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.:

PROTOCOL CONTENTS

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** 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, 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 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.

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5.0 EQUIPMENT DETAILS:

Equipment Name	Sticker Labeling Machine
Equipment ID.	
Model	
Manufacturer's Name	
Supplier's Name	
Sr. No.	
Location of Installation	Packing Hall

6.0 SYSTEM DESCRIPTION:

Automatic Sticker Labeling Machine Model: HMPL/SSVL is used for Precise Labeling on round shaped pet/glass bottles. The machine Operates at the Speed off 60 to 80 Bottles per Minute. Specific Shape and Size of Containers can be accommodated on the same machine with /without the help of change Parts.

Main Assembly:

1. Dispenser assembly.
2. Conveyer with side guide.
3. Wrapping assembly.
4. Dispenser Unit.
5. Main Electrical Panel with SMPS, VFD, and Operating panel HMI, Emergency Switch & PLC's.
6. HSA jet Micron Printer.

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:

- Design Qualification
- Installation Qualification
- Operational Qualification
- SOP for Operation & Cleaning of Sticker Labeling Machine
- SOP for Preventive Maintenance of Sticker Labeling Machine

11.0 TESTS AND CHECKS:

11.1 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 Test Domino Printing

- Coding Detail of Liquid Bottle Label as per set parameter on the basis of requirement such as Batch No., Mfg. Date, Exp. Date, Price & if any other and feed the Height, width, Forward Margin and End Margin.

Product Name	Mfg. Date	Exp. Date	Batch Size

Batch	Set Label Coding Detail	Observe Label Coding Detail
First Batch		
Second Batch		
Third Batch		

11.3 Test For Machine:

- Labeling Orientation
- 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

11.3.1 Method:

- Install product specific change parts and foil 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.
- Record the observations for all the checks in the report.
- Evaluate the performance by Using three Batch of drug product

11.3.2 Test:

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
8.	Counting of Label	Label counter should count correctly and exact no. of Labels.

12.0 CHECKLIST OF ALL TESTS AND CHECKS:

Tests or Checks	Executed (Yes/No)	Remarks
Verification of Performance using Three Batch of drug Product.		
Verification of Performance of domino printer		
Verification of Performance of Labeling Machine		

13.0 REFERENCES:

- 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:

Amp.	:	Ampere
Asst.	:	Assistant
cGMP	:	Current Good Manufacturing Practices
DQ	:	Design Qualification
IQ	:	Installation Qualification
mm	:	Millimetre
No.	:	Number
OQ	:	Operational Qualification
PPQ	:	Performance Qualification Protocol
QA	:	Quality Assurance
SLM	:	Sticker Labelling Machine
WHO	:	World Health Organization