



**DESIGN QUALIFICATION
PROTOCOL CUM REPORT
FOR
HI- CART CODING MACHINE
(THREE PIECE LINE)**

DATE OF QUALIFICATION	
SUPERSEDE PROTOCOL No.	NIL



DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR HI-CART CODING MACHINE

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DESIGN 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)			



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2.0 OBJECTIVE:

- To prepare the Design Qualification on the basis of URS, Purchase Order and information given by Supplier.
- The purpose of Design qualification is to ensure that all Critical Aspects of Process/Product requirement, cGMP and Safety have been considered in designing the equipment and is properly documented.

3.0 SCOPE:

- The Scope of this Qualification Document is limited to the Design Qualification of Hi-Cart Coding Machine (Make: **ACG Pampac**).
- The equipment shall be operated under the dust free environment and conditions as per the cGMP requirements.
- The drawings and P & ID's provided by Vendor shall be verified during Design Qualification.



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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 cum Report:

DEPARTMENTS	RESPONSIBILITIES
Quality Assurance	<ul style="list-style-type: none">• Preparation, Review and Approval of the Protocol cum Report.• Assist in the verification of Critical Process Parameters, Drawings as per the Specification.• Review of Qualification Protocol cum Report after Execution.• Co-ordination with Production and Engineering to carryout Design Qualification.• Monitoring of Design Qualification Activity.
Production	<ul style="list-style-type: none">• Review of the Protocol cum Report.• Assist in the verification of Critical Process Parameters, Drawings as per the Specification.• Review of Qualification Protocol cum Report after Execution.
Engineering	<ul style="list-style-type: none">• Review of the Protocol cum Report.• Assist in the Preparation of the Protocol cum Report.• To co-ordinate and support the Activity.• To assist in Verification of Critical Process Parameter, Drawings as per the Specification i.e.<ul style="list-style-type: none">➤ GA Drawing.➤ Specification of the sub-components/bought out items, their Make, Model, Quantity and backup records/ brochures.➤ Details of utilities.➤ Identification of components for calibration.➤ Material of construction of all components.➤ Brief Process Description.➤ Safety Features and Alarms.• Review of Qualification Protocol after Execution.



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5.0 BRIEF EQUIPMENT 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 upto 180 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

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.



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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.



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6.0 EQUIPMENT SPECIFICATION:

Equipment Specifications are based on User Requirement Specification prepared for the manufacturer of equipment ensures complies with User Requirement Specification.

7.0 CRITICAL VARIABLES TO BE MET:

7.1 PROCESS/PRODUCT PARAMETERS:

Critical variables	Acceptance criteria	Reference
Application: Hi-Cart Plus is continuous motion cartoning machine suitable for automatic cartoning of products.	Should be continuous and automatic	Process Requirement
Working: The machine works on vacuum and pressure principle.	Autocartoning of material should be highly accurate.	Process Requirement
Electrical Control Panel	The system should have Electrical Control Panel.	Design Requirement

7.2 UTILITY REQUIREMENTS/LOCATION SUITABILITY:

Critical variables	Acceptance criteria	Reference
Utility connections should be available as per the manufacturer's specification.		
Electrical Supply	Voltage : 415 V Phase : 3 Phase Frequency : 50 Hz \pm 10%. Power consumption : 6 kW	GMP Requirement
Room Condition	Temperature NMT 25 °C RH : NMT 55 %	Process Requirement
Compressed Air supply	6 Bar	Process Requirement



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7.3 TECHNICAL SPECIFICATIONS/KEY DESIGN FEATURES:

Critical Variables		Acceptance Criteria
Machine Specification		
Type		Continuous ,Automatic
Model		HICART PLUS-4P
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
	Model	EVB-060-8-K4-14BK14
Drive	Make	Mitsubishi
	Model	MR-JE-20A
Prefolded Leaflet Unit		



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Critical Variables		Acceptance Criteria
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 conveyer	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		
Make	Becker	
Model	VT 4.40	
Pressure Gauge		
Make	Festo	
Range	0-16 Bar	
Qty	3	
Vacuum Gauge		
Make	Piab	
Range	-30 to 0 Hg	



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Critical Variables		Acceptance Criteria
PLC		
Make		Mitsubishi
Model		FX 3G-60M
Tower Lamp		
Make		Schnedier
Model		XVGB3S
HMI		
Make		Weintek
Model		MT6070iH-3EV
Operating Panel	SET & RUN mode	Black Key Switch
	Machine START	RED Push Button
	Machine STOP	GREEN Push Button
	Speed Regulator	Black Knob Switch
	Emergency Button	RED Mushroom Button
	Conveyor Speed	Black Knob Switch



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7.4 MATERIAL OF CONSTRUCTION:

S.No.	Parts Name	Material of construction
1.	Chain	MS
2.	Pockets Wall	Plastic
3.	Pusher	MS Hardened rods
4.	Drive and guide assembly	MS
5.	Magazine assembly	SS304, MS, EN9
6.	Carton chain and Flap folding assembly	MS, SS304 and alluminum
7.	Tuck in assembly	MS, SS304 and EN8
8.	Carton discharge assembly	MS, PU, SS304 and aluminum
9.	Interconnection assembly	PU belt and Aluminum section



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7.5 SAFETY:

Critical Variables	Acceptance Criteria
MCB	MCB is provided so that where is an overload in current or any short circuit then MCB shall trip
Joints	Should be properly balanced and leveled.
Metal Parts	Metal parts should be properly ground without any sharp edges.
Guards	Welding of joints should be without any welding burrs.
Lock for SS control panel	Guards for all moving parts
Emergency Switch	Should be Available in working condition
Safety Interlocks	Safety interlocks should provided for doors
Pusher Overload	Machine should stop when pusher overload jam during operation



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7.6 VENDOR SELECTION:

Critical variables	Acceptance criteria	Reference
Selection of Vendor for supplying the Carton Machine.	Selection of Vendor is done on the basis of review of vendor. Criteria for review should include vendor background (general/financial), technical know how, quality standards, inspection of site, costing, feedback from market (customers already using the equipment)	Process Requirement

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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8.0 DOCUMENTS TO BE ATTACHED:

- Any other relevant documents.

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

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10.0 ANY CHANGES MADE AGAINST FORMALLY AGREED PARAMETERS:

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11.0 RECOMMENDATION:

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12.0 ABBREVIATIONS:

cGMP	:	Current Good Manufacturing Practice
CQA	:	Corporate Quality Assurance
DQ	:	Design Qualification
GA	:	General Arrangement
HIC	:	Hi-Cart Coding Machine
HMI	:	Human Machine interface
IB	:	Injection Block
Kg	:	Kilogram
MCB	:	Miniature circuit breaker
MOC	:	Material of Construction
NMT	:	Not more than
P & ID	:	Piping and Instrumentation Diagram
PO	:	Purchase Order
RH	:	Relative Humidity
SS	:	Stainless Steel
URS	:	User requirement specification



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13.0 REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (ENGINEERING)			

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			