

 PHARMA DEVILS	INSTALLATION QUALIFICATION PROTOCOL FOR CARTON PACKING MACHINE	PROTOCOL No.:
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1.0 PROTOCOL APPROVAL:

Signing of this approval page of Protocol indicates agreement with the qualification approach described in this document. If modification to the qualification approach becomes necessary, an addendum shall be prepared and approved. The protocol cannot be used for execution unless approved by the following signatories.

This Installation Qualification protocol of Carton Packing machine has been reviewed and approved by the following signatories:

FUNCTION	NAME	DESIGNATION	DEPARTMENT	SIGNATURE	DATE
PREPARED BY			QUALITY ASSURANCE		
			QUALITY ASSURANCE		
REVIEWED BY			ENGINEERING		
			PRODUCTION		
APPROVED BY			HEAD OPERATION		
			QUALITY ASSURANCE		

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2.0 OVERVIEW:

2.1 OBJECTIVE:

The objective of developing and executing this protocol is to collect sufficient data pertaining to the Carton Packing machine and define the qualification requirements and acceptance criteria for the unit. Successful completion of these qualification requirements will provide assurance that the Carton Packing machine was installed as required in packing line.

The Qualification of Carton Packing machine performed in view of ointment packing hall of manufacturing facility of

2.2 PURPOSE:

The purpose of this protocol is to establish documentary evidence to ensure that the Automatic cartoning machine received matches the Design specification and also to ensure that it is properly and safely installed.

2.3 SCOPE:

The installation qualification protocol shall be followed for installation qualification of Carton Packing machine at This protocol defines the methods and documentation that shall be used to evaluate the system installation in accordance with the specifications and intended use. Successful implementation of this protocol shall verify that the systems installed meet the requirements specified.

2.4 RESPONSIBILITY:

In accordance with protocol, following functions shall be responsible for the qualification of system.

Execution Team (Comprising members from Production, Engineering and Quality Assurance) and their responsibilities are following:

- Prepares the qualification protocol.
- Ensures that the protocol is in compliance with current policies and procedures on system Qualification.



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- Distributes the finalized protocol for review and approval signatures.
- Execution of Qualification protocol.
- Review of protocol, the completed qualification data package, and the final report.
- The installation checks, calibration, SOP identification, identification features, identification of utility supply shall be carried out by engineering persons.
- The production operator / supervisor shall carry out the cleaning and operation of machine.

Head – Production/ Engineering:

- Review of protocol, the completed qualification data package, and the final report.
- Assist in the resolution of validation deficiencies.

Head – Operation and Quality Assurance:

- Review and approval of protocol, the completed qualification data package, and the final report.



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3.0 ACCEPTANCE CRITERIA:

- 3.1 The Carton Packing machine shall meet the system description given in design specification.
- 3.2 The Carton Packing machine shall meet with the acceptance criteria mentioned under the topic "Identification of major components".
- 3.4 Safety feature, Utility & calibration shall be identified.

4.0 REVALIDATION CRITERIA:

The machine has to be revalidated if

- There are any major changes, which affect the performance of the equipment.
- After major breakdown, maintenance is carried out.
- As per revalidation date and schedule.

5.0 INSTALLATION QUALIFICATION PROCEDURE

5.1 EQUIPMENT DESCRIPTION:

Equipment Name	:	Carton Packing machine			
Supplier/Manufacturer	:	ACG Pampac Machines Pvt. Ltd.			
Model	:	CP 150			
Machine No.	:			
Machine Type	:	Continuous motions automatic Cartoning machine.			
Carton size range that can be handled	:		Width	Height	Length
		Minimum	20 mm	14 mm	65 mm
		Maximum	100 mm	65 mm	180 mm
Suitable working temperature range	:	18-30 ⁰ C			
Noise level	:	80 dB (Approx.)			
Suitable humidity range for the machine	:	45 to 90 % RH			
Output	:	Up to 150 cartons/ minute (Depending on product shape & size)			
Electrical supply	:	415 V (±10%), 50 Hz			
Compressed air (Dry)	:	6 bar max.			
Location	:	Ointment Packing Hall			



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Main Functional Areas:

The main modules in the basic machine are as follows:

- Carton loading magazine
- Carton pick up
- Carton discharge
- Printing station
- Carton chain
- Product chain
- Empty carton rejection system
- Ink embossing station
- Tube transfer system
- Pre-folded Leaflet Transfer system

The cartoning machine model CP 150 is a continuous motion machine particularly suited for automatic cartoning of unit product like ampoules, bottles, tubes & blisters.

The machine meets the requirement of high volume production, giving an output of up to 150 cartons/minute depending upon application.

Various kinds of supplementary attachments like leaflet inserter, empty carton ejection, sensing device and make this machine as one that gives solution to many automation requirements.

The machine can be centrally adjusted to take care of various carton lengths. Also it can be easily adjusted for different widths and height of cartons.

Cartons loaded (manually) into the carton magazine are picked up by Oscillating pick up arms and are loaded into the carton chain. Carton moves along with the carton chain. During this process cartons are closed from rear and front flaps are open. Cartons are carried to product loading zone where product is loaded automatically. Cartons are closed from the front and are discharged through discharge belt.



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5.2 INSTRUCTION FOR FILLING THE CHECKLIST

- 5.2.1 In case of identification of major component actual observation should be written in specified location.
- 5.2.2 In case of the compliance of the test actual observation should be written in specified location.
- 5.2.3 For identification of utilities actual observation should be written in specified location.
- 5.2.4 Give the detailed information in the summary and conclusion part of the installation Qualification report.
- 5.2.5 Actual observation of the component should be written in specified location.
- 5.2.6 Whichever column is blank or not used 'NA' shall be used.

5.3 INSTALLATION CHECKLIST:

Installation checklist is as follows:

S.No.	Statement	Method of Verification	Actual observation	Checked By Sign/Date
1.	Verify the purchase order copy and PO no. Shall be written in observation column	Physically		
2.	Verify that the “As Built” drawing is complete and represents the design concept.	Physically		
3.	Verify that major components are securely anchored and shock proof.	Physically		
4.	Verify that there is sufficient room provided for servicing.	Physically		
5.	Verify that all piping and electrical connections are done according to the drawings.	Physically		
6.	All access ports are examined and cleared of any debris.	Physically		
7.	Safe electrical connections.	Physically		
8.	Sufficient room provided for maintenance.	Physically		
9.	Equipment identification nameplate visible.	Physically		
10.	Units installed on foundation are secure in place as per manufacturer’s recommendations.	Physically		
11.	Verify that there is no observable physical damage	Physically		

Remark: -----

Reviewed by (Sign/Date)



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5.4 IDENTIFICATION OF MAJOR COMPONENTS:

Describe each critical component and check them and fill the inspection checklist.

System Components	Design Specification		Method of Verification	Actual Observation	Checked By Sign/Date
Vacuum ventury for Carton Pick-up	Make	Festo	Visually/ Physically		
	Model	Visually/ Physically		
	Qty.	01 No.	Visually/ Physically		
Vacuum ventury For Leaflet Pick up	Make	Festo	Visually		
	Model	Visually/ Physically		
	Qty.	01 No.	Visually/ Physically		
HMI	Location	On operating panel	Visually		
	Make	Weintek	Visually/ Physically		
	Model	MT 6070 iH 3EV	Visually/ Physically		
	Sr. No.	To be recorded	Visually/ Physically		
Air Pressure switch	Location	Inside the machine of front	Visually		
	Make	Festo	Visually/ Physically		
	Model	PEV-1/4-SC-OD	Visually/ Physically		
Main Gear box with motor	Make	Rotomotive	Visually/ Physically		
	Model	Robus 21	Visually/ Physically		
	Ratio	10:1	Visually/ Physically		
	Voltage	380 to 415 V, 3 Ph, 3.5 A	Visually/ Physically		
	Rating	1.5 kW, 1400 RPM	Visually/ Physically		
	Sr. No.	To be recorded	Visually/ Physically		
Power Supply	Make	Mean well	Visually/ Physically		
	Model	S-150-24	Visually/ Physically		



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Single Phase Preventer	Make	Omron	Visually/ Physically		
	Model	K8AK	Visually/ Physically		
PLC for machine	Location	Inside the control cabinet	Visually		
	Make	Mitsubishi	Visually/ Physically		
	Model	Visually/ Physically		
AC drive for main motor	Location	Inside the control cabinet	Visually		
	Make	Danfoss	Visually/ Physically		
	Model	VLT Microdrive	Visually/ Physically		
	Rating	1.5 kW, 2.0 HP	Visually/ Physically		
	Sr. No.	To be recorded	Visually/ Physically		
AC drive for conveyor	Location	Inside the control cabinet	Visually		
	Make	Danfoss	Visually/ Physically		
	Model	VLT Microdrive	Visually/ Physically		
	Rating	0.37 kW, 0.5 HP	Visually/ Physically		
	Sr. No.	To be recorded	Visually/ Physically		
Encoder	Make	Kubler	Visually/ Physically		
	Model	Visually/ Physically		
Additional Card for Input	Make	Mitsubishi	Visually/ Physically		
	Model	Visually/ Physically		
Additional Card for Output	Make	Mitsubishi	Visually/ Physically		
	Model	Visually/ Physically		



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Carton Chain Clutch	Make	Comintec	Visually/ Physically		
	Model	Visually/ Physically		
Geared Motor for tub Transfer Conveyor	Make	Bonfiglioli	Visually/ Physically		
	Model	Visually/ Physically		
	Ratio	7:1	Visually/ Physically		
	Rating	0.18 kW, 1.23 A, 1320 RPM	Visually/ Physically		
MCB	Make	Schneider	Visually/ Physically		
	Location	Inside the control cabinet	Visually/ Physically		
Emergency Stop Push Button	Qty.	03 Nos.	Visually/ Physically		
Main Switch	Location	On control cabinet	Visually		
Speed Control Potentiometer	Location	On operating panel	Visually		
Pressure Regulators	Location	Inside the machine	Visually		
Pneumatic Cylinders					
Tube Stopper on Conveyor	Make	Festo	Visually/ Physically		
	Model	Visually/ Physically		
Tube Transfer Flap	Make	Festo	Visually/ Physically		
	Model	Visually/ Physically		
Empty Carton Ejection	Make	Festo	Visually/ Physically		
	Model	Visually/ Physically		
Carton Top Support	Make	Festo	Visually/ Physically		



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	Model	Visually/ Physically		
Pusher Diverter	Make	Festo	Visually/ Physically		
	Model	Visually/ Physically		
Sensors					
Tube Stopper on Conveyor	Make	IFM	Visually/ Technical specification		
	Model	Visually/ Technical specification		
	Qty.	01 No each	Visually		
Tube check on Conveyor	Make	IFM	Visually/ Technical specification		
	Model	Visually/ Technical specification		
Product Present	Make	IFM	Visually/ Technical specification		
	Model	Visually/ Technical specification		
Leaflet low level in Magazine	Make	IFM	Visually/ Technical specification		
	Model	Visually/ Technical specification		
Leaflet Present	Make	IFM	Visually/ Technical specification		
	Model	Visually/ Technical specification		
Carton Present	Make	IFM	Visually/ Technical specification		
	Model	Visually/ Technical specification		
Carton low level in Magazine	Make	Pepperl & Fuchs	Visually/ Technical specification		



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	Model	Visually/ Technical specification		
Half Product Insertion	Make	IFM	Visually/ Technical specification		
	Model	Visually/ Technical specification		
Sucker arm selection	Make	Pepperl & Fuchs	Visually/ Technical specification		
	Model	Visually/ Technical specification		
Hand wheel out	Make	Pepperl & Fuchs	Visually/ Technical specification		
	Model	Visually/ Technical specification		
Pusher loading safety Switch	Make	Siemens	Visually/ Technical specification		
	Model	Visually/ Technical specification		
Empty carton check	Make	IFM	Visually/ Technical specification		
	Model	Visually/ Technical specification		
Carton chain clutch Overload	Make	Pepperl & Fuchs	Visually/ Technical specification		
	Model	Visually/ Technical specification		
Guard switches	Make	Telemecanique	Visually/ Technical specification		
	Model	Visually/ Technical specification		
Alarms					
Tower Lamp	Location	Over the top of machine on carton magazine wall	Visually		



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Buzzer	Location	Inside the tower lamp	Visually		
HMI Screen	Location	Over the console box	Visually		
Pressure Gauge					
Main FRL Unit	Make	Festo	Visually		
	Range	0-16 bar	Visually		
Rotary Pickup Filter Unit	Make	Festo	Visually		
	Range	0-16 bar	Visually		
Leaflet Vacuum Ventury	Make	Festo	Visually		
	Range	0-16 bar	Visually		
Vacuum Gauge					
Vacuum Gauge for Carton	Make	Piab	Visually		
	Range	-30 to 0" Hg	Visually		

Remark: -----

Reviewed by (Sign/Date)



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5.5 IDENTIFICATION OF SUPPORTING UTILITIES:

Utility	Method of verification	Observation	Checked by Sign/ Date
Electricity: 3 phase, 415V±10% AC, 50 Hz supply with neutral and proper earthing	Physically and with clamp meter		
Compressed air: Minimum pressure 6 bar max	Physically		

Remark: -----

Reviewed by (Sign/Date)



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5.6 IDENTIFICATION OF SAFETY FEATURES: Identify and record the safety features (if any) and their function in following tables:

Safety Features Description	Function	Method Of Verification	Observation	Checked By Sign/Date
Earthing	To avoid electrical shocks due to leakage current	Physically		
Emergency stop button	To stop machine immediately in case of emergency	Physically		
Safety around the machine	All moving parts of the machine are covered by guards to prevent accidents	Physically		
Machine electrical panel	Corresponding MCB trips immediately in case of overload	Physically		
Limit switch	If door open during operation the machine should be stopped	Physically		
Interlocking with electrical supply	Machine stops in case of single phasing & cannot be restarted until 3 phase supply is restored	Physically		

Remark: -----

Reviewed by (Sign/Date)



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5.7 IDENTIFICATION OF STANDARD OPERATING PROCEDURE (SOP)

The following Standard Operating Procedures were identified as important for effective performance of Carton packing machine.

S.No.	SOP TITLE	IDENTIFIED BY	DATE

Remark: -----

Reviewed by (Sign/Date)



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5.11 DEFICIENCY AND CORRECTIVE ACTION (S) REPORT (S)

Following deficiency was verified and corrective actions taken in consultation with the Engineering Department.

Description of deficiency:

Corrective action(s) taken:

**Deviation accepted by
(Sign/Date)**

**Deviation Approved by
(Sign/Date)**



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ABBREVIATIONS

V	: Voltage
AC	: Alternate Current
PLC	: Programmable Logic Controller
Hz	: Hertz
RPM	: Revolution per Minute
HMI	: Human Machine Interface
Max.	: Maximum
A	: Ampere
kW	: Kilowatt
CP	: Carton Packing



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6.0 INSTALLATION QUALIFICATION FINAL REPORT:

6.1 SUMMARY:

6.2 CONCLUSION:

**Prepared By
Sign/ Date**

**Checked By
Sign/ Date**



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6.3 FINAL REPORT APPROVAL

It has been verified that all tests required by this protocol are completed, reconciled and attached to this protocol or included in the qualification summary report. Verified that all amendments and discrepancies are documented, approved and attached to this protocol. If applicable, signature in the block below indicates that all items in this qualification report of Automatic cartoning machine have been reviewed and found to be acceptable and that all variations or discrepancies have been satisfactorily resolved.

FUNCTION	NAME	DESIGNATION	DEPARTMENT	SIGNATURE	DATE
REVIEWED BY			QUALITY ASSURANCE		
			ENGINEERING		
			PRODUCTION		
APPROVED BY			HEAD OPERATION		
			QUALITY ASSURANCE		