



PHARMA DEVILS

**PERFORMANCE RE-QUALIFICATION PROTOCOL
FOR
AUTOMATIC STICKER LABELING MACHINE**

PROTOCOL No.:

**PERFORMANCE RE-QUALIFICATION
PROTOCOL
FOR
STICKER LABELING MACHINE
LIQUID LINE**

EQUIPMENT ID. No.

LOCATION

Packing Hall



PHARMA DEVILS

**PERFORMANCE RE-QUALIFICATION PROTOCOL
FOR
AUTOMATIC STICKER LABELING MACHINE**

PROTOCOL No.:

PROTOCOL CONTENTS

S.No.	TITLE	PAGE No.
1.0	PROTOCOL APPROVAL	3
2.0	OBJECTIVE	4
3.0	SCOPE	4
4.0	RESPONSIBILITY	5
5.0	EQUIPMENT DETAILS	6
6.0	SYSTEM DESCRIPTION	6
7.0	REASON FOR RE-QUALIFICATION	6
8.0	SITE OF STUDY	6
9.0	FREQUENCY OF RE-QUALIFICATION	6
10.0	PRE RE-QUALIFICATION REQUIREMENTS	7
11.0	TESTS & CHECKS	8
12.0	CHECKLIST OF ALL TESTS AND CHECKS	10
13.0	REFERENCES	10
14.0	DOCUMENTS TO BE ATTACHED	10
15.0	NON COMPLIANCE	11
16.0	DEVIATION FROM PRE-DEFINED SPECIFICATION, IF ANY	11
17.0	CHANGE CONTROL, IF ANY	11
18.0	ABBREVIATIONS	11



**PERFORMANCE RE-QUALIFICATION PROTOCOL
FOR
AUTOMATIC 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 (PRODUCTION)			
HEAD (ENGINEERING)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			



PHARMA DEVILS

**PERFORMANCE RE-QUALIFICATION PROTOCOL
FOR
AUTOMATIC STICKER LABELING MACHINE**

PROTOCOL No.:

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 Re-qualification for the **Automatic Sticker Labeling Machine** installed in the packing hall.
- This Protocol will define the methods and documentation used to qualify the Sticker Labeling Machine for Performance Re-qualification.



PHARMA DEVILS

**PERFORMANCE RE-QUALIFICATION PROTOCOL
FOR
AUTOMATIC STICKER LABELING MACHINE**

PROTOCOL No.:

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	<ul style="list-style-type: none">• Preparation, Approval and Compilation of the Performance Re-qualification.• Co-ordination with Production and Engineering to carryout Performance Re-qualification Activity.• Monitoring of Performance Re-qualification.
Production	<ul style="list-style-type: none">• Review of Performance Re-qualification Protocol.• To Execute the Performance Re-qualification Report.
Engineering	<ul style="list-style-type: none">• Reviewing of Performance Re-qualification protocol for correctness, completeness and technical excellence• Responsible for trouble shooting (if occurred during execution).• Maintenance & preventive maintenance as per schedule.



**PERFORMANCE RE-QUALIFICATION PROTOCOL
FOR
AUTOMATIC STICKER LABELING MACHINE**

PROTOCOL No.:

5.0 EQUIPMENT DETAILS:

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

6.0 SYSTEM DESCRIPTION:

The Automatic Sticker Labeling Machine is compact unit totally made of SS structure with height adjustment legs, are provided to adjust the machine height and highly efficient machine with elegant look. This multifunctional multi featured machine meets the GMP requirements of labeling for glass and plastic Bottles. The machine requires manual loading and automatic unloading of Bottles.

The whole design of VSAL-120 labeling machine is reasonable, easy to operate, the flexibility to switch to different round bottle bodies, easy to change for customers, suit for most of the round bottle labeling requirements; extrusion between high elastic scraper and non-powered sponge, to ensure that no bubbles; machine used to strengthen the rigidity of the mechanical structure design, simple, generous and stable. Designed for the application of labels to the side surfaces or wraparound of continuously fed products in oval, round or rectangular shape. The automatic labeler is a versatile high speed machine which can be integrated easily into existing filling or packaging lines. The whole machine is made of 304 stainless steel and aluminum materials, the standardized design, interchangeable parts, completely according with GMP requirements.

7.0 REASON FOR RE-QUALIFICATION:

- Periodically as per qualification planner.
- After any major breakdown or after major modification.
- After Change of Location.

8.0 SITE OF STUDY:

Packing Hall.



**PERFORMANCE RE-QUALIFICATION PROTOCOL
FOR
AUTOMATIC STICKER LABELING MACHINE**

PROTOCOL No.:

9.0 FREQUENCY OF RE-QUALIFICATION:

- Once in Two year \pm 1 month

10.0 PRE – RE-QUALIFICATION REQUIREMENTS:

10.1 Training Record of Validation Team:

All the persons involved in the execution of Re-Qualification Protocol must be trained in all aspects of the Re-qualification activity including the test methodology, acceptance criteria and safety precautions to be followed during working at service floor.

11.0 TESTS AND CHECKS:

11.1 Installation checks:

S.No.	Parameters	ACCEPTANCE CRITERIA
1.	Equipment name	Automatic Sticker Labeling Machine
2.	Equipment I.D	
3.	Place of Installation	Packing Hall
4.	Leveling	Should be properly balanced and leveled.

11.2 Operational checks:

Component	Acceptance Criteria
Turn the Knob ON Position.	HMI Display should be ON.
Turn the Knob OFF Position	HMI Display should be OFF.
Turn the Knob on start Position.	Conveyor Belt will start
Turn the Knob on stop Position.	Conveyor Belt will stop
Turn the Knob for desired speed.	Speed will Increase / Decrease.
If there is no Sticker on conveyor belt	There should no Label.



**PERFORMANCE RE-QUALIFICATION PROTOCOL
FOR
AUTOMATIC STICKER LABELING MACHINE**

PROTOCOL No.:

11.3 Performance verification:

11.3.1 Evaluation of Performance Using Products:

Objective:

- To verify the performance of equipment in the range of operational parameters established in Operational Re-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 products.

11.3.2 Performance Re-Qualification Strategy:

- Install product specific change parts in the 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.
- Performance Re-qualification Test & Checks Performed at Minimum, Optimum & Maximum Speed by using any one Commercial Batch.
- Labeling and printing quality shall be checked initial, middle & end of batch.

11.3.3 Checks for machine:

- Machine Speed Verification
- Labeling Quality

11.3.1 Machine Speed Verification: Bottle Labeling Machine shall be run at Minimum, Optimum & Maximum Speed

Acceptance Criteria: Machine should run smoothly without any abnormality.

11.3.2 Test for Labeling: Following Test Should be considered for Evaluation of Labeling Quality.

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



**PERFORMANCE RE-QUALIFICATION PROTOCOL
FOR
AUTOMATIC STICKER LABELING MACHINE**

PROTOCOL No.:

S.No.	TEST PARAMETERS	ACCEPTANCE CRITERIA
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
Installation checks		
Operational checks		
Performance evaluation at different machine speed		
Verification of machine speed verification		
Verification of labeling quality		

13.0 REFERENCES:

- Validation Master Plan
- Standard operating procedure operation and cleaning of sticker labeling machine SOP No.HP0/060.
- Performance qualification protocol.

14.0 DOCUMENTS TO BE ATTACHED:

- Any other Relevant Document.

15.0 NON COMPLIANCE:

- In case of any Non-compliance observed during re-qualification, 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 re-qualification, same shall be handled through SOP for Handling of Deviation.

17.0 CHANGE CONTROL, IF ANY:

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



PHARMA DEVILS

**PERFORMANCE RE-QUALIFICATION PROTOCOL
FOR
AUTOMATIC STICKER LABELING MACHINE**

PROTOCOL No.:

18.0 ABBREVIATIONS:

No.	:	Number
MRP	:	Master re-qualification Protocol
PRR	:	Performance Re-qualification report
QA	:	Quality Assurance
SLM	:	Sticker Labelling Machine
SOP	:	Standard operating procedure
HMI	:	Human machine interface