PHARMA DEVILS	OPERATIONAL QUALIFICATION FOR CARTON PACKING MACHINE	PROTOCOL No.:

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 authorities.

This Operation Qualification protocol of Carton Packing Machine has been reviewed and approved by the following Persons

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

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 machine and to prove that each operation proceeds as per design specification and the tolerances prescribed there in the document, are the same at utmost transparency.

The Qualification of Carton Packing Machine performed in view of Line of Soft gel packing hall of manufacturing facility.

2.2 PURPOSE:

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

2.3 SCOPE:

The Scope of this protocol is limited to the operational Qualification of Carton Packing Machine in Line II of Soft gel packing hall of manufacturing facility.

Once the operational qualification of Carton Packing Machine has been completed successfully, the equipment shall be preceded for the performance qualification procedure.

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.
- 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 operational checks, calibration, SOP verification, verification of safety features, verification of utility supply shall be carried out by engineering persons and production person.
- 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.

2.5 EXECUTION TEAM:

The satisfactory operation of the Carton Packing Machine shall be verified by executing the qualification studies described in this protocol. The successfully executed protocol documents that the Carton Packing Machine is operational and is satisfactorily working.

Execution team is responsible for the execution of Operational Qualification of Carton Packing Machine. Execution team comprises of:

NAME	DESIGNATION	DEPARTMENT	SIGNATURE	DATE

3.0	ACCEPTANCE CRITERIA:
3.1	The equipment shall be operational as per its specified operating instructions.
3.2	All SOPs for the equipment shall be verified and checked.
3.3	All the functionality of equipment components to be checked.
3.4	All the safety features of the equipment shall be verified and utilities shall be available near the equipment.
3.5	The validity of the calibration of tests instruments shall be checked and all the required calibration of the components of the equipment shall be performed.
3.6	RPM of motor should be in the range of ±5% deviation.

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 OPERATIONAL 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	:	<table><tr><th></th><th>Width</th><th>Height</th><th>Length</th></tr><tr><td>Minimum</td><td>20 mm</td><td>14 mm</td><td>65 mm</td></tr><tr><td>Maximum</td><td>100 mm</td><td>65 mm</td><td>180 mm</td></tr></table>
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
Electrical supply	:	415 V (±10%), 50 Hz
Compressed air	:	6 bar max.
Location	:	Line of Soft gel Packing hall

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.

5.2 INSTRUCTION FOR FILLING THE CHECKLIST

5.2.1 In case of the compliance of the test actual observation should be written in specified location.

5.2.2 For identification of the components of the equipment and utilities actual observation should be written in specified location.

5.2.3 Give the detailed information in the summary and conclusion part of the Operational Qualification report.

5.2.4 Whichever column is blank or not used 'NA' shall be used.

5.3 Verification of Calibrated component :

This test is intended to describe the equipments/instruments and its complete details to have traceability to the national standard, which is to be used for the verification of the operation of the Carton Packing Machine.

S.No.	Name of Instrument	Inst. ID. Number	Calibration done on	Calibration valid up to	Certificate number

Done By & Date:

Remarks:----------

Verified By & Date:

5.4 Test instrument calibration:

Review the calibration status for the test instrument to be utilized in operational qualification testing and record the calibration due dates in the table below. All equipment / instrumentation must remain within the calibration due date for the duration of OQ test for which the item is used. If a due date potentially occurs during the testing period then the instrument must be recalibrated before it can be utilized.

S.No.	Test Instrument	ID	Calibration done Date	Calibration Due Date	Calibration Certificate No

Checked By/Date:

Remarks:----------

Verified By/Date:

5.5 VERIFICATION OF FUNCTIONAL CHECKS:

Name of system component	Specified function	Method of verification	Observation	Sign & Date
Check correct working of the machine	The machine should be operational.	Physically by challenging		
Blister collator system	To transfer the blisters from blister packing machine through conveyor & to drop blisters into the product pocket as per set count in HMI	Visually		
Leaflet pickup & loading system	To stack the leaflets as per requirement & transfer through turret to leaflet clamps provided on leaflet chain	Visually		
Carton loading system	To stack the cartons as per the change part into leaflet magazine & carton to be set with the help of handle & digital ganters	Visually		
Carton pickup & transfer system	To pick up the cartons from carton magazine & transfer into the carton chain pockets	Visually		
Product pushing system	To insert the product into the carton along with the leaflets	Visually		
Carton Closing System	To close (lock) the cartons with the help of tuck in pushers & related guides to be set with the help of handle & digital ganters	Visually		
Carton ejection system	To eject the empty carton	Visually		

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Name of system component	Specified function	Method of verification	Observation	Sign & Date
Verification of Passwords: Set Level 1 password i.e. 111. Set Level 2 password i.e. 222. Set Level 3 password i.e. 333.	Level 1 password is accessible to operator & access of functional keys, optional keys Level 2 password is accessible to Supervisor & access of Level 1 + Set cam + set counter + set pocket + set timer access Level 3 password is accessible to administrator & access of level 1 + level 2 + system setting + password change	Physically by challenging		
Verification Of Sensors				
Blister low level check in collator: Manually take out blisters	Blisters should not dropped into product pocket	Physically by challenging		
Blister high level check in collator Manually operate the sensor	Blisters should Reject from conveyor	Physically		
Product check: Manually takeout blister before sensing	Leaflet should not pickup for particular pocket	Physically		
Leaflet check: Manually takeout leaflet before sensing	Carton should not pickup for particular pocket	Physically		

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Name of system component	Specified function	Method of verification	Observation	Sign & Date
Carton check: Remove carton manually from sucker arm before sensing	Blister should get diverted without insertion	Physically		
Empty carton check: Remove product before insertion into carton	Carton will get ejected at discharge end	Physically		
Leaflet low level check: Remove leaflets from magazine up to the low level sensor lever	Machine should stop immediately	Physically		
Carton low level check: Remove cartons from magazine up to the low level sensor lever	Machine should stop immediately	Physically		
Hand wheel out check: Pull out hand wheel in machine idle condition	Machine should not start in set & run mode	Physically		
Verification of Alarms & Safety interlocks				
Emergency stop at console	Machine should stop immediately	Physically		
Emergency stop at discharge end of machine	Machine should stop immediately	Physically		
Emergency stop at collator	Machine should stop immediately	Physically		
Low air pressure (Below 3 bar)	Machine should stop immediately	Physically		
Carton vacuum key off from HMI	Machine should not start in run mode	Physically		
Carton top support open	Machine should stop immediately/ will not start	Physically		
Hand wheel out	Machine should not start in run/ set mode	Physically		

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Name of system component	Specified function	Method of verification	Observation	Sign & Date
Product not sensed	Leaflet should not picked up	Physically		
Leaflet not sensed	Carton should not picked up	Physically		
Carton not sensed	Product pusher will get diverted	Physically		
No continuous product	Machine should stop as per set count	Physically		
No continuous leaflet	Machine should stop as per set count	Physically		
No continuous carton	Machine should stop as per set count	Physically		
Low level of leaflet	Machine should stop as per the preset timer	Physically		
Low level of carton	Machine should stop as per the preset timer	Physically		
Product pusher loading safety	Machine should stop immediately	Physically		
Empty carton detection	Empty carton without product should be ejected at discharge end	Physically		
Carton chain clutch overload	Machine should stop immediately	Physically		
Guards open	Machine should stop immediately/ will not start	Physically		
Verification of Manually Operated Components				
Speed regulator	Rotate clockwise during running of machine	Speed of the machine should increase	Physically	
	Rotate anti-clockwise during running of machine	Speed of the machine should decrease	Physically	

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Name of system component		Specified function			Method of verification	Observation	Sign & Date
Run/ Set mode key: Turn key to left side for run mode & right side for set mode		Indication will appear on the HMI screen & machine will operate in respective mode			Physically		
Main FRL pressure regulator	Rotate the regulator clockwise	Pressure should increase			Physically		
	Rotate the regulator anti-clockwise	Pressure should decrease			Physically		
Verification of Working of the Displayed Parameter							
Set speed display on HMI		Physical count of total cartons			Physically		
		1	2	3			
	50 CPM				Physically		
	100 CPM				Physically		
	150 CPM				Physically		
Verification of Emergency Switch							
Push emergency stop switch on console		The machine should stop immediately			Physically		
Push emergency stop switch at discharge end		The machine should stop immediately			Physically		
Push emergency stop switch at collator		The machine should stop immediately			Physically		

Remarks: ----------

Done By & Date: **Verified By & Date:**

5.6 VERIFICATION OF SAFETY FEATURES:

Safety Features Description	Method Of Verification	Acceptance Criteria	Observation	Verified By Sign/Date
Emergency stop	Run the machine & Press the emergency stop push button	The machine should stop immediately		
Earthing	Check whole body with multimeter for any current leakage	No current leakage should be observed		
Limit switch	Run the machine & open the door	The machine should stop immediately		

Remark: ----------

Reviewed by (Sign/Date)

5.7 VERIFICATION 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)

5.8 VERIFICATION 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	SOP Number	Verified By (Sign/Date)

Remark: ----------

Reviewed by (Sign/Date)

5.9 TRAINING RECORD OF PERSONNEL (S):

S.No.	Name of Personnel	Designation	Sign. & Date	Trained By	Remark

Remark: ----------

Reviewed by (Sign/Date)

5.10 LIST OF ANNEXURES:

Annexure No.	Document Title

Remarks (if any)**:** ----------

Done By & Date: **Verified By & Date:**

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

Following deficiency was identified 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)

5.12 Abbreviations

CP: Carton Packing

SOP: Standard Operating Procedure

dB: Decibel

RH: Relative Humidity

mm: Milimeter

V: Voltage

Hz: Hertz

6.0 OPERATIONAL QUALIFICATION FINAL REPORT:

6.1 SUMMARY:

6.2 CONCLUSION:

Prepared By
Sign/Date

Checked By
Sign/ Date

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 Operational qualification report of Carton Packing 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		