



PERFORMANCE QUALIFICATION REPORT FOR AUTOMATIC SELF ADHESIVE VERTICAL LABELING MACHINE

**PERFORMANCE QUALIFICATION
REPORT
FOR
AUTOMATIC SELF ADHESIVE
VERTICAL LABELING MACHINE**

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



PERFORMANCE QUALIFICATION REPORT FOR AUTOMATIC SELF ADHESIVE VERTICAL LABELING MACHINE

REPORT CONTENTS

S.NO.	TITLE	PAGE NO.
1.0	Report pre-approval	3
2.0	Objective	4
3.0	Scope	4
4.0	Responsibility	5
5.0	Equipment details	6
6.0	Pre-qualification requirement	6
7.0	Tests & checks	7
8.0	Checklist of all tests and checks	17
9.0	Documents to be attached	17
10.0	Non compliance	17
11.0	Deviation from pre-defined specification, if any	17
12.0	Change control, if any	18
13.0	Review inclusive of follow up action, if any	18
14.0	Conclusion	18
15.0	Recommendations	18
16.0	Abbreviations	19
17.0	Report post approval	20



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QUALITY ASSURANCE DEPARTMENT

PERFORMANCE QUALIFICATION REPORT FOR AUTOMATIC SELF ADHESIVE VERTICAL LABELING MACHINE

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 (ENGINEERING)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			



PERFORMANCE QUALIFICATION REPORT FOR AUTOMATIC SELF ADHESIVE VERTICAL LABELING MACHINE

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.



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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 Qualification Report.

DEPARTMENTS	RESPONSIBILITIES
Quality Assurance	<ul style="list-style-type: none">• Preparation, Approval and Compilation of the Performance Qualification Report.• Co-ordination with, Production and Engineering to carryout Performance Qualification Activity.• Monitoring of Performance Qualification Activity.• Post approval of Performance Qualification Report after execution.
Production	<ul style="list-style-type: none">• Review & Pre Approval of Performance Qualification Report.• To co-ordinate and support Performance Qualification Activity.• Post approval of Performance Qualification Report after execution.
Engineering	<ul style="list-style-type: none">• Review & Pre Approval of Performance qualification Report for correctness, completeness and technical excellence.• Responsible for trouble shooting (if occurred during execution).• Maintenance & preventive maintenance as per schedule.• Post approval of Performance Qualification Report after execution.



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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 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.



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7.0 TESTS AND CHECKS:

7.1 Machine Speed Verification:

Parameter	Trail-01			Trail-02			Trial-03		
	Min.	Opt.	Max.	Min.	Opt.	Max.	Min.	Opt.	Max.
After 1 Minute									
Set									
Display									
Actual									
After 2 minute									
Set									
Display									
Actual									
After 3 minute									
Set									
Display									
Actual									
After 4 minute									
Set									
Display									
Actual									
After 5 minute									
Set									
Display									
Actual									

Checked By
Production
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Verified By
Quality Assurance
Sign/Date:

Inference:
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Reviewed By
Manager QA
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7.2 Test for Labeling: Trial-01

Product Name		Date of Test	
B. No.		B. Size	
Vial Type		Label Size	

Parameter	Observation		
	Minimum speed	Optimum speed	Maximum speed
Labeling Orientation			
Positioning of Label			
Adhesiveness properties of label			
Shrinkage of label			
Affixing of labels			
Overlapping of Label			
Rejection			
Total Rejection %age			

Checked By
Production
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Sign/Date:

Inference:

Reviewed By
Manager QA
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7.2.1 Trial-02:

Product Name		Date of Test	
B. No.		B. Size	
Vial Type		Label Size	

Parameter	Observation		
	Minimum speed	Optimum speed	Maximum speed
Labeling Orientation			
Positioning of Label			
Adhesiveness properties of label			
Shrinkage of label			
Affixing of labels			
Overlapping of Label			
Rejection			
Total Rejection %age			

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Production
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7.2.2 Trial-03:

Product Name		Date of Test	
B. No.		B. Size	
Vial Type		Label Size	

Parameter	Observation		
	Minimum speed	Optimum speed	Maximum speed
Labeling Orientation			
Positioning of Label			
Adhesiveness properties of label			
Shrinkage of label			
Affixing of labels			
Overlapping of Label			
Rejection			
Total Rejection %age			

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Production
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7.3 Test For Printing : Trail-01:

PLC Input	Observation at Minimum Speed	Acceptance Criteria
		Printing Done as per PLC Input

PLC Input	Observation at Optimum Speed	Acceptance Criteria
		Printing Done as per PLC Input

PLC Input	Observation at Maximum Speed	Acceptance Criteria
		Printing Done as per PLC Input

Checked By
Production
Sign/Date:

Verified By
Quality Assurance
Sign/Date:

Inference:

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Reviewed By
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7.3.1 Trail-02:

PLC Input	Observation at Minimum Speed	Acceptance Criteria
		Printing Done as per PLC Input

PLC Input	Observation at Optimum Speed	Acceptance Criteria
		Printing Done as per PLC Input

PLC Input	Observation at Maximum Speed	Acceptance Criteria
		Printing Done as per PLC Input

Checked By
Production
Sign/Date:

Verified By
Quality Assurance
Sign/Date:

Inference:

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7.3.2 Trail-03:

PLC Input	Observation at Minimum Speed	Acceptance Criteria
		Printing Done as per PLC Input

PLC Input	Observation at Optimum Speed	Acceptance Criteria
		Printing Done as per PLC Input

PLC Input	Observation at Maximum Speed	Acceptance Criteria
		Printing Done as per PLC Input

Checked By
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Quality Assurance
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7.4 Test for Camera: Trial-01

Batch Number	Mfg. Date	Exp. Date	MRP

Test	Set Label Coding Detail	Observation
Test -01	Scan by PC	
Test -02	Scanning Detail are previous	
Test -03	Scanning Detail are previous	
	Domino Printer not ON	
Test -04	Scanning Detail are previous	
	Spreading of Ink by Domino Printer	
Test -05	Partial Printing	

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Production
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7.4.1 Trial-02:

Batch Number	Mfg. Date	Exp. Date	MRP

Test	Set Label Coding Detail	Observation
Test -01	Scan by PC	
Test -02	Scanning Detail are previous	
Test -03	Scanning Detail are previous	
	Domino Printer not ON	
Test -04	Scanning Detail are previous	
	Spreading of Ink by Domino Printer	
Test -05	Partial Printing	

Checked By
Production
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Inference:

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Reviewed By
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7.4.2 Trial-03:

Batch Number	Mfg. Date	Exp. Date	MRP

Test	Set Label Coding Detail	Observation
Test -01	Scan by PC	
Test -02	Scanning Detail are previous	
Test -03	Scanning Detail are previous	
	Domino Printer not ON	
Test -04	Scanning Detail are previous	
	Spreading of Ink by Domino Printer	
Test -05	Partial Printing	

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Sign/Date:

Inference:

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Reviewed By
Manager QA
Sign /Date:



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8.0 CHECKLIST OF ALL TESTS & CHECKS:

This checklist is provided to ensure that all tests or checks required in Performance Qualification protocol have been executed.

TESTS OR CHECKS	EXECUTED (YES/NO)	REMARKS
Machine Speed Verification		
Test For Labeling		
Test for Printing		
Challenge Test for Camera System.		

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Inference:

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9.0 DOCUMENTS TO BE ATTACHED:

- Any Other Relevant Documents.

10.0 NON COMPLIANCE:

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11.0 DEVIATION FROM PREDEFINED SPECIFICATION, IF ANY:

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12.0 CHANGE CONTROL , IF ANY:

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

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14.0 CONCLUSION:

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15.0 RECOMMENDATION:

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16.0 ABBREVIATIONS:

SLM	:	Automatic self Adhesive Vertical Labeling Machine.
MRP	:	Maximum Retail Price
Mfg.	:	Manufacturing
Exp.	:	Expiry
HMI	:	Human Machine Interface
PC	:	Personal Computer
IQ	:	Installation Qualification
PLC	:	Programmable Logical Controller
No.	:	Number
PPQ	:	Performance Qualification Protocol
PQ	:	Performance Qualification
QA	:	Quality Assurance
SOP	:	Standard Operation Procedure
WHO	:	World Health Organization



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17.0 REPORT POST – APPROVAL:

PREPARED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

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

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			