



PHARMA DEVILS

**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)			

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 **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.



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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, Review, Authorization 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	
Sr.	
Supplier's Name	
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.

- Executed and approved Design Qualification document
- Executed and approved Installation Qualification document
- Executed and approved Operational Qualification document
- Approved Performance Qualification Protocol
- 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	DOCUMENT / SOP No.	COMPLETED (YES/NO)	CHECKED BY (PRODUCTION) 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:**



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7.2 TEST PRODUCT BATCH INFORMATION:

DATE	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:



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7.3 REPORT OF PERFORMANCE EVALUATION USING DRUG PRODUCT:

First Product:

Batch No.:

Test Parameters	At Minimum Speed (.....)	At Optimum Speed (.....)	At Maximum Speed (.....)
Labeling Orientation			
Positioning of Label			
Adhesiveness properties of label			
Shrinkage of label			
Dent /Rubbing mark on Label			
Affixing of labels edges			
Overlapping of Label			

Acceptance criteria :

Labeling Orientation : Should be Uniform

Positioning of Label : Should be proper and should not be tilted

Adhesiveness properties of label: Label should be properly Adhered to Ampoules

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

**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.:

Second Product:.....

Batch No.:.....

Test Parameters	At Minimum Speed (.....)	At Optimum Speed (.....)	At Maximum Speed (.....)
Labeling Orientation			
Positioning of Label			
Adhesiveness properties of label			
Shrinkage of label			
Dent /Rubbing mark on Label			
Affixing of labels edges			
Overlapping of Label			

Acceptance criteria :

Labeling Orientation : Should be Uniform

Positioning of Label : Should be proper and should not be tilted

Adhesiveness properties of label: Label should be properly Adhered to Ampoules

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

**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.:

Third Product Name:.....

Batch No.:.....

Test Parameters	At Minimum Speed (.....)	At Optimum Speed (.....)	At Maximum Speed (.....)
Labeling Orientation			
Positioning of Label			
Adhesiveness properties of label			
Shrinkage of label			
Dent /Rubbing mark on Label			
Affixing of labels edges			
Overlapping of Label			

Acceptance criteria :

Labeling Orientation : Should be Uniform

Positioning of Label : Should be proper and should not be tilted

Adhesiveness properties of label: Label should be properly Adhered to Ampoules

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

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

**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
DQ	:	Design Qualification
FFS	:	Form Fill & Seal
IQ	:	Installation Qualification
LTD.	:	Limited
No.	:	Number
OQ	:	Operational Qualification
PVT	:	Private
QA	:	Quality Assurance
SLM	:	Sticker Labelling Machine
SOP	:	Standard Operating Procedure



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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)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			