PERFORMANCE QUALIFICATION PROTOCOL FOR AUTOMATIC STICKER LABELLING MACHINE

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

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

PROTOCOL CONTENT

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

1.0 PROTOCOL APPROVAL:

PRPARED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

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

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 automatic sticker labeling machine **(Make:** Maharashi) installed in packing hall.
- This Protocol will define the methods and documentation used to qualify the automatic sticker labeling 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 Performance Qualification Protocol:

DEPARTMENTS	RESPONSIBILITIES
Quality Assurance	• Preparation, Review and, Approval of the Performance Qualification Protocol. • To Co-ordination with Production and Engineering to carryout Performance Qualification Activity. • Monitoring of Performance Qualification Activity.
Production	• Review of Performance Qualification Protocol. • To Execute Performance Qualification Activity.
Engineering	• Review 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	Automatic Sticker Labeling Machine
Equipment ID.	
Manufacturer's Name	Maharshi
Model No.	
Machine No.	
Location of Installation	Packing Hall

6.0 SYSTEM DESCRIPTION:

Automatic sticker machine, model: ……. (Servo with Automation) for

- Apply double side (front/Back) sticker labels up to 150 mm label Ht. on vertical small/ large various flat, oval, square & rectangular containers i.e. bottles, jars etc. with the help of minimum change parts and wrap around label on round bottle with the help of additional warp around attachment. (Wrap around attachment is applicable up to 70% of periphery of round bottle and for full wrap around.)
- For the standard rated speed up to 150 CPM depending upon label length & product shape/ size.
- Machine has some additional automation attachments / features i.e touch screen HMI with "Fatek" PLC, Roll ending alarm system with machine stop facility, missing label detection with pneumatic rejection system, emergency stop & tower light etc.. as per client requirements.

7.0 REASON FOR QUALIFICATION:

- New Machine.

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:

10.1 Document verification

- Approved DQ protocol cum report.
- Approved IQ protocol cum report.
- Approved OQ protocol cum report.
- Approved SOP for Operation & Cleaning of Automatic Sticker Labeling Machine.
- Approved SOP for Preventive Maintenance of Automatic Sticker Labeling Machine.

11.0 TESTS AND CHECKS:

11.1 Machine Speed Verification Test:

11.1.1 Objective: To Demonstrate that the machine Perform the smoothly at Different speed claimed by manufacturer and evaluation of the Rejection.

11.1.2 Equipment/ Instruments Used:

Stopwatch

11.1.3 Method Applied:

- Switch ‘ON’ the mains of the machine.
- Start the Machine as per respective SOP of the Equipment Operation.
- Select the Mode of Operation through the PLC i.e. Auto or Manual Mode.
- Then Set the Speed into the Display of Machine.
- Run the machine at Three Different Parameter i.e. Minimum, Optimum and Maximum speed.
- Check the Machine Speed through the Stopwatch after one Minute interval and compare with the Display of Machine.
- Three run shall be performed.

11.1.4 Acceptance Criteria:

- The machine shall give the output of 50-150 labels per minute.
- Machine should run smoothly.

11.2 Test For Labeling :

11.2.1 Objective: To Demonstrate that the Machine Perform the Smoothly during the Labeling.

11.2.2 Method Applied:

- Fix the label roll in to the both feeder.
- Run the machine as per Respective SOP.
- Check the Below Mention Parameter at Different Speed.
- Calculate the %age of rejection.
- Three run shall be performed.

Parameter	Acceptance Criteria
Both side labeling orientation	Should be Uniform
Positioning of Label	Should be proper and should not be tilted
Adhesiveness properties of label	Label should be properly Adhered to container
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
Percentage of Rejection	Should be Not More than 2.0%

12.0 CHECKLIST OF ALL TESTS AND CHECKS:

S.No.	TESTS AND CHECKS	EXECUTED (Y/N)	REMARKS
1.	Machine Speed Verification		
2.	Test For Labeling		

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.
- Vendor Documents

14.0 DOCUMENTS TO BE ATTACHED:

- Any other Relevant Document.

15.0 NON COMPLIANCE:

- In case of any Non-compliance observed during PQ, same shall be handled through SOP for Handling of Non-Compliance.

16.0 DEVIATION FROM PRE-DEFINED SPECIFICATION, IF ANY:

- In case of any deviation observed during PQ, same shall be handled through SOP for Handling of Deviation.

17.0 CHANGE CONTROL, IF ANY:

- If any change is required during PQ, same shall be handled through SOP for Change Management.

18.0 ABBREVIATIONS:

SLM	:	Automatic Sticker Labeling Machine.
cGMP	:	Current Good Manufacturing Practices
DQ	:	Design Qualification
HMI	:	Human Machine Interface
QB	:	Quality Block
IQ	:	Installation Qualification
OQ	:	Operational Qualification
PLC	:	Programmable Logical Controller
No.	:	Number
WHO	:	World Health Organization