QUALITY ASSURAN

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



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PERFORMANCE QUALIFICATION REPORT FOR AUTOMATIC SELF ADHESIVE VERTICAL LABELING MACHINE

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PERFORMANCE QUALIFICATION REPORT FOR AUTOMATIC SELF ADHESIVE VERTICAL LABELING MACHINE

1.0 **REPORT PRE – 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)			



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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.

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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					
	•	Preparation, Approval and Compilation of the Performance					
		Qualification Report.					
Quality Assurance	•	Co-ordination with, Production and Engineering to carryout					
Quality Assurance		Performance Qualification Activity.					
	•	Monitoring of Performance Qualification Activity.					
	•	Post approval of Performance Qualification Report after execution.					
	•	Review & Pre Approval of Performance Qualification Report.					
Production	•	To co-ordinate and support Performance Qualification Activity.					
	•	Post approval of Performance Qualification Report after execution.					
	•	Review & Pre Approval of Performance qualification Report for					
		correctness, completeness and technical excellence.					
Engineering	•	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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PERFORMANCE QUALIFICATION REPORT FOR AUTOMATIC SELF ADHESIVE VERTICAL LABELING MACHINE

7.0 TESTS AND CHECKS:

7.1 Machine Speed Verification:

7.1	Parameter Parameter				Trail-02	02 Tria			ial-03	
	Speed	Min.	Opt.	Max.	Min.	Opt.	Max.	Min.	Opt.	Max.
After	1 Minute									
Set										
Displa	У									
Actual										
After	2 minute		l							
Set										
Displa	У									
Actual										
After	3 minute						<u>I</u>			
Set										
Displa	у									
Actual										
After	4 minute	l	ı							
Set										
Displa	У									
Actual										
After	5 minute	J	J	•	l	•				
Set										
Displa	У									
Actual										
Check Produ Sign/I	ction Date:						ed By y Assurar pate:			
•••••							ved By ger QA Date:			



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		LABELING	MACHINE					
7.2 Test for 1	Labeling: Trial-01	l						
Product Name			Date of Test					
B. No.	Io.							
Vial Type			Label Size					
Parameter			Observa	ition 				
		Minimum spee	d Optimum	speed	Maximum speed			
Labeling Orient	tation							
Positioning of L	abel							
Adhesiveness pr	roperties of label							
Shrinkage of lal	oel							
Affixing of label	ls							
Overlapping of	Label							
Rejection								
Total Rejection	%age							
Checked By			Verified	Rv				
Production Production				Assurance				
Sign/Date:			Sign/Dat	e:				
Inference:								
				• • • • • • • • • • • • • • • • • • • •				
			Reviewe Manager Sign /Da	r QA				



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PERFORMANCE OUALIFICATION REPORT FOR AUTOMATIC SELF ADHESIVE VERTICAL

FERFORMA	NCE QUALIFICA	LABELING			SELF ADI	HESIVE VERTICAL	
7.2.1 Trial-02:	:						
Product Name			Date of	Test			
B. No.			B. Size				
Vial Type			Label S	lize			
	Observation						
Parameter		Minimum space	4			Maximum spaed	
		Minimum spee	u	Optimum	speed	Maximum speed	
Labeling Orient	tation						
Positioning of L	abel						
Adhesiveness pr	roperties of label						
Shrinkage of lab	bel						
Affixing of label	ls						
Overlapping of	Label						
Rejection							
Total Rejection	%age		·				
Checked By Production Sign/Date:					Assurance		
Inference:							
					• • • • • • • • • • • • • • • • • • • •		
			•••••	Reviewed Managed Sign /Da	· QA		



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PERFORMANCE OUALIFICATION REPORT FOR AUTOMATIC SELF ADHESIVE VERTICAL

TEXT OXIVIAL	NCE QUALIFICA	LABELING		SELF ADI	MESIVE VERTICAL		
7.2.2 Trial-03:							
Product Name			Date of Test				
B. No.	3. No.						
Vial Type			Label Size				
Observation							
Parameter		Minimum anao			Maximum anaad		
		Minimum spee	d Optimum	speea	Maximum speed		
Labeling Orient	ation						
Positioning of L	abel						
Adhesiveness pr	operties of label						
Shrinkage of lab	oel						
Affixing of label	ls						
Overlapping of	Label						
Rejection							
Total Rejection	%age						
Checked By Production				Assurance			
Sign/Date: Inference:	••••••		Sign/Dat	.C			
amerence,							
	• • • • • • • • • • • • • • • • • • • •						
			Reviewe Manage	d By r QA			



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PERFORMANCE QUALIFICATION REPORT FOR AUTOMATIC SELF ADHESIVE VERTICAL LABELING MACHINE

7.3 Test For Printing: Tra	ail-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
necked By		Verified By Quality Assurance
oduction gn/Date:		Verified By Quality Assurance Sign/Date:
oduction gn/Date: ference:		Quality Assurance
roduction gn/Date: ference:		Quality Assurance Sign/Date:
oduction gn/Date: ference:		Quality Assurance Sign/Date:



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PERFORMANCE QUALIFICATION REPORT FOR AUTOMATIC SELF ADHESIVE VERTICAL LABELING MACHINE

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
_		D. C. D. DICL
		Printing Done as per PLC Input
Checked By Production		Verified By Quality Assurance
Sign/Date:		Sign/Date:
Inference:		
		Reviewed By
		Manager QA
		Sign /Date:



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PERFORMANCE QUALIFICATION REPORT FOR AUTOMATIC SELF ADHESIVE VERTICAL LABELING MACHINE

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
hecked By roduction gn/Date:		Verified By Quality Assurance Sign/Date:
ference:		
		Reviewed By Manager QA Sign /Date:



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PERFORMANCE QUALIFICATION REPORT FOR AUTOMATIC SELF ADHESIVE VERTICAL LABELING MACHINE

7.4	Test for	Camera:	Trial-01
/ • T	1 (31 101	Camera.	IIIai-vi

Batch Number	Mfg. Date	Exp. Date	MRP

Test	Set Label Coding Detail	Observation
	Scan by PC	
	-	-
Test -01		
1050 01		
	Scanning Detail are previous	
	Scanning Detail are previous	_
Test -02		
1 est -02		
	Scanning Detail are previous	
Test -03	Domino Printer not ON	_
	Scanning Detail are previous	
Test -04	Spreading of Ink by Domino Printer	
Test -05	Partial Printing	
Checked By		Verified By
Production		Quality Assurance
Sign/Date:		Sign/Date:
Inference:		
		Reviewed By
		Manager QA Sign /Date:
		~-5



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PERFORMANCE QUALIFICATION REPORT FOR AUTOMATIC SELF ADHESIVE VERTICAL LABELING MACHINE

7.4.1 Trial-02:

Batch Numl	Batch Number Mfg. Date		Exp. Date	MRP
Test	Set	Label Coding Detail	Obse	ervation
	Scan	by PC		
Test -01				
	Saann	ing Detail are previous		
	Scalin	ing Detail are previous		
Test -02				
Test -03		ing Detail are previous		
1est -05	Domin	o Printer not ON		
Test -04	Scann	ing Detail are previous		
1 est -04	Spread	ling of Ink by Domino Printer		
Test -05	Partial	Printing		

Test -05	Partial Printing	
Checked By Production Sign/Date:		Verified By Quality Assurance Sign/Date:
Inference:		
		Reviewed By Manager QA Sign /Date:



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PERFORMANCE QUALIFICATION REPORT FOR AUTOMATIC SELF ADHESIVE VERTICAL LABELING MACHINE

7.4.2 Trial-03:

Batch Number	Mfg. Date	Exp. Date	MRP

Test	Set Label Coding Detail	Observation
	Scan by PC	
Test -01		
	Coopping Detail are previous	
	Scanning Detail are previous	
Test -02		
Test -03	Scanning Detail are previous	
Test -05	Domino Printer not ON	
Test -04	Scanning Detail are previous	
Test -04	Spreading of Ink by Domino Printer	
Test -05	Partial Printing	
Checked By		Verified By
Production		Quality Assurance
Sign/Date:		Sign/Date:
Inference:		
		Reviewed By Manager QA
		Sign /Date:



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PERFORMANCE QUALIFICATION REPORT FOR AUTOMATIC SELF ADHESIVE VERTICAL LABELING MACHINE

CHECKLIST OF ALL TESTS & CHECKS: 8.0

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

EXECUTED

	TESTS OR CHECKS	(YES/NO)	REMARKS
Mach	ine Speed Verification		
Test 1	For Labeling		
Test f	or Printing		
Challe	enge Test for Camera System.		
Produ	ked By uction Date:	Verified By Quality Assur Sign/Date:	ance
Infere	ence:		
•••••		Daviewed Dv	
		Reviewed By Manager QA Sign /Date:	
9.0	DOCUMENTS TO BE ATTACHED:		
	• Any Other Relevant Documents.		
10.0	NON COMPLIANCE:		
11.0	DEVIATION FROM PREDEFINED S	SPECIFICATION, IF ANY:	



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12.0	CHANGE CONTROL , IF ANY:
13.0	REVIEW (INCLUSIVE OF FOLLOW UP ACTION, IF ANY):
14.0	CONCLUSION:
15.0	RECOMMENDATION:



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PERFORMANCE QUALIFICATION REPORT FOR AUTOMATIC SELF ADHESIVE VERTICAL LABELING MACHINE

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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PERFORMANCE QUALIFICATION REPORT FOR AUTOMATIC SELF ADHESIVE VERTICAL LABELING MACHINE

17.0 REPORT POST – 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)			