OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT
FOR
CARTON PACKING MACHINE

OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR CARTON PACKING MACHINE

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

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

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)			

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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 the Packing Area catch Cover.
- 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.

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5.0 EQUIPMENT DETAILS:

Equipment Name	Carton Packing Machine
Equipment ID.	
Model	
Sr.No.	
Manufacturer's Name	ACG-Pampac
Supplier's Name	ACG-Pampac
Location of Installation	Packing Area, Catch Covers

6.0 EQUIPEMENT 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.

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

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N. Carton Discharge

O. Head Wheel

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: ……

Verified By
Quality Assurance
Sign/Date:……

Inference:

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8.0 CRITICAL VARIABLES TO BE MET:

8.1 Operational and Functional Checks:

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

Station	Specification	Verification Procedure	Acceptance Criteria Yes/No	Observed By (Engineering) Sign/Date
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		
Prefolded Leaflet transfer system	To Stack the Leaflet as per the Change Part in to Leaflet Magazine and Transfer the Leaflet to Leaflet Through Belts.	Check the Smooth Movement of Stacked Leaflet in the Magazine & Transfer.		
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 Carrier Finger Pockets Properly Without Damages		
Product Feeding	Feed the Product into Carton Manually	The Unfilled Carton are Sensed by Sensor & Rejected at Discharge end		

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Station	Specification	Verification Procedure	Acceptance Criteria Yes/No	Observed By (Engineering) Sign/Date
Carton Closing	To Close the Carton With the help of Tuck in Pusher & all Guide	Check both Main Tuck in Flap are Closed Properly Without Damage.		
Empty Carton rejected	To Rejected the Carton if Product is Missing	Check the Carton and get Rejected as per Specification Mentioned along Side		

Checked By
Production
Sign/Date: ……

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8.2 Verification Of Access Levels and Passwords:

Password Level	Password Set	Level Name	Access to	Acceptance Criteria Yes/No	Observed By (Engineering) Sign/Date
Level 1	111	Operator	Function keys + Optional Keys		
Level 2	222	Supervisor	Operator Access Keys + Set Cam + Set Counter + Set Pocket + Set Timer		
Level 3	333	Administrator	Supervisor Access Keys + System Setting		

Checked By
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8.3 Verification of Sensor Functioning :

Sensor	Action	Expected Result	Acceptance Criteria Yes/No	Observed By (Engineering) Sign/Date
Low Level of Carton	Remove Carton from Magazine	Machine Should be Stop Immediately		
No Continuous Carton Check	Remove Carton Before Setting	Machine Should Stop as per Set Counter		
No Continuous Leaflet Check	Remove Leaflet Before Sensing	Machine Should Stop as per Set Counter		
Carton Presence for Leaflet	Remove Carton Before Setting	Leaflet Should not be Picked up		
Carton Jam at The discharge	Carton stacks (jam)	Machine Should Stop		
Hand Wheel	Pull out Hand Wheel Manually	Machine Should not Start in Run & Set Mode		
Empty Carton	Remove Product from Carton Before Closing	Carton Should Rejected at Discharge end		

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8.4 Verification of Alarm and Safety Interlocks :

Description of Test	Message Displayed on HMI	Result of Test	Acceptance Criteria (Yes/No)	Observed By (Engineering) Sign/Date
Push Emergency Stop on Console	Emergency Stop at Console	Machine Should be Stop Immediately		
Push Emergency Stop at Extension	Emergency Stop at Extension	Machine Should be Stop Immediately		
Push Emergency Stop at Extension	Emergency Stop at Cabinet	Machine Should be Stop Immediately		
Pull the Hand wheel out	Hand wheel Out	Machine Should not immediately		
Air Pressure is Below or Less then set Limit	Low Air pressure	Machine Should Stop immediately		
Low Level Carton In Magazine	Low Level Carton	Machine Should Stop immediately		
Carton Not Presence	NA	Leaflet Should not Picked up		
Leaflet Not Presence at Per Set Count in HMI	No Continues Leaflet	Machine Should Stop.		
Machine Guard Open	Guard Open	Machine Should Stop. Immediately		
Carton Jam at Discharge End	Carton Jam at Discharge End	Machine Should Stop.		

Checked By
Production
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8.5 Verification of Working of Displayed Parameter: Speed (20 CPM to 120 CPM) ± 1CPM.

Speed Display on HMI	Physical Count of Total			Acceptance Criteria (Yes/No)	Observed By (Engineering) Sign/Date
40 Carton Per Minute					
80 Carton Per Minute					
120 carton Per Minute					

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8.6 Verification of Emergency Stop Function :

Action at Defined Location	Result	Acceptance Criteria (Yes /No)	Observed By (Engineering) Sign/Date
Push Emergency Stop on Console.	Machine Should Stop Immediately.		
Push Emergency stop at Extension	Machine Should Stop Immediately.		
Push Emergency Stop at Control Cabinet	Machine Should Stop Immediately.		

Checked By
Production
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8.7 Power Failure Verification:

Item	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Main Power Shut Down	Equipment stops in a safe and secure condition.		
Main Power Restored	Equipment can be restarted with no problems or adverse conditions.		

Checked By
Production
Sign/Date: ……

Verified By
Quality Assurance
Sign/Date: ……

Inference:

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Reviewed By
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Sign/Date: ……

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8.8 Operational Qualification Test Result:

Name of Test	Acceptance Criteria (Yes/No)	Verified by QA
Verification of Functional Unit		
Verification of Access Levels and Passwords		
Verification of Sensor Functioning		
Verification of Alarm & Safety Interlock		
Verification of Manually operated Components		
Verification of Working of Displayed Parameters		
Verification of Emergency Stop Function		
Verification of Power Failure Condition		

Inference:

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Reviewed By
Manager QA
Sign/Date: ……

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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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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

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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)			