



**PERFORMANCE QUALIFICATION
PROTOCOL
FOR
DOUBLE HEAD FULLY AUTOMATIC FILLING ,
CLOSING AND SEALING MACHINE**

PROTOCOL No.:

**PERFORMANCE QUALIFICATION
PROTOCOL
FOR
DOUBLE HEAD FULLY AUTOMATIC
FILLING, CLOSING AND SEALING
MACHINE**

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




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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 (QUALITY CONTROL)			
HEAD (ENGINEERING)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			



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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 **Double Head fully automatic Filling, closing and Sealing machine** installed.
- This Protocol will define the methods and documentation used to qualify the Double Head fully automatic Filling, closing and Sealing machine for PQ.

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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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • Review Performance Qualification Protocol. • To co-ordinate and support Performance Qualification Activity.
Quality Control	<ul style="list-style-type: none"> • Analytical Support (Microbiological Testing/Analysis).
Engineering	<ul style="list-style-type: none"> • Reviewing of qualification protocol for correctness, completeness and technical excellence. • Responsible for trouble shooting (if occurred during execution). • Maintenance & preventive maintenance as per schedule.

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5.0 EQUIPMENT DETAILS:

Equipment Name	Double Head fully automatic Filling, Closing and Sealing machine
Equipment	
Manufacturer's Name	
Model	
Serial No.	
Supplier's Name	
Location of Installation	Filling Room

6.0 SYSTEM DESCRIPTION:

The Equipment is used for automatically filling, closing and sealing for metal plastic and aluminum tubes. This machine is used for the filling of the product inside the tubes. Tube holders are designed as per tube diameter.

75 ltr. SS jacketed Hopper with stirrer is provided to load the product inside the hopper manually. Level sensor maintains the product level. Empty tubes feed manually inside the auto feeder cassettes box. It has to maintain proper direction of tube to avoid. Tubes can be automatically loaded inside the holder by using tube loading arms and gets cleaned by purging dry compressed air and at the same time dust particle can be removed by vacuum.

FOR PLASTIC / LAMI TUBESS:

After loading the tubes, Tubes pass through the tube presence sensor for maintain proper orientation of the machine.

If tube is not present inside the tube holder product is not get filled.

A piston dosing pump, consisting of piston placed in SS cylinder carries out the dosing. One set piston pump. Filling nozzle consisting of a Pneumatic shut off system, helps eliminate product dripping and maintain filling accuracy.

Hot air temperature can be set as per the characteristics. Hot air makes the tubes hot for sealing with maintained temperature. To avoid the outer heating of the heating of the heater ring water cooling is provided.

Tubes gets sealed and coated at tubes sealing at coding station. And extra sealed tube gets cut and removed at trimming station and required tube length dimension gets maintained. Good fill tubes can be ejected at ejection station.



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FOR ALUMINUM TUBES:

After loading the tubes, tubes pass through the presence sensor for maintain proper orientation of the machine

If tube is not present inside the tube holder product is not get filled.

A piston dosing pump, consisting of piston placed in SS cylinder carries out the dosing. One set piston pump. Filling nozzle consisting of a Pneumatic shut off system, helps eliminate product dripping and maintain filling accuracy.

First fold of the tube gets folded at first folding station and second folding at second folding station as per the required length of the tubes.

Batch coding is done at batch coding station and finally filled good filled tubes can be ejected at ejection system.

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:



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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

11.1.2 Test & Method:

Filling Machine Speed Optimization:

1. The Test shall be performed on different- different size of tubes.
2. Load the Bulk in the equipment hopper.
3. Switch "ON" the equipment & operate as per respective SOP.
4. Run the Equipment at different speed.
5. During running, check the Equipment speed synchronization with respect to filling nozzle assembly speed simultaneously.



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6. After that, check the weight variation of filled tubes for minimum 20 tubes.
7. Collect filled 20 tubes from the equipment, measure gross weight & tare weight of tubes, calculate the actual filled weight.
8. Said activity shall be performed initial stage, middle stage & end stage of equipment running.
9. All the collected 20 filled tubes should be pass with-in specified limits.
10. Above step no. 05 to 08 shall be follow for minimum speed optimization of equipment & maximum speed optimization of equipment.

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 Min. and Max. 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.

Leak Test:

1. The test shall be carried out consecutively up to three batches.
2. Collect at least 10 Tubes from both nozzles.
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.

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

11.1.3 Acceptance Criteria

- Filing Machine should deliver the fill weight in each tube as per required qty. or standard filled weight.
- No leakage should be observed.



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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		
Fill Weight Variation		
Leakage Test		
Physical Test		

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.



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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
OFS	:	Double Head fully automatic Filling, closing and Sealing machine
WHO	:	World Health Organization