OPERATIONAL QUALIFICATION
PROTOCOL CUM REPORT
FOR
STICKER LABELING MACHINE

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

PHARMA DEVILS	OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR STICKER LABELING MACHINE	PROTOCOL No.:

PROTOCOL CONTENTS

PHARMA DEVILS	OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR STICKER LABELING MACHINE	PROTOCOL No.:

1.0 PROTOCOL 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)			

2.0 OBJECTIVE:

- To verify that the equipment operates in accordance with the design and user requirements as defined by set Acceptance Criteria and complies with relevant cGMP Requirements.
- To verify the Operational features of Sticker Labeling Machine and to ensure that it produces desired Quality & rated output according to manufactures specifications.
- To verify all the Operational features from user point of view of the Equipment, Cleaning Procedure, Start up & Shut down Procedure and Safety Features.

3.0 SCOPE:

- The scope of this operational qualification protocol cum report is limited to qualification of **Sticker Labeling Machine (Make: …….)** Installed in the **Packing Hall**.
- This Protocol cum Report will define the methods and documentation used to perform OQ activity of Sticker Labeling Machine.
- Successful completion of this Protocol will verify that Sticker Labeling Machine meet all acceptance criteria and ready for Performance Qualification.

4.0 RESPONSIBILITY:

The Validation Group, comprising of a representative from each of the following departments shall be responsible for the overall compliance of this Protocol cum Report:

DEPARTMENTS	RESPONSIBILITIES
Quality Assurance	• Preparation, Review , Authorization, and compilation of the operational Qualification Protocol cum Report. • Co-ordination with Production and Engineering to carryout Operational Qualification. • Monitoring of Operation Process. • Post approval of Operational Qualification Protocol cum Report after execution.
Production	• Review & Pre Approval of Operational Qualification Protocol cum Report. • To Co-ordinate and support for execution of Operational Qualification study as per Protocol. • Post Approval of Operational Qualification Protocol cum Report after Execution.
Engineering	• Review & Pre Approval of Operational Qualification Protocol cum Report. • To co-ordinate and support Operational Qualification Activity.. • Post approval of Operational Qualification Protocol cum Report after execution.

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 EQUIPEMENT DESCRIPTION:

Model-HLC-100 having Vari-speed Green Endless Belt Conveyor on which Respoules are loaded in horizontal position which will carry to an applicating station i.e. below release plate, a product sensor sense the presence of Respoules Cassette at applicating station and give a signal to dispenser motor for dispensing a label and label sensor mounted on modular rail will sense the gap between two labels, indicating a completion of one label dispensing for the Respoules Cassette and that will give signal to stop the dispenser motor and at the same time, it will also forward the signal to On-line Coder (**Optional, If client purchase**) to print necessary details. On-line Coder fixed on modular rail has adjustment in both the direction to adjust the overprinting as per label layout. Now at application station, label is picked up by Respoules Cassettes due to adhesiveness and then enter under sponge label pressure roller, where more pressure will apply & fix the label properly on Respoules Cassettes surface.

7.0 PRE - QUALIFICATION REQUIREMENTS:

7.1 Verification of Documents:

- DQ Protocol cum Report.
- IQ Protocol cum Report.
- SOP for Operation & Cleaning of Sticker Labeling Machine.
- SOP for Preventive Maintenance of Sticker Labeling Machine.

7.1.1 Procedure:

- Verify the above mentioned documents for availability, completeness and approval status.
- If any deviation is observed the same has to be recorded giving reasons for deviation and approved. Deviation should be approved by Authorized person.
- Approved Drawings and supporting documents would form a part of the OQ Protocol cum Report.

7.1.2 Acceptance Criteria:

All the documents should be available, complete and approved by respective authorities.

8.0 CRITICAL VARIABLES TO BE MET:

8.1 Verification of documents:

The results of any tests should meet the limits and acceptance criteria specified in the test documents.

Any deviations or issues should be rectified and documented prior to OQ commencing.

S.No .	DOCUMENT NAME	DOCUMENT / SOP No.	COMPLETED (YES/NO)	CHECKED BY (ENGINEERING) SIGN/DATE
1.	DQ Protocol cum Report			
2.	IQ Protocol cum Report			
3.	SOP for Operation & Cleaning of Sticker Labeling Machine.			
4.	SOP for Preventive Maintenance 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: ……

8.2 Operational and Functional Checks:

Operate the Sticker Labeling Machine as per Manufacturer's Manual/SOP and Check for the following functions of the Equipment. The Equipment should function as desired.

COMPONENT	ACCEPTANCE CRITERIA	OBSERVATIONS	OBSERVED BY (ENGINEERING) SIGN/DATE
Machine ON/OFF Switch			
Turn the Knob ON Position.	Green light will glow on panel.		
Turn the Knob OFF Position	Green light will not glow on panel.		
Function of Conveyor Belt Start / Stop Knob			
Turn the Knob on start Position.	Conveyor Belt will start		
Turn the Knob on stop Position.	Conveyor Belt will stop		
Function of Speed Setting Knob of Conveyor Belt			
Turn the Knob for desired speed.	Speed will Increase / Decrease.		
Function of Label Start / Stop Knob Washing scheme			
Turn the Knob on start Position.	Labeling device will start		
Turn the Knob on stop Position.	Labeling device will stop.		
No Sticker No Label Sensor			
If there is no Sticker on conveyor belt	There should no Label.		

Checked By
(Production)
Sign/Date: ……

Verified By
(Quality Assurance)
Sign/Date: ……

Inference:

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Reviewed By
(Manager QA)
Sign/Date: ……

8.3 LABEL SPEED VERIFICATION : Label Speed Verify for 5 ml Cassette

8.3.1 Trial A

LABEL SPEED	DELAY TIME	OUT PUT (Respoules/Min)	OBSERVED BY (ENGINEERING) (SIGN/DATE)
5 Meter/ Minute	92 Second		
8 Meter/ Minute	92 Second		
10 Meter/ Minute	92 Second		

8.3.2 Trial B

LABEL SPEED	DELAY TIME	OUT PUT (Respoules/Min)	OBSERVED BY (ENGINEERING) (SIGN/DATE)
5 Meter/ Minute	92 Second		
8 Meter/ Minute	92 Second		
10 Meter/ Minute	92 Second		

8.3.3 Trial B

LABEL SPEED	DELAY TIME	OUT PUT (Respoules/Min)	OBSERVED BY (ENGINEERING) (SIGN/DATE)
5 Meter/ Minute	92 Second		
8 Meter/ Minute	92 Second		
10 Meter/ Minute	92 Second		

Checked By
(Production)
Sign/Date: ……

Verified By
(Quality Assurance)
Sign/Date: ……

Inference:

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Reviewed By
(Manager QA)
Sign/Date: ……

8.4 Power Failure Verification:

ITEM	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
Main Power Shut Down	Equipment stops in a safe and secure condition.		
Main Power Restored	Equipment can be restarted with no problems or adverse conditions.		

Checked By
(Production)
Sign/Date: ……

Verified By
(Quality Assurance)
Sign/Date: ……

Inference:

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Reviewed By
(Manager QA)
Sign/Date: ……

8.5 Emergency Operation Verification:

ITEM	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) (SIGN/DATE)
ON/OFF Push button • Press Stop Push Button • Release ON Push Button	Equipment should Stop		
	Equipment should Start		
With the OFF button Pressed in, Try to cause movement of an Operating function.	The Equipment will be inoperative.		

Checked By
(Production)
Sign/Date: ……

Verified By
(Quality Assurance)
Sign/Date: ……

Inference:

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Reviewed By
(Manager QA)
Sign/Date: ……

9.0 REFERENCES:

The Principle Reference is the following:

- Validation Master Plan.
- Schedule - M – "Good Manufacturing Practices and Requirements of Premises, Plant and Equipment for Pharmaceutical Products."
- WHO Essential Drugs and Medicines Policy, QA of Pharmaceuticals, Vol-2. Good Manufacturing Practices and Inspection.
- Operational & maintenance Manual of Sticker Labeling Machine by Party.

10.0 DOCUMENTS TO BE ATTACHED:

- Operation and Maintenance Manual.
- Any other Relevant Documents.

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
HP	:	Horse Power
IQ	:	Installation Qualification
Kg	:	Kilo Gram
KW	:	Kilo Watt
mm	:	Millimetre
No.	:	Number
OQ	:	Operational Qualification
SLM	:	Sticker Labelling Machine
SS	:	Stainless Steel
WHO	:	World Health Organization

17.0 PROTOCOL POST- APPROVAL:

PREPARED BY:

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HEAD (ENGINEERING)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			

AUTHORIZED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			