OPERATIONAL QUALIFICATION

PROTOCOL CUM REPORT

FOR

CARTON PACKING MACHINE

EQUIPMENT ID. No.	
LOCATION	**Packing Area**
DATE OF QUALIFICATION	
SUPERSEDE PROTOCOL No.	**NIL**

OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR CARTON PACKING MACHINE

PROTOCOL CONTENTS

OPERATIONAL 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)			

OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR CARTON PACKING MACHINE

2.0 OBJECTIVE:

- To verify that the equipment operates in accordance with the design requirements as defined by set Acceptance Criteria and complies with relevant cGMP Requirements.
- To verify the Operational features of Carton Packing Machine and to ensure that it produces desired Quality & rated output according to manufactures specifications.

3.0 SCOPE:

- The scope of this operational qualification protocol cum report is limited to qualification of **Carton Packing Machine (Make: ACG Pampac)** installed in Packing Area.
- This Protocol cum Report will define the methods and documentation used to perform OQ activity of Carton Packing Machine.
- Successful completion of this Protocol will verify that Carton Packing Machine meet all acceptance criteria and ready for Performance 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	• Preparation, Review, Authorization and compilation of the operational Qualification Protocol cum Report. • Co-ordination with Production and Engineering to carryout Operational Qualification. • Monitoring of Operation Process. • Post Approval of Qualification Protocol cum Report after Execution.
Production	• Review of Operational Qualification Protocol cum Report. • To Co-ordinate and support for execution of Operational Qualification study as per Protocol. • Post Approval of Operational Qualification Protocol after Execution.
Engineering	• Review of Operational Qualification Protocol cum Report. • To co-ordinate and support Operational Qualification Activity. • Calibration of Process Instruments. • Post Approval of Qualification Protocol cum Report after Execution.

OPERATIONAL 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
Model	HICART PLUS
Serial Number	
Location of Installation	Packing Area

6.0 SYSTEM DESCRIPTION:

HI Cart plus is Continuous Motion cartooning Packing machine, Suitable for automatic Cartoning of Product Like Ampoule Bottle Tubes and blister . the Type of Machine meets the Need of the high Volume Production , Giving an Output of up to 180 Carton /minutes Depending upon Application .the Machine Performed following Function.

- Receive unit Product From Up stream machine on Product Chain .
- Storing of pre Broken Carton in flat from in the Carton Magazine .
- Picking Up The carton 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 Main Functional Areas:

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 adjusted Product Pockets

Individual Product Pocket can be adapted to the Product Size with an adjustment of Chain . Length of the Chain Extension is depends on application, Upstream integration and Room Layout

Product Chain Extension:

The product chain Extension is additional extension for the Product Chain the Extension Provides Additional Space Between Transfer and Cartooning Machine for Customer Specific use i.e. For Manual Product Insertion Into the Product Chain.

B. Carton Chain:

The Carton Chain Transport open Carton from carton Landing to Carton Closing. Following Process take Place on the Carton Chain:

- 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.

The Individual Chain Pocket can be adapted to the Carton Size with an Adjustment of Chain .

Note : Range of Carton Depending on Chain Configuration selected while order Finalization. Machine will be Based on the Customer Need Defined during order Finalization.

C. Carton Loading Magazine :

The carton Magazine Hold Various Size of Carton .Magazine Parts can be adjusted Easily to Accommodation Various Sizes of Carton With the Help of Numeric scales . For each Type each size/ Type of Carton , Values Can be 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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D. Carton Pick up & Transfer System: 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.

An Integrated Carton Pre Breaking system Is provided along with the Carton Pick up System . this unit open /from Carton Before Placing it on the Carton Chain Various Gears along with belt drive Rotates Rotary Pick unit . this Unit rotate Continuously . Sucker arms are mounted on Bracket, which in Turn Mounted on Rotary Pickup unit Through Small Gears.

There are Three Vacuum & air Control Valve used in the Unit. Two Valve are Connected to the Vacuum Lines of the Sucker and one to the Pre- Breaker.

In Run Mode , Whenever the Product is not Present in any Pocket of the Product Chain or the Leaflet is not Released for some Pocket , the Signal is Sent to the Vacuum & air control Valve by a Sensor.

Then the Valve for the Corresponding Sucker Operates , the Vacuum Is Vacuum is Not off and carton is Picked for the product Pocket in which the Product or Leaflet is not Present.

The Valve for the Pre Breakers Operation is Mode .the Position of the Sucker arm for which the vacuum in the Pre Breaker is to be Made on and off are Set.

Thus the operation the Position comes, making the Vacuum in the Pre Breaker On at the start of Pre Pre Braking and Cutting it OFF at the end of Pre Breaking .

Carton pre Breaking unit is Provided to Pre Break the Carton Before Placing Them on the Carton Chain .

E. Carton Positioning: The Carton Position unit Consist of a Carton To ward the product Chain From Rear side of the Machine.

The Carton is pushed Forward in the Forward :

- The Carton Partially pushed Forward
- The Carton Pushed Forward Unit Flaps come in the Contact with the Outer surface of the Cell angle along with Their Full Length.

The side Flap Opener Opens the Side Flaps of the carton for Smooth Insertion of the Product from Product Chain Side.

F. **Rear Side Flaps Closing :** The Side Flap Closing Takes Places Between Carton Loading on the Carton Chain and product Pushing . Stationary Guide Close Left Side Flap and Folding Finger closes the Right Side Flap , Folding Finger is Moveable and Driven Through the Same Drives of Carton Positioning.

G. **Product Pushing system :** The Product Pushing system is Provided to Push the Carton. It Consist of Product Pusher That Push the Product and Leaflet into the Carton . Pushing Takes Places when Product and Carton Comes to the Insertion point.

Folded Leaflet Gets Release by the Leaflet Clamp at this Station and then Inserted into the Carton with the product.

Pusher assembly Consist of a Pusher With rod and pre Pusher . if Product gets Stuck in Between , due to some Reason , It Operates the Overload Safety switch that Stop the Machine .

H. **Carton Closing :** After Slide Flaps Closing Carton system to Main Flap Closing station . front and Rear Flap Closing Takes Place Simultaneously in 3 step.

Flap Position for Closing is done by Creasing guide and guide Rod. These are arranged to blend locking flap with main flap.

Pre- closing: Pre closing and completed closing is done by tuck in closers. In pre closing , tuck in closer pushes the locking flap to lock the carton.

Complete closing : Pre closing and completed closing is done by tuck in closers. In pre closing , tuck in closer pushes the locking flap over the side flap to lock the carton

I. **Carton Discharge**

The closed carton from the carton chain are transferred to the discharge belt. Discharge belt continuously carry these carton to the next point which may be either Collection bin or Line conveyor.

Discharge belt assembly includes two flat belts , driven through the main drive. Speed of both the belts is synchronized and slightly higher than the carton chain speed.

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J. Empty Carton Rejection System

This system is provided to detect and reject the empty carton from the discharge conveyor. A sensor is provided to detect the presence of the product in the carton .If the product is not available in carton , the sensor gives signal to the control system, and it operates an ejection lever, which is operated by a pneumatic cylinder. The rejected carton will then collected in a separate bin.

K. Printing Station

This station has batch code embossing provision. A metallic roller holds embossing letters for coding on the carton flap. Carton flap is passed through the metallic roller and pressure roller to get the impressions of letters on the carton flap.

L. Pre- folded Leaflet Transfer System

This attachment is provided to transfer the folded leaflet into the carton.

Pre folded leaflets are stored in magazine. The leaflets are picked up by the sucker arm and then transferred to the transfer belts. Belts carry these leaflet up to leaflet clamps with rotary turret. Then clamps along with chain carry these leaflets to the pusher station for insertion in the carton.

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7.0 PRE - QUALIFICATION REQUIREMENTS:

7.1 Verification of documents:

The results of any tests should meet the limits and acceptance criteria specified in the test documents. Any deviations or issues should be rectified and documented prior to OQ commencing.

S. No.	Document Name	Document / SOP No.	Completed (Yes/No)	Checked By (Engineering) Sign/Date
1	DQ Protocol cum Report			
2	IQ Protocol cum Report			
3	Draft SOP for Operation & Cleaning of Carton Packing Machine			
4	Draft SOP for Preventive Maintenance of Carton Packing Machine			

Checked By
Production
Sign/Date: ……

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8.0 CRITICAL VARIABLES TO BE MET:

8.1 Verification of Functional Unit:

Operate the machine as per Manufacturer's Manual/SOP and Check for the following functions of the Equipment.

STATION	SPECIFICATION	VERIFICATION PROCEDURE	OBSERVATION COMPLIES /NON COMPLIES	OBSERVED BY (ENGINEERING) SIGN/DATE
Product Feeding System	To Transfer the Bottle Into the Product Pocket at Rated Speed	Check the Bottle Dropped without Damage		
Prefolded Leaflet transfer system	The Leaflet as per Requirements Transfer Through Turret to Leaflet Clamps Provided on leaflet Chain.	Check the Leaflet Smooth Transfer of Leaflet Without Damage .		
Carton Loading System	To Stack /Load the Carton as per Change Part into Carton Magazine & Carton to be Set With the Help of Adjustable Guides	Check Smooth Movement of Stacked Cartons in Carton Magazine for Easy Pickup		
Carton Pick Up Transfer System	To Pick Up the Carton From Carton Magazine into Carrier Finger	Carton are Picked and Placed In The Carton Chain Pockets Properly Without Damages		

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STATION	SPECIFICATION	VERIFICATION PROCEDURE	OBSERVATION COMPLIES /NON COMPLIES	OBSERVED BY (ENGINEERING) SIGN/DATE
Product Pushing System	To Insert the Product into Carton along with Leaflets	Ensure that Smooth Insertion of Product & Leaflets into Carton Without Damage		
Carton Closing System	To Close (Lock) the Cartons with the help of Tuck in Pusher & all Guide to be set with the help of Handle and Digital Ganters	Check the Carton are Getting Closed (locked) properly without damage.		
Carton rejection System	To Reject the Carton which are Having No Product.	Check the carton and gets rejected as per specification mentioned along side		

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8.2 Verification Of Access Levels and Passwords:

Password Level	Password Set	Level Name	Access to	Observation Complies /Non Complies	Observed By (Engineering) Sign/Date
Level 1	111	Operator	Home Screen, Function keys, Optional Keys, Alarm/Events, Monitor, Shift array, PLC Input, PLC Output, ECR Monitor.		
Level 2	222	Supervisor	Home Screen ,Function keys , Optional Keys, Machine Settings, cam, Pockets setting, Counter, timers, Blister Drop, Alarm/Event, Monitor ,Shift array. PLC Input Output, ECR Monitor,		
Level 3	333	Administrator	Set all above, System Setting +Project Setting, Print Information		

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8.3 Verification of Sensor Functioning :

Sensor	Action	Expected Result	Observation Yes/No	Observed By (Engineering) Sign/Date
Product Check	Manually Take out Product Before Sensing	Leaflet Should not Picked up for the Particular Pocket		
Vertical Bottle check	Keep Bottle Vertical Before Sensing	Machine Should Stop Immediately		
Leaflet Check	Remove Leaflet Manually Before Sensing	Carton Should not Picked up for the Particular Pocket		
Carton Check	Remove Carton Manually from Sucker arm Before Sensing	Product should get Diverted Without insertion		
Carton low Level Check	Remove Carton From Magazine up to the low level Sensor Lever	Machine Should Stop Immediately		
Leaflet low Level Check	Remove Leaflet From Magazine up to the low level Sensor Lever	Machine Should Stop Immediately		
Empty Carton Check	Remove Product Before Insertion into Carton	Carton should get Rejected at Discharge end.		
Half Product	Operate the Sensor Manually	Machine Should Stop		

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Sensor	Action	Expected Result	Observation Yes/No	Observed By (Engineering) Sign/Date
Insertion Check				
Vertical Bottle Detected	Manually Make Vertical Bottle Sensed by sensor	Machine Should Stop		
Hand Wheel out check	Pull Out Hand Wheel in machine Idle Condition	Machine should not Start in set & Run mode		
Product Check	Manually Take out Product Before sensing,	Booklet should not Picked up		

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8.4 Verification of Alarm and Safety Interlocks :

DESCRIPTION OF TEST	MESSAGE DISPLAYED ON HMI	RESULT OF TEST	OBSERVATION (YES/NO)	OBSERVED BY (ENGINEERING) SIGN/DATE
Emergency Switch Pressed on HMI	Emergency Stop at Console	Machine Should be Stop Immediately		
Push Emergency Switch Pressed on Discharge end	Emergency Stop at Discharge end	Machine Should be Stop Immediately		
Emergency Switch at Pressed at Infeed	Emergency Stop at Machine Infeed	Machine Should be Stop Immediately		
Air Pressure is Less or Below the set Value	Low Air pressure	Machine Should Stop immediately/Should not start		
Carton Vacuum Key off From HMI	Carton Vacuum Off	Machine Should not Start in Run Mode		
Leaflet Vacuum Key off From HMI	Leaflet Vacuum Off	The Machine Should not Stop /should run in Run Mode		
Carton top Support key on from HMI	Carton Top Support open	Machine Should Stop. Should not Start.		
Pull Hand wheel on Out	Hand wheel out	Machine Should not Start		
Product not Sensed	NA	The Leaflet will not be Picked up		
Leaflet not sensed	NA	The Carton will not Picked up		
Carton Not Sensed	NA	The carton Pusher will not get Diverted		
Product as per set Count in HMI Not	No Continuous Product	The Machine Should stop as per set Count		

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DESCRIPTION OF TEST	MESSAGE DISPLAYED ON HMI	RESULT OF TEST	OBSERVATION (YES/NO)	OBSERVED BY (ENGINEERING) SIGN/DATE
Present				
Leaflet as per set Count in HMI not Present	No Continuous Leaflet	The Machine Should stop as per set Count		
Carton as Per set Count in HMI Not Present	No Continuous Product	The Machine Should stop as per set Count		
Carton Low Level detected by sensor	Low Level of Leaflet	The Machine Should Stop as per the Set Time.		
Carton low Level	Low Level Leaflet warning	Machine should display alarm for Operator Action, Machine Should not Stop.		
Leaflet low Level	Low Level carton warning	Machine should display alarm for Operator Action, Machine Should not Stop.		
Bottle is not Pushed properly inside the Carton	Half Bottle Insertion	The Machine Should Stop immediately		
Carton Chain Clutch Overload	Loading Safety at Carton Chain	The Machine Should Stop immediately		
Pusher Loading Safety	Loading safety at pusher	The Machine Should Stop immediately		
Line machine not Ready	Up Stream Machine Not Ready	The Machine Should Stop immediately		

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DESCRIPTION OF TEST	MESSAGE DISPLAYED ON HMI	RESULT OF TEST	OBSERVATION (YES/NO)	OBSERVED BY (ENGINEERING) SIGN/DATE
Star Wheel Loading Safety	Star Wheel Loading Safety	The Machine Should Stop immediately		
Vertical Bottle Detected by Sensor	Vertical Bottle Insertion	The Machine Should Stop immediately		
Machine Guard Open in Run Mode	Guard Open	The Machine Should Stop immediately in Run Mode		

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8.5 Verification of Manually Operated Components:

COMPONENT NAME	LOCATION ON MACHINE	ACTION	RESULT	OBSERVATION (COMPLIES/NON COMPLIES)	OBSERVED BY (ENGINEERING) SIGN/DATE
M/C Speed Regulator	Console Panel Front	Rotate Clock wise during Running of Machine	Speed of Machine Increases		
		Rotate Anti clock Wise During Running of Machine	Speed of Machine Decreases		
Run / Set Mode key	Console Panel Front	Turn key to left side for Mode and Right side for Set mode	Indication will appear on the HMI Screen & Machine will Operate in Respective mode		
Main FRL Pressure Regulator	Below Discharge Unit	Rotate the Regulator Clockwise	Pressure Increases		
		Rotate the regulator anti clockwise	Pressure Increases		

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8.6 Verification of Working of Displayed Parameter:

SPEED DISPLAY ON HMI	PHYSICAL COUNT OF TOTAL CARTON			OBSERVATION (COMPLIES/NON COMPLIES)	OBSERVED BY (ENGINEERING) SIGN/DATE
100 Carton per Minute					
125 Carton per Minute					
150 Carton per Minute					
Acceptance Criteria : ± 1 CPM					

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8.7 Verification of Emergency Stop Function :

ACTION AT DEFINED LOCATION	RESULT	OBSERVATION (COMPLIES/NON COMPLIES)	OBSERVED BY (ENGINEERING) SIGN/DATE
Push Emergency Stop on Console.	Machine Should Stop Immediately.		
Push Emergency stop at Discharge end of Machine	Machine Should Stop Immediately.		
Push Emergency Stop at infeed	Machine Should Stop Immediately.		

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8.8 Operational Qualification Test Results:

NAME OF TEST	ACCEPTANCE CRITERIA		DEVIATION FOUND		OBSERVED BY (ENGINEERING) SIGN/DATE
	YES	NO	YES	NO	
Verification Functional Unit					
Verification of Access Level and Passwords					
Verification of Sensor Functioning					
Verification of Alarm & Safety Interlock					
Verification of Functional Components					
Verification of Working Displayed Parameter					
Verification of Emergency Stop Function					

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9.0 REFERENCES:

- Vendor Documents
- Operation and Mantainence Manual.

10.0 DOCUMENTS TO BE ATTACHED:

- Any other Relevant Documents.

11.0 DEVIATION FROM PREDEFINED 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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OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR CARTON PACKING MACHINE

16.0 ABBREVIATIONS:

No.	:	Number
WHO	:	World Health Organization
cGMP	:	Current Good Manufacturing Practices
DQ	:	Design Qualification
IQ	:	Installation Qualification
OQ	:	Operational Qualification
SOP	:	Standard Operating Procedure
MOC	:	Material of Construction
SS	:	Stain less Steel
ID	:	Inner Diameter

OPERATIONAL 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:

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HEAD (QUALITY ASSURANCE)			