



**PHARMA DEVILS**

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

**PROTOCOL No.:**

**PERFORMANCE QUALIFICATION  
REPORT  
FOR  
AUTOMATIC STICKER LABELLING  
MACHINE**

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

 <b>PHARMA DEVILS</b>	<b>PERFORMANCE QUALIFICATION  REPORT  FOR  AUTOMATIC STICKER LABELING MACHINE</b>	<b>PROTOCOL No.:</b>
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**PROTOCOL No.:**

**1.0 REPORT PRE – APPROVAL:**

**PREPARED BY:**

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

**REVIEWED BY:**

<b>DESIGNATION</b>	<b>NAME</b>	<b>SIGNATURE</b>	<b>DATE</b>
<b>OPERATING MANAGER (QUALITY ASSURANCE)</b>			
<b>HEAD (ENGINEERING)</b>			
<b>HEAD (PRODUCTION)</b>			

**APPROVED BY:**

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



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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 sticker labeling machine (Make: Maharashi) installed in packing hall.
- This Protocol will define the methods and documentation used to qualify the automatic sticker labeling machine for PQ.

**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
<b>Quality Assurance</b>	<ul style="list-style-type: none"><li>• Preparation, Approval and Compilation of the Performance Qualification Report.</li><li>• To Co-ordination with, Production and Engineering to carryout Performance Qualification Activity.</li><li>• Monitoring of Performance Qualification Activity.</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 Execute Performance Qualification Activity.</li></ul>
<b>Engineering</b>	<ul style="list-style-type: none"><li>• Review of Performance qualification Report 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></ul>



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**5.0 EQUIPMENT DETAILS:**

<b>Equipment Name</b>	Automatic Sticker Labeling Machine
<b>Equipment ID.</b>	
<b>Manufacturer's Name</b>	Maharshi
<b>Model No.</b>	
<b>Machine No.</b>	
<b>Location of Installation</b>	Packing Hall

**6.0 PRE – QUALIFICATION REQUIREMENTS:**

**6.1 Document verification**

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.	Executed Design Qualification Protocol cum Report			
2.	Executed Installation Qualification Protocol cum Report			
3.	Executed Operational Qualification Protocol cum Report			
4.	Performance Qualification Protocol			
5.	Draft SOP for Operation & Cleaning of Automatic Sticker Labeling Machine			
6.	Draft SOP for Preventive Maintenance of Automatic Sticker Labeling Machine			

**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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**7.0 TESTS AND CHECKS:**

**7.1 Machine Speed Verification:**

Parameter	Run-01			Run-02			Run-03		
Speed	Min. 60 CPM (6 meter / min.)	Opt. 80 CPM (8 meter / min.)	Max. 100 CPM (10 meter / min.)	Min. 60 CPM (6 meter / min.)	Opt. 80 CPM (8 meter / min.)	Max. 100 CPM (10 meter / min.)	Min. 60 CPM (6 meter / min.)	Opt. 80 CPM (8 meter / min.)	Max. 100 CPM (10 meter / min.)
<b>After 1 Minute</b>									
Set (Meter/Min)									
Display (CPM)									
Actual (CPM)									
<b>After 2 minute</b>									
Set (Meter/Min)									
Display (CPM)									
Actual (CPM)									
<b>After 3 minute</b>									
Set (Meter/Min)									
Display (CPM)									
Actual (CPM)									
<b>After 4 minute</b>									
Set (Meter/Min)									
Display (CPM)									
Actual (CPM)									
<b>After 5 minute</b>									
Set (Meter/Min)									
Display (CPM)									
Actual (CPM)									

**Checked By**  
**Production**  
**Sign/Date:** .....  
**Inference:**

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

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



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**7.2 Test for Labeling: Run-01**

<b>Product Name</b>		<b>Date of Test</b>	
<b>B. No.</b>		<b>B. Size</b>	
<b>Bottle Type</b>		<b>Label Size</b>	

<b>Parameter</b>	<b>Observation</b>		
	<b>Minimum speed</b>	<b>Optimum speed</b>	<b>Maximum speed</b>
<b>Both side Labeling Orientation</b>			
<b>Positioning of Label</b>			
<b>Adhesiveness properties of label</b>			
<b>Shrinkage of label</b>			
<b>Dent/ Rubbing mark on label</b>			
<b>Affixing of labels</b>			
<b>Overlapping of Label</b>			

**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.:**

**7.2.1 Run-02:**

<b>Product Name</b>		<b>Date of Test</b>	
<b>B. No.</b>		<b>B. Size</b>	
<b>Bottle Type</b>		<b>Label Size</b>	

<b>Parameter</b>	<b>Observation</b>		
	<b>Minimum speed</b>	<b>Optimum speed</b>	<b>Maximum speed</b>
<b>Both side Labeling Orientation</b>			
<b>Positioning of Label</b>			
<b>Adhesiveness properties of label</b>			
<b>Shrinkage of label</b>			
<b>Dent/ Rubbing mark on label</b>			
<b>Affixing of labels</b>			
<b>Overlapping of Label</b>			

**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 Run-03:**

<b>Product Name</b>		<b>Date of Test</b>	
<b>B. No.</b>		<b>B. Size</b>	
<b>Bottle Type</b>		<b>Label Size</b>	

<b>Parameter</b>	<b>Observation</b>		
	<b>Minimum speed</b>	<b>Optimum speed</b>	<b>Maximum speed</b>
<b>Both side Labeling Orientation</b>			
<b>Positioning of Label</b>			
<b>Adhesiveness properties of label</b>			
<b>Shrinkage of label</b>			
<b>Dent/ Rubbing mark on label</b>			
<b>Affixing of labels</b>			
<b>Overlapping of Label</b>			

**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 in Performance Qualification protocol have been executed.

TESTS OR CHECKS	EXECUTED (YES/NO)	REMARKS
Machine Speed Verification		
Test For Labeling		

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

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

**Inference:**

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

**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	:	Sticker Labeling Machine
CPM	:	Container Per Minute
HMI	:	Human Machine Interface
QB	:	Quality Block
DQ	:	Design Qualification
IQ	:	Installation Qualification
OQ	:	Operational 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:**

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

**REVIEWED BY:**

<b>DESIGNATION</b>	<b>NAME</b>	<b>SIGNATURE</b>	<b>DATE</b>
<b>OPERATING MANAGER (QUALITY ASSURANCE)</b>			
<b>HEAD (ENGINEERING)</b>			
<b>HEAD (PRODUCTION)</b>			

**APPROVED BY:**

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