PERFORMANCE QUALIFICATION REPORT FOR VIAL SEALING MACHINE

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

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

REPORT CONTENTS

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

1.0 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 the test parameters meet the pre-defined acceptance criteria.
- To confirm the suitability of the Standard Operating Procedures for all routine activities associated with the system.

3.0 SCOPE:

- The scope of this report is limited for qualification of Vial Sealing Machine installed in Vial Capping Room.
- This report provides all the relevant information of the performance qualification activity, In-process observations and analytical data of testing of collected samples.

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 Report:

DEPARTMENTS	RESPONSIBILITIES
Quality Assurance	• Preparation, Authorization, Approval and Compilation of the Performance Qualification Report. • Co-ordination with Quality Control, Production and Engineering to carryout Performance Qualification Activity. • Monitoring of Performance Qualification.
Production	• Review of Report. • To co-ordinate and support Performance Qualification Activity.
Quality Control	• Review of Report. • 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 PRE – QUALIFICATION REQUIREMENTS:

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.

7.0 TESTS AND CHECKS:

7.1 Verification of Documents:

Record the observations for documents in the below mentioned table.

S.No.	Document Name	Document/SOP No.	Completed (Yes/No)	Checked By (Engineering) Sign/Date	Verified By (QA) Sign/Date
1.	**Executed and approved Design Qualification document**				
2.	**Executed and approved Installation Qualification document**				
3.	**Executed and approved Operational Qualification document**				
4.	**PQ Protocol approved**				
5.	**SOP for Operation & Cleaning of Vial Sealing Machine.**				
6.	**SOP for Preventive Maintenance of Vial Sealing Machine.**				

Checked By
(Production)
Sign/Date: ……

Verified By
(Quality Assurance)
Sign/Date: ……

Inference:

……

……

……

Reviewed By
(Manager QA)
Sign/Date: ……

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

7.2 Capping Quality:

Date of Test	
Vial Size	

Cycle ……				
Parameter	**Low Speed ( )**			
Sample after …….(min.)				
Vials No.	**1**	**2**	**3**	**4**
Proper Sealing (Vacuum Leak Test)				
Proper Crimping				
Breakage of Flip off Seals				
Cut on Aluminium Seals				
Aluminium seal Rotation				
Parameter	**Optimum Speed ( )**			
Proper Sealing (Vacuum Leak Test)				
Proper Crimping				
Breakage of Flip off Seals				
Cut on Aluminium Seals				
Aluminium seal Rotation				

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

Parameter	High Speed ( )			
Proper Sealing (Vacuum Leak Test)				
Proper Crimping				
Breakage of Flip off Seals				
Cut on Aluminium Seals				
Aluminium Seal Rotation				

Checked By
(Production)
Sign/Date: ……

Verified By
(Quality Assurance)
Sign/Date: ……

Inference:

……

……

……

……

……

Reviewed By
(Manager QA)
Sign/Date: ……

8.0 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 DQ, IQ & OQ & Other Documents		
Verification of Machine Performance		

Checked By
(Production)
Sign/Date: ……

Verified By
(Quality Assurance)
Sign/Date……

Inference:

……

……

……

……

……

Reviewed By
(Manager QA)
Sign/Date: ……

9.0 DOCUMENTS TO BE ATTACHED:

- Operation and Maintenance Manual.
- Copy of SOP's.
- Any Other Relevant Documents.

10.0 NON COMPLIANCE:

……

……

……

……

……

……

11.0 DEVIATION FROM PREDEFINED SPECIFICATION IF, ANY:

……

……

……

……

……

……

……

12.0 CHANGE CONTROL, IF ANY:

……

……

……

……

……

……

13.0 REVIEW (INCLUSIVE OF FOLLOW UP ACTION, IF ANY):

……

……

……

……

……

……

14.0 CONCLUSION:

……

……

……

……

……

……

……

……

15.0 RECOMMENDATION:

……

……

……

……

……

……

……

……

16.0 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

17.0 POST 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)			