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

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		

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. Performance qualification of the equipment is planned after the successful completion of the installation and operational qualification.

The equipment working capacity is recommended by manufacturer challenged by charging the tablets with the maximum and minimum capacity of the pan.

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 ointment packing hall of manufacturing facility at …….

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

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.
- 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

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
- Ink embossing station
- Tube transfer system
- Pre-folded Leaflet Transfer system

The Carton Packing 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	Minimum 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.	Guards are open machine will not start.

5.3 Methodology:

Read all notes for each steps before beginning the test steps. Verify and record the verification of all critical operation 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 to enable the compliance with the operation Protocol 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 challenge will be generated and approved by each department.

The filled tubes are transferred from tube filling 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 tubes 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**".

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 : _____

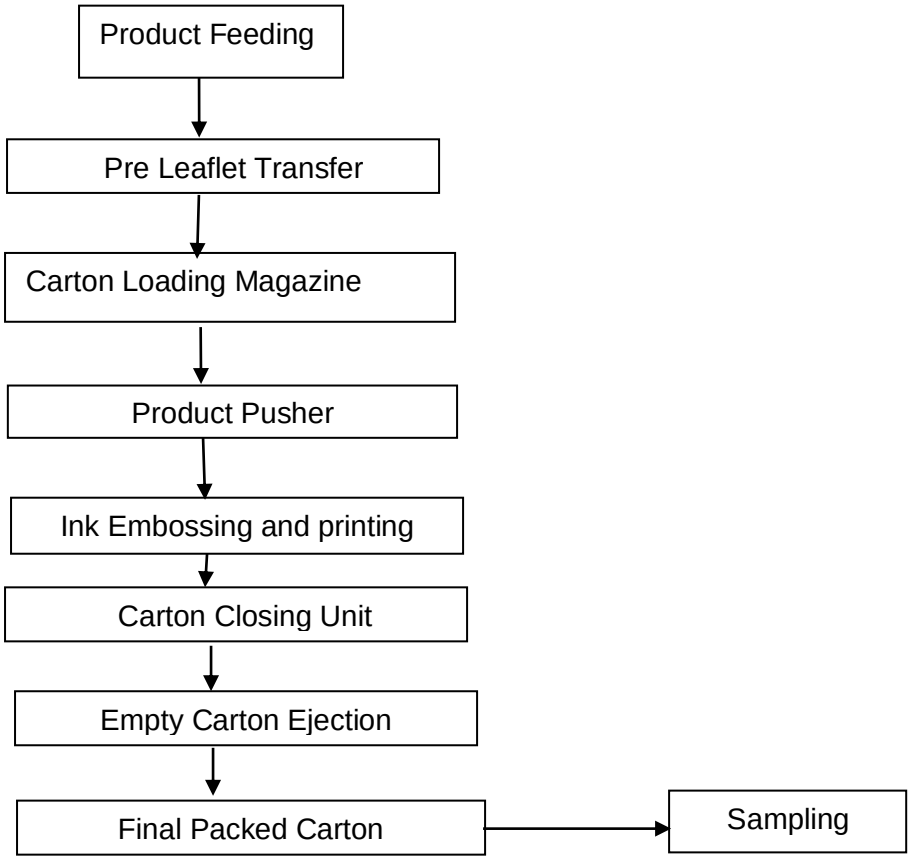
MRP : _____

Pack size : _____

BMR Number : _____

5.5 PROCESS FLOW DIAGRAM WITH QUALIFICATION PARAMETERS OF CARTONING MACHINE:

Process flow diagram of Cartoning Machine is mentioned below:



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	Pack Size
				15 gm
1	Opening of carton	60, 100 & 140	Carton Should open properly.	√
2	Proper Insertion of tube in carton		Tube Should properly insert in carton.	√
3	Closing of carton		Carton Should close properly.	√
4	Carton Check for physical damage		Carton Should not damage	√

5.6.2 CHALLENGE TEST:

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	3.5 Bar to 6 Bar.

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.
- Tube Presence – Tube should be present.

5.9 RECORDING OF SAMPLING:

BATCH:

DATE	TIME	BATCH NUMBER	SAMPLING POINT	QUANTITY	SAMPLED BY (SIGN. & DATE)

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

Reviewed by (Sign/Date)

5.10 OBSERVATIONS AND RESULTS OF CHALLENGE TESTS:

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

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 tube in carton	Tube Should properly insert in carton.			
Closing of carton	Carton Should close properly.			
Carton Check for physical damage	Carton Should not damage			
Date	**Start Time**			
	End Time			
Done By				

Pack Size:				
Test Parameter	**Acceptance criteria**	**Speed: _____ (Optimum)**		
		Trial No. :		
		I	**II**	**III**

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

Pack Size:				
Test Parameter	**Acceptance criteria**	**Speed: _____ (Optimum)**		
		Trial No. :		
		I	**II**	**III**
Opening of carton	Carton Should open properly.			
Proper Insertion of tube in carton	Tube Should properly insert in carton.			
Closing of carton	Carton Should close properly.			
Carton Check for physical damage	Carton Should not damage			
Date	**Start Time**			
	End Time			
Done By				

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

Pack Size:				
Test Parameter	**Acceptance criteria**	**Speed: _____ (Maximum)**		
		Trial No. :		
		I	**II**	**III**
Opening of carton	Carton Should open properly.			
Proper Insertion of tube in carton	Tube Should properly insert in carton.			
Closing of carton	Carton Should close properly.			
Carton Check for physical damage	Carton Should not damage			
Date	**Start Time**			
	End Time			
Done By				

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

Reviewed by (Sign/Date)

Challenge Test:

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					

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

Pack Size					
Test Parameter	**Acceptance Criteria**	**Carton No**	**Speed: _____ (Optimum)**		
			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					

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

Pack Size					
Test Parameter	**Acceptance Criteria**	**Carton No**	**Speed: _____ (Maximum)**		
			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)

5.11 INPROCESS CHECKS DURING PACKING:

BATCH No.: _____

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

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

Reviewed by (Sign/Date)

5.12 Environmental Monitoring During Process

Environmental monitoring shall be done and record in the following table during manufacturing process run:

Limit: Temperature (°C) : ____ ± ____°C

RH : ____ ± ____% **(Every one Hour)**

BATCH No.:_____

DATE	TIME	BATCH NO.	TEMPERATURE	% RH	DONE BY

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

Reviewed by (Sign/Date)

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)

7.0 PERFORMANCE QUALIFICATION FINAL REPORT:

7.1 SUMMARY:

7.2 CONCLUSION:

Prepared By
Sign/ Date

Checked By
Sign/ Date

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 repot. (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		