



# **PERFORMANCE QUALIFICATION REPORT FOR STICKER LABELING MACHINE**

<b>EQUIPMENT ID. No.</b>	
<b>LOCATION</b>	<b>Packing Hall</b>
<b>DATE OF QUALIFICATION</b>	
<b>SUPERSEDES PROTOCOL No.</b>	<b>NIL</b>



**PERFORMANCE QUALIFICATION REPORT FOR STICKER LABELING MACHINE**

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**PHARMA DEVILS**  
QUALITY ASSURANCE DEPARTMENT

**PERFORMANCE QUALIFICATION REPORT FOR STICKER LABELING MACHINE**

**1.0 REPORT PRE – APPROVAL:**

**INITIATED BY:**

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

**REVIEWED BY:**

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			
HEAD (ENGINEERING)			

**APPROVED BY:**

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			



**PERFORMANCE QUALIFICATION REPORT FOR STICKER 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 **Sticker Labeling Machine** (**Make: .....**) installed in the Packing Hall.
- This Protocol will define the methods and documentation used to qualify the Blister Packing Machine for PQ.



**PERFORMANCE QUALIFICATION REPORT FOR STICKER LABELING MACHINE**

**4.0 RESPONSIBILITY:**

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

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



**PERFORMANCE QUALIFICATION REPORT FOR STICKER LABELING MACHINE**

**5.0 EQUIPMENT DETAILS:**

<b>Equipment Name</b>	Sticker Labeling Machine
<b>Equipment ID.</b>	
<b>Manufacturer's Name</b>	
<b>Supplier's Name</b>	
<b>S.No.</b>	
<b>Location of Installation</b>	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.

- Executed and approved Design Qualification document
- Executed and approved Installation Qualification document
- Executed and approved Operational Qualification document
- SOP for operation & Cleaning of Sticker Labeling Machine.
- SOP for Preventive Maintenance Sticker Labeling Machine.



**PERFORMANCE QUALIFICATION REPORT FOR STICKER LABELING MACHINE**

**7.0 TESTS AND CHECKS:**

**7.1 Verification of Documents:**

Record the observations for documents in the below mentioned table:

S. No.	Document Name	Document / SOP No.	Completed (Yes/No)	Checked By (Engineering) Sign/Date	Verified By (QA) Sign/Date
1.	Executed and approved Design Qualification document				
2.	Executed and approved Installation Qualification document				
3.	Executed and approved Operational Qualification document				
4.	PQ Protocol approved				
5.	SOP for operation & Cleaning of Sticker Labeling Machine				
6.	SOP for Preventive Maintenance Sticker Labeling Machine				

**Inference:**

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**Reviewed By**  
**(Manager QA)**  
**Sign/Date: .....**



**PERFORMANCE QUALIFICATION REPORT FOR STICKER LABELING MACHINE**

**7.2 TEST PRODUCT BATCH INFORMATION:**

S. No.	Product Name	Batch No.	Pack Size	Batch Size	Mfg. Date	Expiry Date

**Compiled By**  
**(QA)**

**Sign/Date:** .....

**Inference:**

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**Reviewed By**  
**(Manager QA)**

**Sign/Date:** .....





**PERFORMANCE QUALIFICATION REPORT FOR STICKER LABELING MACHINE**

**7.3 REPORT OF PERFORMANCE EVALUATION USING DRUG PRODUCT:**

**First Product Name: -**

**Batch No.:**

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 Vial			

**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 vials

**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 Vial:** Vial counter should count correctly and exact no. of vials

**Checked By**

**(Production)**

**Sign/Date:** .....

**Verified By**

**(Quality Assurance)**

**Sign/Date:** .....

**Inference:**

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**Reviewed By**

**(Manager QA)**

**Sign / Date:** .....



**PERFORMANCE QUALIFICATION REPORT FOR STICKER LABELING MACHINE**

**Second Product Name: -**

**Batch No.:**

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 Vial			

**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 vials

**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 Vial:** Vial counter should count correctly and exact no. of vials

**Checked By**

**(Production)**

**Sign/Date:** .....

**Verified By**

**(Quality Assurance)**

**Sign/Date:** .....

**Inference:**

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**Reviewed By**

**(Manager QA)**

**Sign/Date:** .....



**PERFORMANCE QUALIFICATION REPORT FOR STICKER LABELING MACHINE**

**Third Product Name: -**

**Batch No.:**

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 Vial			

**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 vials

**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 Vial:** Vial counter should count correctly and exact no. of vials

**Checked By**

**(Production)**

**Sign/Date:** .....

**Verified By**

**(Quality Assurance)**

**Sign/Date:** .....

**Inference:**

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**Reviewed By**

**(Manager QA)**

**Sign/Date:** .....



**PERFORMANCE QUALIFICATION REPORT FOR STICKER LABELING MACHINE**

**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 DQ, IQ & OQ & other documents		
Verification of Performance using Product.		

**Checked By**  
**(Production)**  
**Sign/Date:** .....

**Verified By**  
**(Quality Assurance)**  
**Sign/Date**.....

**Inference:**

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**Reviewed By**  
**(Manager QA)**  
**Sign/Date:** .....



**PERFORMANCE QUALIFICATION REPORT FOR STICKER LABELING MACHINE**

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

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

**16.0 ABBREVIATIONS:**

cGMP	:	Current Good Manufacturing Practices
DQ	:	Design Qualification
IQ	:	Installation Qualification
LTD.	:	Limited
No.	:	Number
OQ	:	Operational Qualification
PVT	:	Private
QA	:	Quality Assurance
RPQ	:	Performance Qualification Report
SOP	:	Standard Operating Procedure
SLM	:	Sticker Labelling Machine



**PHARMA DEVILS**  
QUALITY ASSURANCE DEPARTMENT

**PERFORMANCE QUALIFICATION REPORT FOR STICKER LABELING MACHINE**

**17.0 REPORT POST – APPROVAL:**

**INITIATED BY:**

DESIGNATION	NAME	SIGNATURE	DATE
<b>OFFICER/EXECUTIVE (QUALITY ASSURANCE)</b>			

**REVIEWED BY:**

DESIGNATION	NAME	SIGNATURE	DATE
<b>HEAD (PRODUCTION)</b>			
<b>HEAD (ENGINEERING)</b>			

**APPROVED BY:**

DESIGNATION	NAME	SIGNATURE	DATE
<b>HEAD (QUALITY ASSURANCE)</b>			