PERFORMANCE QUALIFICATION PROTOCOL FOR AUTOMATIC SELF ADHESIVE VERTICAL LABELING MACHINE

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

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PROTOCOL CONTENTS

PERFORMANCE QUALIFICATION PROTOCOL FOR AUTOMATIC SELF ADHESIVE VERTICAL LABELING MACHINE

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)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			

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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 self Adhesive Vertical Labeling Machine **(Make:** ……..) installed in packing hall.
- This Protocol will define the methods and documentation used to qualify the Automatic self Adhesive Vertical 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, Authorization of the Performance Qualification Protocol. • Co-ordination with Quality Control, Production and Engineering to carryout Performance Qualification Activity. • Monitoring of Performance Qualification Activity.
Production	• Review & Approval of Performance Qualification Protocol. • To co-ordinate and support Performance Qualification Activity.
Engineering	• Review & Approval 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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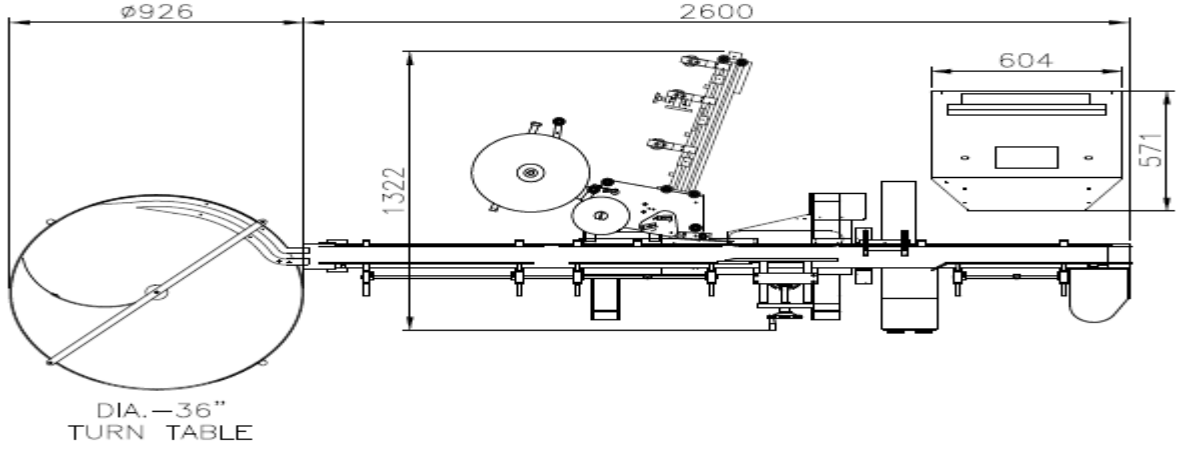
5.0 EQUIPMENT DETAILS:

Equipment Name	Automatic self Adhesive Vertical Labeling Machine
Equipment ID.	
Manufacturer's Name	
Machine No.	
Model No.	
Supplier's Name	
Location of Installation	Packing Hall

6.0 SYSTEM DESCRIPTION:

This machine is designed to give High Output of Labeling on Bottle. After inspection the Bottle are loaded on In-feed turn table. From in feed turn table, Bottle entered in to infeed conveyor belt. Before the discharge the label device is positioned. Label device having a Printer for printing of batch no/mfg. date/expiry date & then camera system to inspect the printing matter OCR, Pharma code, Barcode etc. & once camera inspect the matter & if found any error then same Bottle with Rejected label is collected into a Box provided for rejected Bottle. The label applicator gets activated as soon as Bottle comes in the position of label; it gets sticks on the Bottles. After this, Bottles move toward the pressing belt meant for proper fixing of label. After pressing of the labels, good Bottles are move forward for further process

GA of Automatic Self Adhesive Vertical Labelling machine:



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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:

- SOP for Operation & Cleaning of Automatic self Adhesive Vertical Labeling Machine.
- SOP for Preventive Maintenance of Automatic self Adhesive Vertical Labeling Machine.

PERFORMANCE QUALIFICATION PROTOCOL FOR AUTOMATIC SELF ADHESIVE VERTICAL 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 Trials shall be performed in Both Auto and Manual Mode.

11.1.4 Acceptance Criteria:

- The machine shall give the output of 200-220 labels per minute.
- Machine should run smoothly.

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11.2 Test For Labeling :

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

11.2.2 Method Applied:

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

Parameter	Acceptance Criteria
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 Ampoules
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%

11.3 Test for Printing:

11.3.1 Objective: To Demonstrate that the Printing Efficiency of Machine Perform as per manufacturer specification.

11.3.2 Method Applied:

- Select The Mode of Operation in the Main screen.
- Give the Command to PLC of printing machine as input. Resulting PLC of printing machine gives the Output & Print on Label. Such as

Detail	PLC Input	PLC Out Put
Batch Number:		
Mfg Date:		
Exp Date:		
MRP:		

Acceptance Criteria: Coding Imprint Should be Clear & Legible

11.4 Challenge Test for Camera:

11.5 Test For Camera: Evaluation of Performance of Camera by Challenge test**.** Using Defective Printed Label with help of Domino Printer, First of We Set a Coding detail in PLC of Domino Printer and Scan by camera & give Command to PLC.

Batch Number	Mfg. Date	Exp. Date	MRP

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Test	Set Label Coding Detail	Observation
Test -01	**Scan by Laptop**	Should be Compiles with set Coding Detail
	PC/IB/SLM-001 6X/Y7 6X/ Y9 123.0	
Test -02	**Scanning Detail are previous**	Should be rejected by Camera
	PC/IB/SLM-010 6X/Y7 6X/ Y9 124.0	
Test -03	**Scanning Detail are previous**	Should be rejected by Camera
	Domino Printer not ON	
Test -04	**Scanning Detail are previous**	Should be rejected by Camera
	Spreading of Inc by Domino Printer	
Test -05	Partial Printing	Should be rejected by Camera

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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		
3.	Test for Printing		
4.	Challenge Test for Camera System.		

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:

SLM	:	Automatic self Adhesive Vertical Labeling Machine.
Vol.	:	Volume
MRP	:	Maximum Retail Price
Mfg.	:	Manufacturing
Exp.	:	Expiry
GA	:	General Arrangement
cGMP	:	Current Good Manufacturing Practices
DQ	:	Design Qualification
HMI	:	Humen Machine Interface
PLC	:	Programmable Logical Controller
No.	:	Number
WHO	:	World Health Organization