PERFORMANCE QUALIFICATION PROTOCOL FOR STICKER LABELING MACHINE

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

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

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

1.0 PROTOCOL APPROVAL:

PREPARED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OPERATING MANAGER (QUALITY ASSURANCE)			
HEAD (ENGINEERING)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			

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 **Sticker Labeling Machine (Make: ……)** 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, Review, Authorization 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 Performance Qualification Protocol. • To co-ordinate and support Performance Qualification Activity.
Engineering	• Reviewing of Performance 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	Sticker Labeling Machine
Equipment ID.	
Model	
Manufacturer's Name	
Sr.	
Supplier's Name	
Location of Installation	Packing Hall

6.0 SYSTEM DESCRIPTION:

Model-HLC-100 having Vari-speed Green Endless Belt Conveyor on which Ampoule Cassettes are loaded in horizontal position which will carry to an applicating station i.e. below release plate, a product sensor sense the presence of Ampoule Cassette at applications station and give a signal to dispenser motor for dispensing a label and label sensor mounted on modular rail will sense the gap between two labels, indicating a completion of one label dispensing for the Ampoule Cassette and that will give signal to stop the dispenser motor and at the same time, it will also forward the signal to On-line Coder (**Optional, If client purchase**) to print necessary details. On-line Coder fixed on modular rail has adjustment in both the direction to adjust the overprinting as per label layout. Now at application station, label is picked up by Ampoule Cassettes due to adhesiveness and then enter under sponge label pressure roller, where more pressure will apply & fix the label properly on Ampoule Cassettes surface.

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:

- After any major breakdown or after major modification.
- After Change of Location.
- Once in Two year

10.0 PRE – QUALIFICATION REQUIREMENTS:

The below mentioned activities should be completed prior to commencing the performance qualification activity:

- Executed and approved Design Qualification document
- Executed and approved Installation Qualification document
- Executed and approved Operational Qualification document
- SOP for Operation & Cleaning of Sticker Labeling Machine
- SOP for Preventive Maintenance of Sticker 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 Sticker Labeling Machine.
- SOP for Preventive Maintenance Sticker 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 Sticker 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
- Positioning of Label
- Adhesiveness properties of label
- Shrinkage of label
- Dent /Rubbing mark on Label
- Affixing of labels edges
- Overlapping of Label

  All test Evaluate at Minimum, Optimum & maximum Speed of Sticker Labeling Machine

11.2.2 Method:

- Install product specific change parts and Label Roll in the machine.
- Load the product in the hopper of machine
- Perform packing of product using machine as per the product specific parameters of the machine.
- Perform checks on the packed.
- Evaluation of Performance of Sticker Labeling Machine by Using Three batch at Minimum Speed, Optimum Speed & Maximum Speed
- Record the observations for all the checks in the Performance Qualification report.

11.2.3 Acceptance Criteria:

S.No.	TEST PARAMETERS	ACCEPTANCE CRITERIA
1.	Labeling Orientation	Should be Uniform
2.	Positioning of Label	Should be proper and should not be tilted
3.	Adhesiveness properties of label	Label should be properly Adhered to Stickers
4.	Shrinkage of label	Should be absent
5.	Dent /Rubbing mark on Label	Should be absent
6.	Affixing of labels edges	Label should be intact and properly fixed
7.	Overlapping of Label	Should be absent

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 Three Batch 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:

- 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:

cGMP	:	Current Good Manufacturing Practices
DQ	:	Design Qualification
FFS	:	Form Fill & Seal
mm	:	Millimetre
No.	:	Number
OQ	:	Operational Qualification
PPQ	:	Performance Qualification Protocol
QA	:	Quality Assurance
SLM	:	Sticker Labelling Machine
WHO	:	World Health Organization