




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

PROTOCOL No.:

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

EQUIPMENT ID. No.	
LOCATION	Packing Hall
DATE OF RE-QUALIFICATION	
MASTER REPORT No.	

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REPORT
FOR
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PROTOCOL No.:

1.0 REPORT PRE – 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)			



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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 Re-qualification for the **Automatic Sticker Labeling Machine (Make:.....)** installed in the Packing Hall.
- This Protocol will define the methods and documentation used to qualify the Sticker labeling Machine for Performance Re-qualification.



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4.0 RESPONSIBILITY:

The Validation Group, comprising of a representative from each of the following departments, shall be responsible for execution of Performance Re-qualification

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.• Post approval of Performance Re-qualification Report after execution.
Production	<ul style="list-style-type: none">• Review of Performance Re-qualification Report.• To Execute the Performance Re-qualification Report..
Engineering	<ul style="list-style-type: none">• Reviewing of re-qualification protocol• 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 Sticker Labeling Machine
Equipment ID.	
Model	
Manufacturer's Name	
Supplier's Name	
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:

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8.0 SITE OF STUDY:

- Packing Hall, Liquid Line.

9.0 FREQUENCY OF RE-QUALIFICATION:

- Once in Two year ± 1 month

10.0 PRE – RE-QUALIFICATION REQUIREMENTS:

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.



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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.

S.No	NAME OF EMPLOYEE	EMPLOYEE CODE	DEPARTMENT	DESIGNATION	SIGN/DATE

Trainer name.....



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11.0 TESTS AND CHECKS:

11.1 Installation checks:

S.No.	Parameters	ACCEPTANCE CRITERIA	OBSERVATION	COMPLIES / DOES NOT COMPLIES
1.	Equipment name	Automatic Sticker Labeling Machine		
2.	Equipment ID			
3.	Place of Installation	Packing Hall Ointment Line		
4.	Leveling	Should be properly balanced and leveled.		

Inference:

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Checked By
Engineering
Sign/Date:

Verified By
Quality Assurance
Sign/Date:



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11.2 Operational checks:

S.No.	COMPONENT	ACCEPTANCE CRITERIA	OBSERVATION	COMPLIES / DOES NOT COMPLIES
1.	Turn the Knob ON Position.	HMI Display should be ON.		
2.	Turn the Knob OFF Position	HMI Display should be OFF.		
3.	Turn the Knob ON Position.	HMI Display should be ON.		
4.	Turn the Knob OFF Position	HMI Display should be OFF.		
5.	Turn the Knob on start Position.	Conveyor Belt will start		
6.	Turn the Knob on stop Position.	Conveyor Belt will stop		

Inference:

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Checked By
Production
Sign/Date:

Verified By
Quality Assurance
Sign/Date:



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11.3 Machine Speed Verification :

Product name		Batch no.	
Mfg. date		Exp. date	
Pack size		Date of test	

Parameter	Run-01			Run-02			Run-03		
	Min. CPM	Opt. CPM	Max CPM	Min. CPM	Opt. CPM	Max.) CPM	Min. CPM	Opt. CPM	Max. CPM
Speed									
After 1 Minute									
Display (CPM)									
Actual (CPM)									
After 2 minute									
Display (CPM)									
Actual (CPM)									
After 3 minute									
Display (CPM)									
Actual (CPM)									
After 4 minute									
Display (CPM)									
Actual (CPM)									
After 5 minute									
Display (CPM)									
Actual (CPM)									

Inference:

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Checked By
Production
Sign/Date:

Verified By
Quality Assurance
Sign/Date:



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11.4 Labeling Quality


11.4.1 Labeling Quality at different- different speed:

Product name		Batch no.	
Mfg. date		Exp. date	
Pack size		MRP.	

Observation at Minimum Speed	Observation
Labeling Orientation	
Positioning of Label	
Adhesiveness properties of label	
Shrinkage of label	
Dent /Rubbing mark on Label	
Affixing of labels	
Overlapping of Label	

Observation at Optimum Speed	Observation
Labeling Orientation	
Positioning of Label	
Adhesiveness properties of label	
Shrinkage of label	
Dent /Rubbing mark on Label	
Affixing of labels	
Overlapping of Label	

Observation at Maximum Speed	Observation
Labeling Orientation	
Positioning of Label	
Adhesiveness properties of label	
Shrinkage of label	
Dent /Rubbing mark on Label	
Affixing of labels	
Overlapping of Label	

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Acceptance Criteria:

TEST	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 bottles
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

Inference:

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**Checked By
(Production)**

Sign/Date:

Verified By

(Quality Assurance)

Sign/Date:

11.4.2 Labeling Quality During Initial, Middle & End of Batch:

Product name		Batch no.	
Mfg. date		Exp. date	
Pack size		MRP.	

Observation at Initial of Batch	Observation
Labeling Orientation	
Positioning of Label	
Adhesiveness properties of label	
Shrinkage of label	
Dent /Rubbing mark on Label	
Affixing of labels	
Overlapping of Label	

Observation at Middle of Batch	Observation
Labeling Orientation	



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Positioning of Label	
Adhesiveness properties of label	
Shrinkage of label	
Dent /Rubbing mark on Label	
Affixing of labels	
Overlapping of Label	

Observation at End of Batch	Observation
Labeling Orientation	
Positioning of Label	
Adhesiveness properties of label	
Shrinkage of label	
Dent /Rubbing mark on Label	
Affixing of labels	
Overlapping of Label	

Acceptance Criteria:

TEST	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 bottles
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

Inference:

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Checked By
(Production)
Sign/Date:

Verified By
(Quality Assurance)
Sign/Date:

11.4.3 CHECKLIST OF ALL TESTS & CHECKS:

This checklist is provided to ensure that all tests or checks required for this protocol have been executed.

S.No	Tests or Checks	Executed (Yes/No)	Remarks
1.	Installation checks		
2.	Operational checks		
3.	Verification of Performance using Commercial Batch of drug Product.		
(i)	Verification of machine speed verification		
(ii)	Verification of labeling quality		

Verified By
Quality Assurance

Sign/Date:.....

Inference:

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12.0 REFERENCES

- Validation Master Plan
- Standard operating procedure operation and cleaning of sticker labeling machine SOP.
- Performance qualification protocol.

13.0 DOCUMENTS TO BE ATTACHED:

- Any Other Relevant Documents.

14.0 NON COMPLIANCE:

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15.0 DEVIATION FROM PREDEFINED SPECIFICATION IF, ANY:

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16.0 CHANGE CONTROL, IF ANY:

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17.0 REVIEW (INCLUSIVE OF FOLLOW UP ACTION, IF ANY):

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18.0 CONCLUSION:

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19.0 RECOMMENDATION:

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20.0 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

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21.0 REPORT POST – 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)			