PERFORMANCE QUALIFICATION PROTOCOL FOR SINGLE HEAD SEMI AUTOMATIC TUBE FILLING, CRIMPING AND SEALING MACHINE

EQUIPMENT ID. No.	
LOCATION	**FILLING ROOM**
DATE OF QUALIFICATION	
SUPERSEDES PROTOCOL No.	**NIL**

PHARMA DEVILS	PERFORMANCE QUALIFICATION PROTOCOL FOR SINGLE HEAD SEMI AUTOMATIC TUBE FILLING, CRIMPING AND SEALING MACHINE	PROTOCOL No.:

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1.0 PROTOCOL APPROVAL:

INITIATED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			
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 Single Head Semi Automatic Tube Filling, Crimping and Sealing Machine.
- This Protocol will define the methods and documentation used to qualify the Single Head Semi Automatic Tube Filling, Crimping and Sealing Machine 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	Single Head Semi Automatic Filling, Crimping and Sealing Machine
Equipment	
Manufacturer's Name	
Model	cGMP
Supplier's Name	
Location of Installation	Filling Area

6.0 SYSTEM DESCRIPTION:

The Automatic linear plastic tube filling machine is designed with high speed for filling the plastic tubes and Lami Tubes.

The operator has to feed the product inside the jacketed hopper. The tube insert manually passes to each and every station for performing the filling operation of filling is described thoroughly.

All the safety features are provided in the machine, which are as per the GMP standard and is in compliance with set industrial standards.

STRUCTURAL OVERVIEW:

- **Driving clutch system:** motor, speed reducer, chain, gear wheel.
- **Filling system:** Filling cam, filling travel adjusting device, filling shaft, main valve, nozzle, blowing device etc.
- **Cream Transferring system:** Cam, Transfer travel adjusting device, shaft, pump, hopper etc.
- **Heating system:** Heating cam, shaft, heating drum, heater air fan, temperature control system and cooling system.
- **Cutting system:** Cutting manipulator, cooler etc.
- **Trimming system:** Trimming manipulator
- **Tube output system:** Cam shaft pushing rod etc.
- **Electrical system;** Controlling transformer, frequency inverter PLC set.
- **Optional equipments:** 2P chiller, 0.7 Mpa air compressors.

7.0 REASON FOR QUALIFICATION:

- New equipment installed.
- 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:

- Filling room.

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 Double Head fully automatic Filling, closing and Sealing machine.
- SOP for Preventive Maintenance of Double Head fully automatic Filling, closing and Sealing machine.

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 filling of tubes. The objective of the test is to determine whether the machine is able to filling the containers with desired level of Bulk.

11.1.1 Checks for machine:

- Filling Machine Speed
- Fill Weight Variation
- Hopper Level
- Leak test
- Physical Test

11.2 Filling Machine Speed Optimization:

11.2.1 Method applied:

- The Test shall be performed on different- different size of tubes.
- Load the Bulk in the equipment hopper.
- Switch "ON" the equipment & operate as per respective SOP.
- Run the Equipment at different speed.
- Set the machine speed (Tubes / Minute) through Stopwatch as per below table.

Bottle Size	Maximum Speed	Optimized Speed	Minimum Speed
5 gm	48 Tubes / min.	30 Tubes / min.	12 Tubes / min
10 gm	48 Tubes / min.	30 Tubes / min.	12 Tubes / min
15 gm	48 Tubes / min.	30 Tubes / min.	12 Tubes / min
20 gm	40 Tubes / min	25 Tubes / min	10 Tubes / min
30 gm	40 Tubes / min	25 Tubes / min	10 Tubes / min
50 gm	40 Tubes / min	25 Tubes / min	10 Tubes / min

- Start the machine with individual speed & count the Tubes after 10 minute for each speed.
- Repeat it three times at each speed.
- Final machine output shall be decided & verified after performing the test

11.2.2 Acceptance Criteria:

The machine should be smooth running at minimum and maximum speed.

11.3 Fill Weight Variation:

1. The test should be carried out for minimum & maximum strength.

2. Switch "ON" the machine & Operate as per respective SOP.
3. Perform the test by filling bulk at optimized speed of machine.
4. Perform the filling operation at 3 different speeds, for each strength & check the weight variation of 20 Tubes duly sampled at 3 cycles of the filling operation.
5. Collect Filled tubes from the machine & measure gross wt. and tare weight of the tubes & calculate filled bulk weight.

11.3.1 Acceptance Criteria

- Filing Machine should deliver the fill weight in each tube as per required qty. or standard filled weight. The variation should be ±1.5% of target filled wt.

11.4 Leak Test:

1. The test shall be carried out consecutively up to three batches.
2. Collect at least 10 Tubes from nozzle.
3. Perform the leak test as per respective SOP.
4. During running, check the Equipment speed synchronization.
5. After that, check the tubes and discard as per respective SOP.

11.4.1 Acceptance Criteria

No leakage should be observed.

11.5 Physical Test:

1. Collect the 10 tube from each Nozzle.
2. Check the tube Physically i.e. Dent , Engraving , Physical appearance and Printing matter
3. Record the observation in Qualification Report

11.5.1 Acceptance Criteria:

12.0 CHECKLIST OF ALL TESTS & CHECKS:

A checklist shall be provided to ensure that all tests or checks required for this protocol have been executed. After execution observations shall be recorded in Performance Qualification Report.

The list includes:

- Verification of performance by executing test for Optimization of Filling Machine Speed, Fill Weight Variation, and Hopper level.

13.0 REFERENCES:

The Principle References are as following:

- 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
CQA	:	Corporate Quality Assurance
PQ	:	Performance Qualification
Vol.	:	Volume
i.e.	:	That is
SS	:	Stainless steel
Ltr.	:	Litre
Nos.	:	Numbers.
SOP	:	Standard Operating Procedure
SS	:	Stain less Steel
WHO	:	World Health Organization