# PERFORMANCE QUALIFICATION PROTOCOL FOR DOUBLE HEAD TUBE FILLING MACHINE GAN COMBI

| | |
|---|---|
| **EQUIPMENT ID. No.** | |
| **LOCATION** | **Filling Room** |
| **DATE OF QUALIFICATION** | |
| **SUPERSEDES PROTOCOL No.** | **NIL** |

| PHARMA DEVILS | PERFORMANCE QUALIFICATION PROTOCOL FOR DOUBLE HEAD TUBE FILLING MACHINE GAN COMBI | PROTOCOL No.: |
|---|---|---|

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| PHARMA DEVILS | PERFORMANCE QUALIFICATION PROTOCOL FOR DOUBLE HEAD TUBE FILLING MACHINE GAN COMBI | PROTOCOL No.: |
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## 1.0 PROTOCOL APPROVAL:

**PREPARED BY:**

| DESIGNATION | NAME | SIGNATURE | DATE |
|---|---|---|---|
| OFFICER/EXECUTIVE (QUALITY ASSURANCE) | | | |

**REVIEWED BY:**

| DESIGNATION | NAME | SIGNATURE | DATE |
|---|---|---|---|
| OPERATING MANAGER (QUALITY ASSURANCE) | | | |
| HEAD (ENGINEERING) | | | |

**APPROVED BY:**

| DESIGNATION | NAME | SIGNATURE | DATE |
|---|---|---|---|
| HEAD (PRODUCTION) | | | |

## 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 Tube filling machine GAN combi** installed.
- This Protocol will define the methods and documentation used to qualify the Double Head Tube Filling machine GAN combi 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.<br>• Protocol Training.<br>• Co-ordination with Quality Control, Production and Engineering to carryout Performance Qualification Activity.<br>• Monitoring of Performance Qualification. |
| **Production** | • Review Performance Qualification Protocol.<br>• 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.<br>• Responsible for trouble shooting (if occurred during execution).<br>• Maintenance & preventive maintenance as per schedule. |

## 5.0 EQUIPMENT DETAILS:

| | |
|---|---|
| **Equipment Name** | Double Head fully Automatic Filling, Closing and Sealing machine |
| **Equipment** | |
| **Manufacturer's Name** | |
| **Model** | GAN COMBI |
| **Serial No.** | |
| **Supplier's Name** | |
| **Location of Installation** | Filling room |

## 6.0 SYSTEM DESCRIPTION:

**Application:**

Double Head Tube Filling Machine is used for filling and sealing / closing of Lami/ Plastic tube of Dia.16-50mm (beyond Ø42 tube machine will operate on single head) with filling variation of 2 cc to 250 cc depending on the material properties.

**Major System Components:** Tube filling Machines is comprised of following major subassemblies/ Components.

**Automatic Tube Loading on Machine:**

Consist of Polycarbonate Cassettes with S.S.304frame, Al tube tilter, Cassette motor and S.S.304 Rocker.

**Tube Registration Device:**

Two Stepper motors attached to Magnetic lifting head, S.S 304 cone, and Color mark Sensors.

**Tube Cleaning:**

Tube cleaning by means of suction & ionized compressed air by ionized system.

**Tube Filling Device.**

S.S 316L Jacked Hopper with 75 liters capacity having surface finish of internal 0.5Ra & external 0.9 Ra, mounted on the machine. Jacketed hopper fitted with cover, electrical, digital temperature controller, level sensor, & cream stirring device which stirs the material to make it free flow with separate motor & VFD (Allen Bradley).S.S 316L-make nozzle with air blow off device attached to the reciprocating S.S. pump.

Complete material transfer device (from hopper to filling nozzle) is made of SS 316L.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.

For Lami /Plastic tube, tube inner surface is heated by a hot air blowing station then tube is pressed in between two jaws by sealing unit mounted on the sealing station. Then sealed tube is cooled before the trimming operation, which is carried out by the trimming unit.

For Metal tubes folding is done three stations (Flattening, 1st Fold & 2nd Fold) which are placed adjacent to each other in sealing station. Tube is transferred after filling to the flattening station.

In case of a combi sealer lami sealing units will be idle during sealing however they will be placed in the same location.

For switching from Lami tube to Metal Tube or Vice-Versa, the machine requires some change over, Hence either of the tube can only manufacture in each batches. Change over should be done by Standard tooling.

In the ejection station, lifting ejection pin should be set proper, so that the tube lifted entirely Clear of the holder and is then rolled down into the chute.

DK-20 P&F (Visolex) make photo scanner is provided for ensuring wrong orientation & no Filling of tube (no I-mark no filling), tube automatically gets rejected at rejection side in empty Condition (it is in interlock).

## 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 Tube Filling machine GAN combi.
- SOP for Preventive Maintenance of Double Head Tube Filling machine GAN combi.

### 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.
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.

## 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.

## 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 |
| Vol. | : | Volume |
| i.e. | : | That is |
| SS | : | Stainless steel |
| Ltr. | : | Litre |
| Nos. | : | Numbers. |
| SOP | : | Standard Operating Procedure |
| SS | : | Stain less Steel |
| OFS | : | Double Head Tube Filling machine GAN combi |
| WHO | : | World Health Organization |