitsubishi		
Model	FX 3G -60 M		
Single Phase Preventure			
Make	Omron		
Model	K8AK-PM2		
Vacuum Pump			
Make	Festo		
Tower Lamp			
Make	Schnedier		
Model	XVGB3S		
Transformer			
Make	Shilchar Technology		
Model	S-RC465-0550 PRI: 0-220-380-415 V, 50 Hz SEC: 0-220 V, 2.5 A		
Encoder			



**INSTALLATION QUALIFICATION PROTOCOL CUM REPORT
FOR
CARTON PACKING MACHINE**

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
Make	Kubler		
Model	8.5000.835A.0360.0050		
Driven For Main Motor			
Make	Danfoss (VLT Micro Drive)		
Model	Rating 1.5 Kw, 2.0 HP		
Pneumatic Cylinder For Carton Holding			
Make	Festo		
Model	AEVC -20- 5-I-P		
Vacuum Venturi for Carton Pickup			
Make	Festo		
Model	VN-30-H-T6-PQ4-VQ5-RO2-M (02)		
Vacuum Venturi for Leaflet Pickup			
Make	Festo		
Model	VN-20-H-T6-PQ4-VQ5-RO2-M		
Air Pressure Switch			
Make	Festo		
Model	PEV-1/4 SC-OD		
Pneumatic Cylinder for Product Pusher			
Make	Festo		
Model	ADN-20-50-A-P-A		
Pneumatic Cylinder for Empty Carton Rejection			
Make	Festo		
Model	DSN-20-50-P		
Carton Low Level Check in Magazine			



PHARMA DEVILS
QUALITY ASSURANCE DEPARTMENT

**INSTALLATION QUALIFICATION PROTOCOL CUM REPORT
FOR
CARTON PACKING MACHINE**

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
Make	Telemecanique		
Model	XCJ110		
Guard Switch			
Make	Telemecanique		
Model	XCJ110		
Carton Check Sensor			
Make	IFM		
Model	OJ5148		
Leaflet Check Sensor			
Make	IFM		
Model	OJ5148		
Carton Stage at Discharge			
Make	IFM		
Model	OJ5148		
Hand wheel Out Check			
Make	Pepperi & Fuchs		
Model	NBB4-12 GM50-E2		
Empty Carton Check			
Make	IFM		
Model	KB 5004		

Checked By
Production
Sign/Date:

Inference:

Verified By
Quality Assurance
Sign/Date:

.....

.....

.....

Reviewed By
Manager QA
Sign/Date:



**INSTALLATION QUALIFICATION PROTOCOL CUM REPORT
FOR
CARTON PACKING MACHINE**

8.1 MATERIAL OF CONSTRUCTION:

PARTS NAME	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
Chain	MS		
Pockets Wall	Plastic		
Pusher	MS Hardened rods		
Drive and guide assembly	MS		
Magazine assembly	SS304, MS, EN9		
Carton chain and Flap folding assembly	MS, SS304 and alluminum		
Tuck in assembly	MS, SS304 and EN8		
Carton discharge assembly	MS, PU, SS304 and aluminum		
Interconnection assembly	PU belt and Aluminum section		

Checked By
Production
Sign/Date:

Verified By
Quality Assurance
Sign/Date:

Inference:

.....
.....
.....

Reviewed By
Manager QA
Sign/Date:



**INSTALLATION QUALIFICATION PROTOCOL CUM REPORT
FOR
CARTON PACKING MACHINE**

8.3 Safety:

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
MCB	MCB is provided so that where is an overload in current or any short circuit then MCB shall trip		
Leveling	Should be properly balanced and leveled.		
Edges of parts	Metal parts should be properly ground without any sharp edges.		
Welding of Joints	Welding of joints should be without any welding burrs.		
Guards	Guards for all moving parts		
No Product no Carton sensor	To give Signal to suction station for carton erection		
Emergency stop switch on the operator panel	Should be Available in working condition		
Pusher Overload	Machine should stop when pusher overload jam during operation		

Checked By
Production
Sign/Date:

Verified By
Quality Assurance
Sign/Date:

Inference:.....
.....
.....
.....

Reviewed By
Manager QA
Sign/Date:



**INSTALLATION QUALIFICATION PROTOCOL CUM REPORT
FOR
CARTON PACKING MACHINE**

9.0 REFERENCES:

- Design Qualification
- Vendor Documents

10.0 DOCUMENTS TO BE ATTACHED:

- Calibration certificates.
- Any other relevant documents.

11.0 DEVIATION FROM PRE-DEFINED SPECIFICATION IF, ANY:

.....
.....
.....
.....
.....

12.0 CHANGE CONTROL, IF ANY:

.....
.....
.....
.....
.....
.....
.....

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

.....
.....
.....
.....
.....



**INSTALLATION QUALIFICATION PROTOCOL CUM REPORT
FOR
CARTON PACKING MACHINE**

16.0 ABBREVIATIONS:

cGMP	:	Current Good Manufacturing Practice
CPM	:	Carton Packing Machine
HP	:	Horse Power
Hz	:	Hertz
IQ	:	Installation Qualification
MCB	:	Miniature circuit breaker
mm	:	Millimeter
NLT	:	Not less than
NMT	:	Not More Than
RH	:	Relative Humidity
RPM	:	Revolution per minute
SS	:	Stainless steel



**INSTALLATION QUALIFICATION PROTOCOL CUM REPORT
FOR
CARTON PACKING MACHINE**

17.0 PROTOCOL POST- 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)			