PERFORMANCE QUALIFICATION PROTOCOL FOR VIAL FILLING & STOPPERING MACHINE

EQUIPMENT ID. No.	
LOCATION	**Vial Filling & Stoppering Room**
DATE OF QUALIFICATION	
SUPERSEDES PROTOCOL No.	**NIL**

PHARMA DEVILS	PERFORMANCE QUALIFICATION PROTOCOL FOR VIAL FILLING & STOPPERING MACHINE	PROTOCOL No.:

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 PHARMA DEVILS	PERFORMANCE QUALIFICATION PROTOCOL FOR VIAL FILLING & STOPPERING MACHINE	PROTOCOL No.:

1.0 PROTOCOL PRE – 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 **Vial Filling & Stoppering Machine,** installed in the Vial Filling & Stoppering Room ……
- This Protocol will define the methods and documentation used to qualify the Vial Filling & Stoppering 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, Review, Approval and Compilation of the Performance Qualification. • Protocol Training. • Co-ordination with Quality Control, Production and Engineering to carryout Performance Qualification Activity. • Monitoring of Performance Qualification.
Production	• Review of Protocol. • To co-ordinate and support Performance Qualification Activity.
Quality Control	• Review of Protocol. • 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	Vial Filling & Stoppering Machine
Equipment	…….
Manufacturer's Name	Amba Sale & Services
Supplier's Name	Amba Sale & Services
Location of Installation	Vial Filling & Stoppering Room

6.0 SYSTEM DESCRIPTION:

The equipment is an automated means to fill sterile dry powder with different weights in different sizes of vials & rubber stoppered the same as well pressing of rubber stopper vial. The equipment having four heads with double track filling action. This machine works on vacuum filling principle giving guarantee of high accuracy of fill weight with minimal spillage.

Sterile dry powder loads into powder hopper. Powder hopper will agitate the powder & delivers to the port wheel through powder agitator .When wheel port come under the powder hopper, vacuum will take place.

Powder hopper agitator will push down the powder & due to vacuum in.

Wheel port, powder will enter into the port & fills in it. As soon as wheels start rotating, Doctor Blades will scrap out the excess powder from wheel.

An electro mechanical sensor will sense the presence of vial & pass signal to the solenoid valve. Once powder slug purge into vial, vial separators will carry the vial & pass on the same conveyor belt for the rubber stoppering process.

Filled vials convey on slat conveyor belt for next operation, as soon as filled vial comes to the lateral belt, same will hold the vial firmly from body diameter & will carry vial underneath the rubber stopper chute, the filled vial will pick one rubber stopper from rubber stopper chute & belt will carry the same vial for pressing the rubber stopper under the two pressing roller.

The first roller will position the rubber stopper & second will press the rubber stopper. Still lateral belts are holding the vial after pressing the rubber stopper, lateral belt will push out the vial on conveyor & conveyor will transfer the vial on scrambler turn table for next Operation.

7.0 REASON FOR QUALIFICATION:

- New equipment in Vial Filling & Stoppering Room.
- 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:

- Vial Filling & Stoppering Room.

9.0 FREQUENCY OF QUALIFICATION:

- 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:

- Design Qualification.
- Installation Qualification.
- Operational Qualification.
- Calibration of all critical Components of Equipment.
- Preparation of SOP for Operation & Cleaning of Vial Filling & Stoppering Machine
- Preparation of SOP for Preventive Maintenance of Vial Filling & Stoppering Machine.

11.0 TESTS AND CHECKS:

11.1 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.

- Executed and approved Design Qualification document.
- Executed and approved Installation Qualification document.
- Executed and approved Operational Qualification document.
- SOP for Operation & Cleaning of Vial Filling & Stoppering Machine.
- SOP for Preventive Maintenance of Vial Filling & Stoppering Machine.

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Procedure:

- Verify the above mentioned documents for availability, completeness and approval status.
- If any deviation is observed the same has to be recorded giving reasons for deviation and approved.
- Supporting documents would form a part of the PQ report.

Acceptance Criteria:

All the documents should be available, complete and approved by respective authorities.

11.2 Evaluation of Performance:

Objective:

To evaluate and to provide documented evidences for performance of equipment for proper filling of vials. The objective of the test is to determine whether the machine is able to filling the containers with desired level of powder.

11.2.1 Checks for machine:

- Optimization of Filling Machine Speed
- Fill Weight Variation
- Bung Pressing Quality

11.2.2 Test & Method:

Powder Filling Machine Speed Optimization:

1. The Test shall be performed on different- different size vials.
2. Load the Sterile Lactose Bulk in the equipment hopper.
3. Switch “ON” the equipment & operate as per respective SOP.
4. Run the Equipment at an optimum speed up to 05 minutes.
5. During running, Check the Equipment speed synchronization with respect to powder filling assembly speed simultaneously ensure all the vials are being pass with filled powder.
6. After that, check the weight variation of filled vials for minimum 20 vials.
7. Collect filled 20 vials from the equipment, measure gross weight & tare weight of vials, calculate the actual filled powder weight.
8. Said activity shall be performed initial stage, middle stage & end stage of equipment running.
9. All the collected 20 filled vials 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. Load the filling with Rubber Stoppering Machine with the vials.
3. Switch “ON” the machine & Operate as per respective SOP.
4. Perform the test by filling Sterile Lactose at optimized speed of machine.

5. Perform the filling operation at 3 different speeds, for each strength & check the weight variation of 20 vials duly sampled at 3 cycles of the filling operation.
6. Collect Filled vials from the machine & measure gross wt. and tare weight of the vials & calculate filled powder weight.

Bung Pressing Quality

1. The test shall be carried out consecutively up to three batches.
2. Load the filling machine with rubber stopper in the hopper.
3. Switch "ON" the equipment & operate as per respective SOP.
4. During running , Check the Equipment speed synchronization with respect to stopper filling Simultaneously ensure all the vials are being passed with stopper.
5. After that, check the plugged vials for minimum 20 nos.
6. All the collected 20 plugged vials should be properly plugged.
7. Said activities shall be divided in to three stage of plugging i.e. initial, middle & end stage.
8. Above step no. 04 to 08 shall be follow for minimum speed optimization of equipment & Maximum speed optimization of equipment.

11.2.3 Acceptance Criteria

- Filled vials filling should be free from Breakage, vials without Stopper, Machine Jam.
- Filing Machine should deliver the fill weight in each vial as per required qty. or standard filled weight.
- Bungs should be properly plugged in vial neck.

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 DQ, IQ & OQ & other documents.
- Verification of performance by executing test for Optimization of Filling Machine Speed, Fill Weight Variation, Bung Pressing Quality.

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:

- Operation and Maintenance Manual
- Copy of SOPs
- 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:

Sr.	:	Senior
Asst.	:	Assistant
No.	:	Number
WHO	:	World Health Organization
cGMP	:	Current Good Manufacturing Practices
mm	:	Millimetre
Amp.	:	Ampere
DQ	:	Design Qualification
IQ	:	Installation Qualification
OQ	:	Operational Qualification
PQ	:	Performance Qualification
SOP	:	Standard Operating Procedure
SS	:	Stain less Steel
VFS	:	Vial Filling & Stoppering Machine
ID	:	Inner Diameter