PERFORMANCE QUALIFICATION REPORT FOR VIAL FILLING & STOPPERING MACHINE

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

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

REPORT CONTENTS

PHARMA DEVILS	PERFORMANCE QUALIFICATION REPORT FOR VIAL FILLING & STOPPERING 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 Filling & Stoppering Machine installed in Vial Filling & Stoppering Room of ……...
- 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 execution of Performance Qualification Report.

DEPARTMENTS	RESPONSIBILITIES
Quality Assurance	• Preparation, Authorization, Approval and Compilation of the Performance Qualification. • Co-ordination with Quality Control, Production and Engineering to carryout Performance Qualification Activity. • Monitoring of Performance Qualification. • Post Approval of Performance Qualification Report after Execution.
Production	• Review of Performance Qualification Report. • To co-ordinate and support Performance Qualification Activity. • Post Approval of Performance Qualification Report after Execution.
Quality Control	• Review of Performance Qualification Report. • Analytical Support (Microbiological Testing/Analysis). • Post Approval of Performance Qualification Report after Execution.
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. • Post Approval of Performance Qualification Report after Execution.

5.0 EQUIPMENT DETAILS:

Equipment Name	Vial Filling & Stoppering Machine
Equipment	……
Manufacturer's Name	Amba Sale & Services
Model	cGMP Model
Supplier's Name	Amba Sale & Services
Location of Installation	Vial Filling & Stoppering 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 Filling & Stoppering Machine.
- SOP for Preventive Maintenance Vial Filling & Stoppering 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 Filling & Stoppering Machine**				
6.	**SOP for Preventive Maintenance Vial Filling & Stoppering Machine**				

Checked By
(Production)
Sign/Date: ……

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

Inference:

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

7.2 Performance evaluation for Machine Speed Optimization

Date of Test		Equipment ID	
Total Vials taken for test		Vial Size	
Parameter	**Low Speed ( )**	**Optimum Speed( )**	**High Speed ( )**
Sample after …….(min)			
Vial Breakage			
Machine jam			
Vials without stopper			
Rejection	……..(B1)	……..(B2)	……..(B3)
Sample after …….(min)			
Vial Breakage			
Machine jam			
Vials without stopper			
Rejection	……..(B1)	……..(B2)	……..(B3)
Sample after …….(min)			
Vial Breakage			
Machine jam			
Vials without stopper			
Rejection	……..(B1)	……..(B2)	……..(B3)
Total rejection	Σ B1=	Σ B2=	Σ B3=

Checked By
(Production)
Sign/Date: ……

Verified By
(Quality Assurance)
Sign/Date……

Inference:

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

7.3 Fill Weight Variation:

Date of test	
Product Name	
Standard. Fill Weight - ……..mg **(Limit: ± …….. % of standard Filled Weight)**	
Vial Size	
Total Operation Time	

Cycle-……

Vial No.	Low Speed ( )			Optimum Speed ( )			High Speed ( )		
	Gross wt.	Empty wt	Net wt.	Gross wt.	Empty wt	Net wt.	Gross wt.	Empty wt	Net wt.
1									
2									
3									
4									
5									
6									
7									
8									
9									
10									
11									

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

Vial No.	Low Speed ( )			Optimum Speed ( )			High Speed ( )		
	Gross wt.	Empty wt	Net wt.	Gross wt.	Empty wt	Net wt.	Gross wt.	Empty wt	Net wt.
12									
13									
14									
15									
16									
17									
18									
19									
20									

Checked By
(Production)
Sign/Date: ……

Verified By
(Quality Assurance)
Sign/Date……

Inference:

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

7.4 Bung Pressing Quality

Date of test	
Product Name	
Vial Size	

Cycle:……

Vial No.	Initial Stage (Bung Pressing Quality)	Middle Stage (Bung Pressing Quality)	End Stage (Bung Pressing Quality)
1			
2			
3			
4			
5			
6			
7			
8			
9			
10			
11			
12			
13			
14			
15			
16			
17			

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

Vial No.	Initial Stage (Bung Pressing Quality)	Middle Stage (Bung Pressing Quality)	End Stage (Bung Pressing Quality)
18			
19			
20			

Checked By
(Production)
Sign/Date: ……

Verified By
(Quality Assurance)
Sign/Date……

Inference:

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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:

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

9.0 DOCUMENTS TO BE ATTACHED:

- Operation and Maintenance Manual.
- Copy of SOPs.
- Any Other Relevant Documents.

10.0 NON COMPLIANCE:

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11.0 DEVIATION FROM PREDEFINED SPECIFICATION IF, ANY:

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12.0 CHANGE CONTROL, IF ANY:

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

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14.0 CONCLUSION:

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15.0 RECOMMENDATION:

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16.0 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

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)			