PERFORMANCE QUALIFICATION PROTOCOL FOR VIAL SEALING MACHINE

EQUIPMENT ID. No.	
LOCATION	**Vial Capping Room**
DATE OF QUALIFICATION	
SUPERSEDES PROTOCOL No.	**NIL**

PHARMA DEVILS	PERFORMANCE QUALIFICATION PROTOCOL FOR VIAL SEALING MACHINE	PROTOCOL No.:

PROTOCOL CONTENTS

 PHARMA DEVILS	PERFORMANCE QUALIFICATION PROTOCOL FOR VIAL SEALING 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 Sealing Machine,** installed in the Vial Capping Room.
- This Protocol will define the methods and documentation used to qualify the Vial 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, 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 Sealing Machine
Equipment	……
Manufacturer's Name	Aegis Pharma Tech
Supplier's Name	Aegis Pharma Tech
Location of Installation	Vial Capping Room

6.0 SYSTEM DESCRIPTION:

The equipment is an automated means of cap sealing for different size of vial. The equipment has eight head for the capping action. The filled vials from the vial filling machine are conveyed through the conveyor and enter into the feed worm; same will pick-up the vial and place into the star wheel where the vials pick up the caps from the cap-releasing shoe.

The filled and Stoppard vials having capped placed on their heads then pass towards the Sealing heads. Star wheel will place the vial on lifter bowl and same will hold the vial from bottom and from top. Chucks will grip the vial positively and firmly.

Single sealing roller will seal the vial during the planetary motion of vial and exit star wheel will gain pick-off the sealed vial and place on the conveyor for further operation.

The equipment can be operated either in auto mode or in manual mode. The Aluminium Seal Vibratory Bowl fitted with electromagnetic coil with pot, increases or decreases the vibration of feeder bowl. It also sense the presence of cap in the cap releasing shoe & interlocked with ON/OFF main motor and detect the tilted bottle and interlocked with the main motor.

7.0 REASON FOR QUALIFICATION:

- New equipment in Vial Capping 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 Capping 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 Sealing Machine
- Preparation of SOP for Preventive Maintenance of Vial Sealing 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 Sealing Machine.
- SOP for Preventive Maintenance of Vial Sealing 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:

11.2.1 Objective:

To evaluate and to provide documented evidences for performance of equipment for proper sealing of filled vials. The objective of the test is to determine whether the machine is able to seal the Vial with aluminum seal properly.

11.2.2 Checks for machine:

- Proper Sealing (Vacuum Leak Test)
- Proper Crimping
- Breakage of Flip off Seals
- Cut on Aluminium Seals
- Aluminium seal Rotation

11.2.3 Test & Method:

- The Equipment shall be checked for its performance attributes for different-different pack size vials.
- 04 Vials (Sample for verification) shall be taken in different-different time interval from three cycles at Low, Optimum and High speed for verification of Sealing Quality and Sealing speed.

11.2.4 Acceptance Criteria:

- Vials should be properly sealed. (Vacuum leak test).
- Proper crimping on Aluminum seals.
- Flip off seals should not break.
- Aluminum seals should not cut during Sealing.
- Aluminium seal should not rotate by rotating with hands.

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 sealing performance.

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:

WHO	:	World Health Organization
FDA	:	Food and Drug Administration
CFR	:	Code of Federal Regulations
cGMP	:	Current Good Manufacturing Practices
EU	:	European Union
QC	:	Quality Control
DQ	:	Design Qualification
IQ	:	Installation Qualification
OQ	:	Operational Qualification
PQ	:	Performance Qualification
SOP	:	Standard Operating Procedure
NLT	:	Not Less Than
KW	:	Kilo watt
SS	:	Stainless Steel
ID.	:	Identification
mm	:	Mili meter
MCB	:	Miniature Circuit Breaker
ID	:	Inner Diameter