



PHARMA DEVILS

**PERFORMANCE QUALIFICATION
FOR
CARTON PACKING MACHINE**

PROTOCOL No.:

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1.0 REPORT 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 performance 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		
			QUALITY CONTROL		
APPROVED BY			HEAD OPERATION		
			QUALITY ASSURANCE		



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2.0 OVERVIEW:

2.1 OBJECTIVE:

The objective of developing and executing this protocol is to

- Document the verification of all aspects of the equipment that can affect product quality.
- To establish, check and document the performance of equipment in the established/predetermined operating ranges.

2.2 PURPOSE:

The purpose of this protocol is to verify that the equipment produces the desired output meeting its predetermined specification. Performance qualification of the equipment is planned after the successful completion of the installation and operational qualification.

2.3 SCOPE:

The protocol shall define the test procedures, documentation, references and acceptance criteria to establish that the performance of the equipment shall meet the predetermined acceptance criteria.

The Scope of this protocol is limited to the performance qualification of Carton Packing Machine installed in Line of Soft Gel Packing hall of manufacturing facility.

Once the performance qualification of Carton Packing Machine has been completed successfully, the equipment shall be released for the production purpose.

2.4 RESPONSIBILITY:

In accordance with protocol, following functions shall be responsible for the qualification of system.

Execution Team (Comprising members from Production, Quality control , Engineering and Quality Assurance) and their responsibilities are following:

- Prepares the performance qualification protocol.
- Ensures that the protocol is in compliance with current policies and procedures on system Qualification.



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- 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 analysis of sample shall be carried out by quality control department.
- Engineering department shall support for execution.
- The production operator / supervisor shall carry out the cleaning and operation of machine.

Head – Quality control / 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 performance 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 performance qualification of the Carton Packing Machine. Execution team comprises of:

NAME	DESIGNATION	DEPARTMENT	SIGNATURE	DATE



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3.0 PREREQUISITE:

- 3.1 Approved Standard operating procedure of the equipment shall be available.
- 3.2 The maximum and minimum capacity of the equipment shall be verified by taking the batch/lot to suit the requirement.
- 3.3 The installation and operational qualification of the equipment shall be successfully completed before the execution of the performance qualification.
- 3.4 All the deficiencies and discrepancies related to the equipment which affect the product quality and corrective action taken shall be recorded in the appropriate section of the protocol.
- 3.5 After completion of PQ activities, equipment shall be cleaned as per respective cleaning SOP's and released for manufacturing.

4.0 REVALIDATION CRITERIA:

The machine shall be revalidated if:

- There are any major changes, which affect the performance of the equipment.
- Batch/lot size taken out of the range on which performance is done.
- As per revalidation date and schedule.

5.0 PERFORMANCE QUALIFICATION PROCEDURE:

5.1 BRIEF DESCRIPTION OF EQUIPMENT

5.1.1 Cartoning Machine:

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



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- Ink embossing station
- Blister 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 Risk Analysis:

- Compressed Air Pressure.
- Emergency Stop.
- Interlocking of machine guards.

S.No.	Risk identified	Control measures	Impact Analysis
1.	Compressed Air Pressure.	4 Bar to 6 Bar.	Machine will stop until desired air pressure is obtained.
2.	Emergency Stop.	Machine should stop.	Machine will not start.
3.	Interlocking of machine guards.	Machine will not start.	Machine will not start if the guards are opened.



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5.3 Methodology:

Read all notes for each steps before beginning the test steps. Verify and record the observations of all critical operational functions. Challenge each of the control system and each sub system. Any function, system or subsystem that fails a particular challenge should be identified and proceeding to the next section of the testing criteria. Any modification to the equipment enable the compliance with the operation must be documented and approved prior to completion of the challenged section. Any modification that has an effect to the operation of the equipment must be challenged. Each generated challenge tests must be approved by each department.

The filled blisters are transferred from blister packing machine through conveyor to the magazine of Carton Packing machine. Operate the machine as per standard operating procedure. Carton Packing machine will open the carton and blisters are transferred from the magazine to the carton. Collect the filled carton and carry out the checks. Performance of the machine shall be carried out on three consecutive run. The key process parameters are:

- Machine Speed.
- Different Pack size.

Record the results in the observation.

➤ Detail of the PQ batches shall be mentioned under the heading of “**Product Details**”.



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5.4 PRODUCT PROFILE:

Product details of the batches shall be verified from the BPR of the product and record in the following section:

5.4.1 Product Detail:

Product Name : _____

Generic Name : _____

Product Code: _____

Batch Number : _____

Batch Size : _____

Mfg. Date : _____

Exp. Date : _____

MRP : _____

Pack size : _____

BMR Number : _____



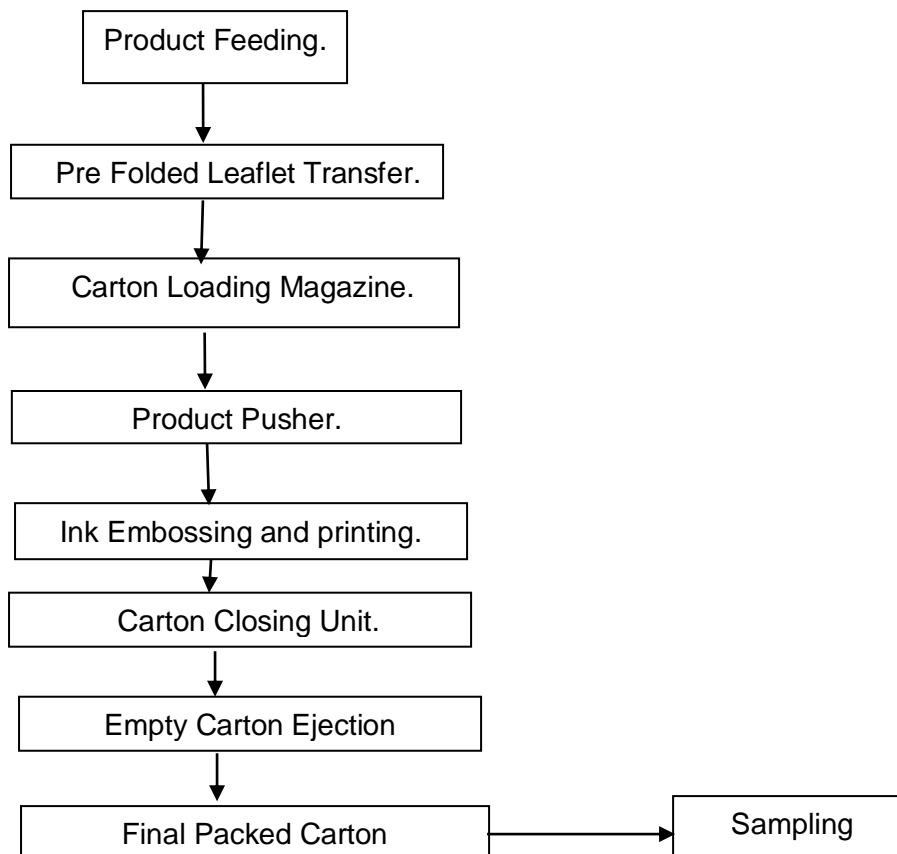
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5.5 PROCESS FLOW DIAGRAM WITH QUALIFICATION PARAMETERS OF CARTONING MACHINE:

Process flow diagram of Cartonning Machine is mentioned below:





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5.6 SAMPLING MATRIX:

The qualification matrix is as following, the challenge run shall be performed for machine:

5.6.1 CARTONING MACHINE:

S.No.	Process Parameter	Speed	Acceptance Criteria
1.	Opening of carton.	60, 100 & 150	Carton should open properly.
2	Proper Insertion of prefolded leaflet in carton.		Prefolded Leaflet should be inserted in carton properly.
3	Proper Insertion of blister in carton.		Blister should be inserted in carton properly.
4	Closing of carton.		Carton should be closed properly.
5	Carton Check for physical damage.		Carton should be free from any type of damage.

5.6.2 CHALLENGE TEST:

Challenge test shall be performed for proper insertion of blisters and leaflets (if applicable) into individual cartons and carton check for any physical damage.

Challenge test shall be performed for empty carton rejection test at minimum, optimum and maximum machine speed only. Empty carton study shall be performed with 10 cartons out of which three i.e. 3, 6 & 9 shall be kept empty knowingly and shall be verified for rejection at discharge end.

5.7 SET PARAMETERS:

5.7.1 SET PARAMETERS FOR CARTONING MACHINE

S.No.	Test	Specification
1.	Compressed Air	4 Bar to 6 Bar.
2.	Speed	As per requirement.



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5.8 ACCEPTANCE CRITERIA:

The test will be considered failed if the actual test results do not correspond to the expected results as following:

- Carton Check for physical damage – Carton should not damage.
- Blister Presence – Blister should be present.
- Leaflet presence (if applicable)- Leaflet should be present.
- Empty cartons rejection- Empty cartons should be rejected.



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5.10 OBSERVATIONS AND RESULTS OF CHALLENGE TESTS:

Test: 1

Batch No.: _____

Pack Size:				
Test Parameter	Acceptance criteria	Speed: _____ (Minimum)		
		Trial No. :		
		I	II	III
Opening of carton.	Carton should open properly.			
Proper Insertion of pre-folded leaflets in carton.	Pre-folded leaflets should be inserted in carton properly.			
Proper Insertion of Blister in carton.	Blister should be inserted in carton properly.			
Closing of carton.	Carton should be closed properly.			
Check carton for physical damage.	Carton should be free from any type of damage.			
Date:				
Start Time:				
End Time:				
Done by,				
Checked by,				



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PROTOCOL No.:

Test: 2

Pack Size:				
Test Parameter	Acceptance criteria	Speed: _____ (Minimum)		
		Trial No. :		
		I	II	III
Opening of carton.	Carton should open properly.			
Proper Insertion of pre-folded leaflets in carton.	Pre-folded leaflet should be inserted in carton properly.			
Proper Insertion of Blister in carton.	Blister should be inserted in carton properly.			
Closing of carton.	Carton should be closed properly.			
Check carton for physical damage.	Carton should be free from any type of damage.			
Date:				
Start Time:				
End Time:				
Done by,				
Checked by,				



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PROTOCOL No.:

Test: 3

Pack Size:				
Test Parameter	Acceptance criteria	Speed: _____ (Minimum)		
		Trial No. :		
		I	II	III
Opening of carton.	Carton should open properly.			
Proper Insertion of pre-folded leaflets in carton.	Pre-folded leaflet should be inserted in carton properly.			
Proper Insertion of Blister in carton.	Blister should be inserted in carton properly.			
Closing of carton.	Carton should be closed properly.			
Check carton for physical damage.	Carton should be free from any type of damage.			
Date:				
Start Time:				
End Time:				
Done By,				
Checked By,				

Remark: -----

Reviewed by (Sign/Date)



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Test: 4

Pack Size					
Test Parameter	Acceptance Criteria	Carton No	Speed: _____ (Minimum)		
			Trial No. :		
			I	II	III
Empty Carton Rejection	Carton No. 3, 6, 9 shall be rejected and rest of the carton shall not be rejected at the discharge end.	1			
		2			
		3			
		4			
		5			
		6			
		7			
		8			
		9			
		10			
Date:					
Start Time:					
End Time:					
Done By,					
Checked By,					



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Test: 5

Pack Size

Test Parameter	Acceptance Criteria	Carton No	Speed: _____ (Minimum)		
			Trial No. :		
			I	II	III
Empty Carton Rejection	Carton No. 3, 6, 9 shall be rejected and rest of the carton shall not be rejected at the discharge end.	1			
		2			
		3			
		4			
		5			
		6			
		7			
		8			
		9			
		10			
Date:					
Start Time:					
End Time:					
Done By,					
Checked By,					



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PROTOCOL No.:

Test: 6

Pack Size

Test Parameter	Acceptance Criteria	Carton No	Speed: _____ (Minimum)		
			Trial No. :		
			I	II	III
Empty Carton Rejection	Carton No. 3, 6, 9 shall be rejected and rest of the carton shall not be rejected at the discharge end.	1			
		2			
		3			
		4			
		5			
		6			
		7			
		8			
		9			
		10			
Date:					
Start Time:					
End Time:					
Done By,					
Checked By,					

Remark: -----

Reviewed by (Sign/Date)



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5.11 INPROCESS CHECKS DURING PACKING:

BATCH No.: _____

S.No.	Parameter	Frequency	Specification	Result	Done By
1	Compressed Air	Start	4 Bar to 6 Bar		
2	Compressed Air	Middle	4 Bar to 6 Bar		
3	Compressed Air	End	4 Bar to 6 Bar		

Remark: -----

Reviewed by (Sign/Date)



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

Following deficiency was verified 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)**



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7.0 PERFORMANCE QUALIFICATION FINAL REPORT:

7.1 SUMMARY:

7.2 CONCLUSION:

**Prepared By
Sign/ Date**

**Checked By
Sign/ Date**



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7.3 FINAL REPORT APPROVAL

The final report shall be signed after verifying that all the tests required in the qualification report of Carton Packing machine are completed, reconciled and attached to the Qualification report or included in the qualification summary report and also verified that all amendments and discrepancies are documented, approved and attached to respective report (If applicable) Signature in the block below indicates that all items in the qualification report of Carton Packing machine have been reviewed and found to be acceptable and that all variations or discrepancies (if any) have been satisfactorily resolved.

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