PERFORMANCE QUALIFICATION REPORT FOR VIAL LABELING MACHINE

EQUIPMENT ID. No.	**……..**
LOCATION	**Packing Hall**
DATE OF QUALIFICATION	
SUPERSEDES PROTOCOL No.	**NIL**

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

REPORT CONTENTS

S.No.	TITLE	PAGE No.
1.0	Report Pre-Approval	3
2.0	Objective	4
3.0	Scope	4
4.0	Responsibility	5
5.0	Equipment Details	6
6.0	Pre-Qualification Requirement	6
7.0	Tests & Checks	7
8.0	Checklist Of All Tests And Checks	12
9.0	Documents To Be Attached	12
10.0	Non Compliance	12
11.0	Deviation From Pre–Defined Specification, If Any	13
12.0	Change Control, If Any	13
13.0	Review Inclusive of Follow Up Action, If Any	14
14.0	Conclusion	14
15.0	Recommendations	14
16.0	Abbreviations	15
17.0	Report Post Approval	16

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

1.0 REPORT 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 Protocol covers all aspects of Performance Qualification for the **Vial Labeling Machine (Make: Ambica Pharma Machines Pvt. Ltd.,) installed** in the Packing Hall**.**
- This Protocol will define the methods and documentation used to qualify the Blister Packing Machine for PQ.

.

4.0 RESPONSIBILITY:

The Validation Group, comprising of a representative from each of the following departments, shall be responsible for execution of Performance Qualification

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 Protocol. • To co-ordinate and support Performance Qualification Activity. • Post approval of Performance Qualification Report after execution.
Quality Control	• Review of Protocol. • 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 Labeling Machine
Equipment	……
Manufacturer's Name	Ambica Pharma Machines Pvt. Ltd
Model	…….
Supplier's Name	Ambica Pharma Machines Pvt. Ltd Pampac
Location of Installation	Packing Hall

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 Labeling Machine.
- SOP for Preventive Maintenance Vial Labeling 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 Labeling Machine				
6.	SOP for Preventive Maintenance Vial Labeling Machine				

Inference:

……

……

……

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

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

7.2 TEST PRODUCT BATCH INFORMATION:

S.No.	Product Name	Batch No.	Pack Size	Batch Size	Mfg. Date	Expiry Date

Compiled By
(QA)
Sign/Date: ……..

Inference:

……

……

……

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

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

7.3 REPORT OF PERFORMANCE EVALUATION USING DRUG PRODUCT:

First Product Name: - **Batch No.:**

Vial Size: -

Test Parameters	Initial stage	Middle stage	End stage
Labeling Orientation Coding Imprint Positioning of Label Adhesiveness properties of label Shrinkage of label Dent /Rubbing mark on Label Affixing of labels edges Overlapping of Label Counting of Vial			

Acceptance criteria :

Labeling Orientation : Should be Uniform

Coding Imprint : Clear & legible

Positioning of Label : Should be proper and should not be tilted

Adhesiveness properties of label: Label should be properly Adhered to vials

Shrinkage of label: Should be absent

Dent /Rubbing mark on Label : Should be absent

Affixing of labels edges : Label should be intact and properly fixed

Overlapping of Label: Should be absent

Counting of Vial: Vial counter should count correctly and exact no. of vials

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 LABELING MACHINE	PROTOCOL No.:

Second Product Name: - **Batch No.:**

Vial Size: -

Test Parameters	Initial stage	Middle stage	End stage
Labeling Orientation Coding Imprint Positioning of Label Adhesiveness properties of label Shrinkage of label Dent /Rubbing mark on Label Affixing of labels edges Overlapping of Label Counting of Vial			

Acceptance criteria :

Labeling Orientation : Should be Uniform

Coding Imprint : Clear & legible

Positioning of Label : Should be proper and should not be tilted

Adhesiveness properties of label: Label should be properly Adhered to vials

Shrinkage of label: Should be absent

Dent /Rubbing mark on Label : Should be absent

Affixing of labels edges : Label should be intact and properly fixed

Overlapping of Label: Should be absent

Counting of Vial: Vial counter should count correctly and exact no. of vials

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 LABELING MACHINE**	**PROTOCOL No.:**

Third Product Name: - **Batch No.:**

Vial Size: -

Test Parameters	Initial stage	Middle stage	End stage
Labeling Orientation Coding Imprint Positioning of Label Adhesiveness properties of label Shrinkage of label Dent /Rubbing mark on Label Affixing of labels edges Overlapping of Label Counting of Vial			

Acceptance criteria :

Labeling Orientation : Should be Uniform

Coding Imprint : Clear & legible

Positioning of Label : Should be proper and should not be tilted

Adhesiveness properties of label: Label should be properly Adhered to vials

Shrinkage of label: Should be absent

Dent /Rubbing mark on Label : Should be absent

Affixing of labels edges : Label should be intact and properly fixed

Overlapping of Label: Should be absent

Counting of Vial: Vial counter should count correctly and exact no. of vials

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 Performance using product		

Checked By
(Production)
Sign/Date: ……

Verified By
(Quality Assurance)
Sign/Date……

Inference:

……

……

……

……

……

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

9.0 DOCUMENTS TO BE ATTACHED:

- Copy of finished product certificate of analysis
- 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:

Sr.	:	Senior
No.	:	Number
WHO	:	World Health Organization
CFR	:	Code of Federal Regulations
cGMP	:	Current Good Manufacturing Practices
QA	:	Quality Assurance
DQ	:	Design Qualification
IQ	:	Installation Qualification
OQ	:	Operational Qualification
PQ	:	Performance Qualification
SOP	:	Standard Operating Procedure
No.	:	Number
Ltd.	:	Limited

17.0 REPORT 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)			