PERFORMANCE QUALIFICATION PROTOCOL FOR VIAL LABELING MACHINE

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

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

PROTOCOL CONTENTS

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

1.0 PROTOCOL 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 the overall compliance of this Protocol:

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.
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 Labeling Machine
Equipment ID No.	…….
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 SYSTEM DESCRIPTION:

The Equipment means to Label the Round Objects for different size with over printing in single straight line operation.

The filled & sealed containers load on turn table and turn table will feed the containers in signal track to the transport conveyor. Now container convey on conveyor in signal track in a queue position and reaches to the container separator. The separator picks container one by one and releases the container at a specified pitch to the conveyor for labeling operation. When containers are arriving below the product sensor, product sensor gives signal of presence of the container at labeling station and microprocessor will start dispense label and as soon as one label is applied to the container, the label sensor give signal to stop the label. Then the container moves through pressing device for firmly stick the label.

7.0 REASON FOR QUALIFICATION:

- New equipment in Packing Hall..
- 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:

Packing Hall.

9.0 FREQUENCY OF QUALIFICATION:

- Once in a two year ± 01 month
- After Change of Location.
- After any major breakdown or after major modification.

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 Labeling Machine
- Preparation of SOP for Preventive Maintenance of Vial Labeling 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 Labeling Machine.
- SOP for Preventive Maintenance Vial Labeling Machine

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 Using Products:

Objective:

- To verify the performance of equipment in the range of operational parameters established in Operational Qualification Activity.
- To establish documented evidence that the Vial Labeling Machine is performing consistently and the result of all test parameters meet the pre – defined acceptance criteria of sifted products.

11.2.1 Checks:

- 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 Label

11.2.2 Method:

- Install product specific change parts and foil in the machine.
- Load the product in the hopper of machine
- After attaining the required temperature perform initial run of machine without product to verify formed Blister packs initially.
- Perform packing of product using machine as per the product specific parameters of the machine.
- Perform checks on the packed Blister Packs.
- Record the observations for all the checks in the report.

11.2.3 Acceptance Criteria:

S.No.	TEST PARAMETERS	ACCEPTANCE CRITERIA
1.	Labeling Orientation	Should be Uniform
2.	Coding Imprint	Clear & legible
3.	Positioning of Label	Should be proper and should not be tilted
4.	Adhesiveness properties of label	Label should be properly Adhered to vials
5.	Shrinkage of label	Should be absent
6.	Dent /Rubbing mark on Label	Should be absent
7.	Affixing of labels edges	Label should be intact and properly fixed
8.	Overlapping of Label	Should be absent
9.	Counting of Label	Label counter should count correctly and exact no. of Labels.

12.0 CHECKLIST OF ALL TESTS AND 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 using product.

13.0 REFERENCES:

The Principle Reference is the 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:

- Technical details for Equipment Requirement with Engineering Drawings.
- Operation and Maintenance Manual.

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
FDA	:	Food and Drug Administration
CFR	:	Code of Federal Regulations
cGMP	:	Current Good Manufacturing Practices
EU	:	European Union
QA	:	Quality Assurance
IQ	:	Installation Qualification
mm	:	Millimetre
Amp.	:	Ampere