PERFORMANCE QUALIFICATION PROTOCOL FOR AUTOCARTONATOR

EQUIPMENT ID. No.	
LOCATION	**PACKING HALL**
DATE OF QUALIFICATION	
SUPERSEDES PROTOCOL No.	**NIL**

PROTOCOL CONTENTS

PHARMA DEVILS	PERFORMANCE QUALIFICATION PROTOCOL FOR AUTOCARTONATOR	PROTOCOL No.:

1.0 PROTOCOL APPROVAL:

INITIATED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			
HEAD (QUALITY CONTROL)			
HEAD (ENGINEERING)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			

2.0 OBJECTIVE:

- To provide documented evidence that the Equipment is performing consistently, repeatedly and reproducibly within its established operating range and the results of all test parameters meet the pre-defined acceptance criteria.

3.0 SCOPE:

- The Protocol covers all aspects of Performance Qualification for the **Autocartonator**.
- This Protocol will define the methods and documentation used to qualify the Autocartonator for PQ.

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.

DEPARTMENTS	RESPONSIBILITIES
Quality Assurance	• Preparation and Approval of the Performance Qualification Protocol. • Protocol Training. • Co-ordination with Quality Control, Production and Engineering to carryout Performance Qualification Activity. • Monitoring of Performance Qualification.
Production	• Review Performance Qualification Protocol. • To co-ordinate and support Performance Qualification Activity.
Quality Control	• Analytical Support (Microbiological Testing/Analysis).
Engineering	• Reviewing of qualification protocol for correctness, completeness and technical excellence. • Responsible for trouble shooting (if occurred during execution). • Maintenance & preventive maintenance as per schedule.

5.0 EQUIPMENT DETAILS:

Equipment Name	Autocartonator
Equipment	
Manufacturer's Name	Wimco Ltd.
Location of Installation	Packing Hall

6.0 SYSTEM DESCRIPTION:

Filled tube form Tube Filling Machine are been transferred to the product conveyor with the help of interconnection assembly then after it the tubes gets dropped into product conveyor which is driven with the help of drive of machine after the tube gets inserted in the product conveyor the leaflet assembly takes out leaflets and transfer it to the chain (leaflet Chain) which travels parallel with tube in product conveyor, When the tube is passes the leaflet station a sensor sense the presence of product in pocket of conveyor then the cartons is drawn from magazine assembly and carried to the carton chain, Once all the products, carton & leaflet are sensed, product pusher does the loading. If for any reason carton or leaflet is not available, the loading system will bypass the said products & machine stops.

When the tube and leaflet reach at pushing stations multiple pushers' starts pushing the tube in the direction of carton and when it reaches to its end limit the tube and leaflet are inserted inside the carton with help of pushers further the side flaps of carton are folded with the help of folders and guides then the carton chain take the cartons to the gluing station (Tuck in station) where the glue is applied to enclose the flaps of cartons (or Flaps are pushed inside during tuck in cartons) after which the carton chain push the carton into ejection assembly where the two belt conveyors takes the carton to the end of machine and ejects the cartons.

7.0 REASON FOR QUALIFICATION:

- New equipment installed in **Packing Hall** .
- After completion of the Operation Qualification of the Equipments, it is imperative to perform the Performance Qualification. The study will establish that the parameters are followed, critical variables are under control and the quality of the output is, as desired.

8.0 SITE OF STUDY:

- Packing Hall.

9.0 FREQUENCY OF QUALIFICATION:

- Once in every Two Year ±1 month.
- After any major breakdown or after major modification.
- After Change of Location.

10.0 PRE – QUALIFICATION REQUIREMENTS:

The below mentioned activities should be completed prior to commencing the performance qualification activity:

10.1 Verification of Documents:

Verification for availability, completeness and approval status of all the required relevant documents shall be done and observations shall be recorded in the performance qualification report.

- SOP for Operation & Cleaning of Autocartonator.
- SOP for Preventive Maintenance of Autocartonator.

10.2 Training Record of Validation Team:

- All the persons involved in the execution of Qualification Protocol must be trained in all aspects of the qualification activity including the test methodology, acceptance criteria and safety precautions to be followed during working at service floor.

11.0 TESTS AND CHECKS:

11.1 Evaluation of Performance:

Objective:

To evaluate and to provide documented evidences for performance of equipment for proper Cartoning of tubes. The objective of the test is to determine whether the machine is able to cartoning the tubes.

11.1.1 Checks for machine:

- Autocartonator Speed

11.1.2 Test & Method:

Autocartonator Machine Speed Optimization:

1. The Test shall be performed on different- different size of tubes.
2. Switch “ON” the equipment & operate as per respective SOP.
3. Run the Equipment at different speed.
4. During running, check the Equipment speed synchronization with respect to Cartoning assembly speed simultaneously.
5. After that, check the packed tubes for minimum 120 tubes from each Trial.
6. Said activity shall be performed initial stage, middle stage & end stage of equipment running.
7. All the collected 120 packed tubes should be pass with-in specified limits.
8. Above step shall be follow for minimum speed optimization of equipment & maximum speed optimization of equipment.

11.1.3 Acceptance Criteria

Equipment runs trouble free without any problems after maintain up to working Capacity i.e. 120 Carton Packing with Tube per min.

11.2 VERIFICATION OF UNIFORMITY IN PACKING OF PRODUCT OR TUBES:

11.2.1 Objective :

The purpose of this test is to ensure that Equipment Perform trouble free & uniform packing of filled Tube into Carton as per set pack size.

11.2.2 Test Method :

Check the uniformity in packing of filled tubes into Carton by taking 10 packed Cartons & check the individual packed Carton for presence of filled tube and following parameter at different speed min, max and optimum:

1. Printing Matter
2. Batch Coding
3. Flap Folding
4. Damage Carton

Three consecutive trials must be tested as described before, in order to demonstrate Consistent performance.

After performing the test calculate the % age of Rejection.

11.2.3 Acceptance Criteria :

At different time Interval Equipment should be uniformly pack filled Tube into Carton. And the rejection should be NMT 2.0%.

Performance of Equipment should be trouble free throughout the Performance cycle.

12.0 CHECKLIST OF ALL TESTS & CHECKS:

This checklist is provided to ensure that all tests or checks required for this protocol have been executed.

Tests or Checks	Executed (Yes/No)	Remarks
Verification of Documents		
Speed Synchronization		
Uniformity of Packed Tube		

13.0 REFERENCES:

- Validation Master Plan.
- Schedule - M – “Good Manufacturing Practices and Requirements of Premises, Plant and Equipment for Pharmaceutical Products.”
- WHO Essential Drugs and Medicines Policy, QA of Pharmaceuticals, Vol-2. Good Manufacturing Practices and Inspection.

14.0 DOCUMENTS TO BE ATTACHED:

- Raw data generated during testing.
- Protocol training record.
- Any other relevant document.

15.0 NON COMPLIANCE:

All the Non-compliances of procedure, specifications, and sampling, analysis and documentation activities shall be monitored & recorded.

16.0 DEVIATION FROM PRE-DEFINED SPECIFICATION, IF ANY:

- In case of any deviation observed during PQ, inform to Head QA for necessary action.
- Document the deviation detail in observed deviation section.
- The Head QA will study the impact of deviation. If deviation is acceptable and it does not have an Impact on operation as well as on performance of the machine & prepare final conclusion.

17.0 CHANGE CONTROL, IF ANY:

- If any change control is required during PQ, inform to Head QA for necessary action.
- Document the details observed.
- The Head QA will study the impact of change. If change is acceptable and it does not have an Impact on operation as well as on performance of the machine & prepare final conclusion.

18.0 ABBREVIATIONS:

Asst.	:	Assistant
cGMP	:	Current Good Manufacturing Practices
PQ	:	Performance Qualification
Vol.	:	Volume
i.e.	:	That is
SS	:	Stainless steel
Ltr.	:	Litre
Nos.	:	Numbers.
SOP	:	Standard Operating Procedure
SS	:	Stain less Steel
ACN	:	Autocartonator
WHO	:	World Health Organization