



**PERFORMANCE QUALIFICATION
REPORT
FOR
STICKER LABELING MACHINE**

PROTOCOL No.:

**PERFORMANCE QUALIFICATION
REPORT
FOR
STICKER LABELING MACHINE**

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



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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)			



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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 **Sticker Labeling Machine (Make: Harikrushna Machinery)** installed in the Packing Hall.
- This Protocol will define the methods and documentation used to qualify the Blister Packing 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

DEPARTMENTS	RESPONSIBILITIES
Quality Assurance	<ul style="list-style-type: none">• Preparation, Approval and Compilation of the Performance Qualification.• Co-ordination with, Production and Engineering to carryout Performance Qualification Activity.• Monitoring of Performance Qualification.• Post approval of Performance Qualification Report after execution.
Production	<ul style="list-style-type: none">• Review 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">• Reviewing of qualification protocol 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	Sticker Labeling Machine
Equipment ID.	
Model	
Manufacturer's Name	
Supplier's Name	
Sr. No.	
Location of Installation	Packing Hall

6.0 PRE – 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.

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



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7.0 TESTS AND CHECKS:

7.1 Verification of Documents:

Record the observations for documents in the below mentioned table:

S.No.	Document Name	Completed (Yes/No)	Checked By (Engineering) Sign/Date	Verified By (QA) Sign/Date
1.	PQ Protocol approved			
2.	Revise SOP for operation & Cleaning of Sticker Labeling Machine			
3.	SOP for Preventive Maintenance Sticker Labeling Machine			

Inference:

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**Reviewed By
Manager QA
Sign/Date:**



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7.2 REPORT OF PERFORMANCE EVALUATION FIRST USING DRUG PRODUCT:

Product Name: -

Batch No.:

Date of test:

7.2.1 Test for Domino Printer:

Trial	Set Label Coding Detail	Observe Label Coding Detail
Trial-01		
Trial-02		
Trial-03		

**Checked By
Production
Sign/Date:**

**Verified By
Quality Assurance
Sign/Date:**

Inference:

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**Reviewed By
Manager QA
Sign/Date:**



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7.2.2 Test for Labeling Machine :

Test Parameters	Initial stage	Middle stage	End stage
Labeling Orientation			
Coding Imprint			
Positioning of Label			
Adhesiveness properties of label			
Shrinkage of label			
Dent /Rubbing mark on Label			
Affixing of labels edges			
Overlapping of Label			
Counting of Bottle			

Acceptance criteria :

Labeling Orientation : Should be Uniform

Coding Imprint : Clear & legible

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

Counting of Bottle: Bottle counter should count correctly and exact no. of bottles

Checked By
Production
Sign/Date:

Verified By
Quality Assurance
Sign/Date:

Inference:

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Reviewed By
Manager QA
Sign/Date:



**PERFORMANCE QUALIFICATION
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PROTOCOL No.:

7.3 REPORT OF PERFORMANCE EVALUATION SECOND USING DRUG PRODUCT:

Product Name: -

Batch No.:

Date of Test:

7.3.1 Test for Domino Printer:

Trial	Set Label Coding Detail	Observe Label Coding Detail
Trial-01		
Trial-02		
Trial-03		

**Checked By
Production
Sign/Date:**

**Verified By
Quality Assurance
Sign/Date:**

Inference:

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**Reviewed By
Manager QA
Sign/Date:**



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7.3.2 Test for Labeling Machine :

Test Parameters	Initial stage	Middle stage	End stage
Labeling Orientation			
Coding Imprint			
Positioning of Label			
Adhesiveness properties of label			
Shrinkage of label			
Dent /Rubbing mark on Label			
Affixing of labels edges			
Overlapping of Label			
Counting of Bottles			

Acceptance criteria :

Labeling Orientation : Should be Uniform

Coding Imprint : Clear & legible

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

Counting of Bottle: Bottle counter should count correctly and exact no. of bottles

Checked By
Production
Sign/Date:

Verified By
Quality Assurance
Sign/Date:

Inference:

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Reviewed By
Manager QA
Sign/Date:



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PROTOCOL No.:

7.4 REPORT OF PERFORMANCE EVALUATION THIRD USING DRUG PRODUCT:

Product Name: -

Batch No.:

Date of Test:

7.4.1 Test for Domino Printer:

Trial	Set Label Coding Detail	Observe Label Coding Detail
Trial-01		
Trial-02		
Trial-03		

**Checked By
Production
Sign/Date:**

**Verified By
Quality Assurance
Sign/Date:**

Inference:

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**Reviewed By
Manager QA
Sign/Date:**



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7.4.2 Test for Labeling Machine :

Test Parameters	Initial stage	Middle stage	End stage
Labeling Orientation			
Coding Imprint			
Positioning of Label			
Adhesiveness properties of label			
Shrinkage of label			
Dent /Rubbing mark on Label			
Affixing of labels edges			
Overlapping of Label			
Counting of Bottles			

Acceptance criteria :

Labeling Orientation : Should be Uniform

Coding Imprint : Clear & legible

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

Counting of Bottle: Bottle counter should count correctly and exact no. of bottles

Checked By
Production
Sign/Date:

Verified By
Quality Assurance
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 for this protocol have been executed.

Tests or Checks	Executed (Yes/No)	Remarks
Verification of Performance using Three Batch of drug Product.		
Verification of Performance of domino printer		
Verification of Performance of Labeling Machine		

Verified By
Quality Assurance
Sign/Date:.....

Inference:

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Reviewed By
Manager QA
Sign/Date:



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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:

- cGMP : Current Good Manufacturing Practices
- LTD. : Limited
- No. : Number
- PPQ : Performance Qualification Protocol
- PQ : Performance Qualification
- PVT : Private
- QA : Quality Assurance
- RPQ : Performance Qualification Report
- SOP : Standard Operating Procedure
- SLM : Sticker Labelling Machine



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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)			