INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR HI- CART CODING MACHINE

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

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INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR HI-CART CODING MACHINE

1.0 PRE – 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)			

INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR HI-CART CODING MACHINE

2.0 OBJECTIVE:

- To provide documented evidence for the Installation Qualification of Hi-Cart Coding Machine.
- 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 Hi-Cart Coding Machine (Make: ……..) to be installed in the Packing Hall.
- This document provides all the relevant information related to specification, installation checks and acceptance criteria to be required to perform installation qualification activity of Hi-Cart Coding 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	• Preparation, Review, Approval 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	• Review & Pre Approval of Protocol cum Report. • To Co-ordinate and support for Execution of Qualification study as per Protocol. • Post Approval of Qualification Protocol after Execution.
Engineering	• Review & Pre Approval of Protocol cum Report. • Co-ordination, Execution and technical support in VFS Installation Qualification Activity. • Calibration of Process Instruments. • Responsible for Trouble Shooting (if occurs during execution). • Post Approval of Qualification Protocol after Execution.

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5.0 EQUIPMENT DETAILS:

Equipment Name	Hi-Cart Coding Machine
Equipment ID.	
Manufacturer's Name	
Supplier's Name	
Location of Installation	Packing Hall

6.0 SYSTEM DESCRIPTION:

HICART PLUS is continuous motion cartoning 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 upto180 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. Product in feed occurs:

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

B. **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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C. **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.

D. **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.

E. **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.

F. **Rear Side Flaps Closing :** Rear side flaps closing takes place between carton loading on the carton chain and product pushing.

G. **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.

H. **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.

I. **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.

J. **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.

K. **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.

L. **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.

M. **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 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.

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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 Hall		
Room Condition	RH : NMT 55 % TEMP : NMT 25 ºC		
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:

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Reviewed By
Manager QA
Sign/Date: ……

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8.2 Installation Checks:

Critical Variables		Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Machine Specification				
Type		Continuous ,Automatic		
Model		HICART PLUS-4P		
Serial No.		……		
Dimensions		2400 mm x 2400 mm x 1650 mm		
Output		Upto 180 cartons/min		
Carton Size	Length	65-180 mm		
	Width	20-75 mm		
	Height	20-65 mm		
Leaflet size	Length	110-170 mm		
	Width	20-35 mm		
Main Motor				
Make		Bonfiglioli		
Power		1.5 kW		
RPM		1390 RPM		
Gear Box				
Make		Bonfiglioli		
Model		MAS 25/P P90		
Drive				
Make		Danfoss		
Power		2 HP		
Carton Pusher Rear				
Servo Motor	Make	Mitsubishi		
	Power	200 W		
	RPM	3000 RPM		
Gear Box	Make	Shimpo-Nidec		

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Critical Variables		Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
	Model	EVB-060-8-K4-14BK14		
Drive	Make	Mitsubishi		
	Model	MR-JE-20A		
Prefolded Leaflet Unit				
Gear Box	Make	KMT		
	Model	120 4:1E0		
Bottle Transfer System				
Motor for turn Table	Make	Bonfiglioli		
	RPM	1370 RPM		
Gear Box	Make	Bonfiglioli		
	Model	W63 U 100 P71 B5 B3		
Drive	Make	Danfoss		
	Power	2 HP		
Motor for accelerated conveyor	Make	Bonfiglioli		
	RPM	1350 RPM		
Gear Box	Make	Bonfiglioli		
	Model	VF 30 F1 20 P63 B5 B3		
Drive	Make	Danfoss		
	Power	0.5 HP		
Air pressure switch				
Make		Festo		
Model		PEV-1/4-SC-OD		
Pneumatic Cylinder				
Make		Festo		
Vacuum Pump				

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR HI-CART CODING MACHINE

Critical Variables		Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Make		Becker		
Model		VT 4.40		
Pressure Gauge				
Make		Festo		
Range		0-16 Bar		
Location		1 for Main FRL		
		1 for Rotary Pick up		
		1 for leaflet ventury		
Vacuum Gauge				
Make		Piab		
Range		-30 to 0 Hg		
Location		Carton		
PLC				
Make		Mitsubishi		
Model		FX 3G-60M		
Tower Lamp				
Make		Schnedier		
Model		XVGB3S		
HMI				
Make		Weintek		
Model		MT6070iH-3EV		
Operating Panel	Main Switch	Power ON/OFF		
	SET & RUN mode	Black Key Switch		
	Machine START	RED Push Button		
	Machine STOP	GREEN Push Button		
	Speed Regulator	Black Knob Switch		

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Critical Variables		Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
	Emergency Button	RED Mushroom Button		
	Conveyor Speed	Black Knob Switch		

Checked By
Production
Sign/Date: ……

Verified By
Quality Assurance
Sign/Date: ……

Inference:

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Reviewed By
Manager QA
Sign/Date: ……

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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:……..

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Reviewed By
Manager QA
Sign/Date: ……

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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:

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12.0 CHANGE CONTROL, IF ANY:

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

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14.0 CONCLUSION:

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15.0 RECOMMENDATION:

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16.0 ABBREVIATIONS:

cGMP	:	Current Good Manufacturing Practice
HIC	:	Hi-cart Coding
HP	:	Horse Power
Hz	:	Hertz
MCB	:	Miniature circuit breaker
mm	:	Millimeter
NLT	:	Not less than
NMT	:	Not More Than
RH	:	Relative Humidity
RPM	:	Revolution per minute
SS	:	Stainless steel
URS	:	User requirement specification

17.0 POST 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)			