



**PERFORMANCE QUALIFICATION REPORT
FOR
AUTOMATIC HORIZONTAL STICKER LABELING MACHINE**

**PERFORMANCE QUALIFICATION
REPORT
FOR
AUTOMATIC HORIZONTAL STICKER
LABELING MACHINE**

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



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**PERFORMANCE QUALIFICATION REPORT
FOR
AUTOMATIC HORIZONTAL STICKER 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)			
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 Horizontal Sticker Labeling Machine (**Make:** Harikrushna Machinetech Pvt. Ltd.) installed in Packing Hall
- This Protocol will define the methods and documentation used to qualify the Automatic Horizontal Sticker 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 Horizontal Sticker Labeling Machine
Equipment ID.	
Manufacturer's Name	Harikrushna Machinetech Pvt. Ltd.
Machine No.	4486
Model No.	
Supplier's Name	Harikrushna Machinetech Pvt. Ltd.
Location of Installation	Packing Hall

6.0 PRE – QUALIFICATION REQUIREMENTS:

- SOP for operation & Cleaning of Automatic Horizontal Sticker Labeling Machine.
- SOP for Preventive Maintenance of Automatic Horizontal Sticker Labeling Machine.



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7.0 TESTS AND CHECKS:

7.1 Machine Speed Verification:

Parameter	Trail-01			Trail-02			Trial-03		
Speed	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									

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7.2 Test for Labeling: Trial-01

Product Name		Date of Test	
B. No.		B. Size	
Bottle Size			

Parameter	Observation		
	Minimum speed	Optimum speed	Maximum speed
No. of Bottle taken			
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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Quality Assurance
Sign/Date:

Inference:

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Sign/Date:



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7.2.1 Trial-02:

Product Name		Date of Test	
B. No.		B. Size	
Bottle Size			

Parameter	Observation		
	Minimum speed	Optimum speed	Maximum speed
No. of Bottle taken			
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	
Bottle Size			

Parameter	Observation		
	Minimum speed	Optimum speed	Maximum speed
No. of Bottle taken			
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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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:

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Sign/Date:

Inference:
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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:

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Sign/Date:

Inference:

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1.1.1 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
Production
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1.2 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	Domino Printer not ON	
Test -04	Spreading of Ink by Domino Printer	
Test -05	Partial Printing	

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QUALITY ASSURANCE DEPARTMENT

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1.2.1 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	Domino Printer not ON	
Test -04	Spreading of Ink by Domino Printer	
Test -05	Partial Printing	

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1.2.2 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	Domino Printer not ON	
Test -04	Spreading of Ink by Domino Printer	
Test -05	Partial Printing	

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Sign/Date:



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2.0 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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Quality Assurance
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3.0 DOCUMENTS TO BE ATTACHED:

- Any Other Relevant Documents.

4.0 NON COMPLIANCE:

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5.0 DEVIATION FROM PREDEFINED SPECIFICATION, IF ANY:

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6.0 CHANGE CONTROL , IF ANY:

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

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8.0 CONCLUSION:

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9.0 RECOMMENDATION:

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10.0 ABBREVIATIONS:

SLM : Automatic Horizontal Sticker 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



PHARMA DEVILS
QUALITY ASSURANCE DEPARTMENT

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11.0 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)			
HEAD (PRODUCTION)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			