OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT
FOR
AUTOMATIC HORIZONTAL STICKER LABELING MACHINE

OPERATIONAL QUALIFICATION

PROTOCOL CUM REPORT

FOR

AUTOMATIC HORIZONTAL STICKER LABELING MACHINE

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

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PROTOCOL CONTENTS

OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR AUTOMATIC HORIZONTAL STICKER LABELING MACHINE

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)			
HEAD (PRODUCTION)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			

OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR AUTOMATIC HORIZONTAL STICKER LABELING MACHINE

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 Automatic Horizontal 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 Automatic Horizontal Sticker Labeling Machine **(Make:** Harikrushna Machinetech Pvt. Ltd.) Installed in Packing Hall.
- This Protocol cum Report will define the methods and documentation used to perform OQ activity of Automatic Horizontal Sticker Labeling Machine.
- Successful completion of this Protocol will verify that Automatic Horizontal Sticker Labeling Machine meet all acceptance criteria and ready for Performance Qualification.

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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	• 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 of Operational Qualification Protocol cum Report. • To co-ordinate and support Operational Qualification Activity.. • Post approval of Operational Qualification Protocol cum Report after execution.

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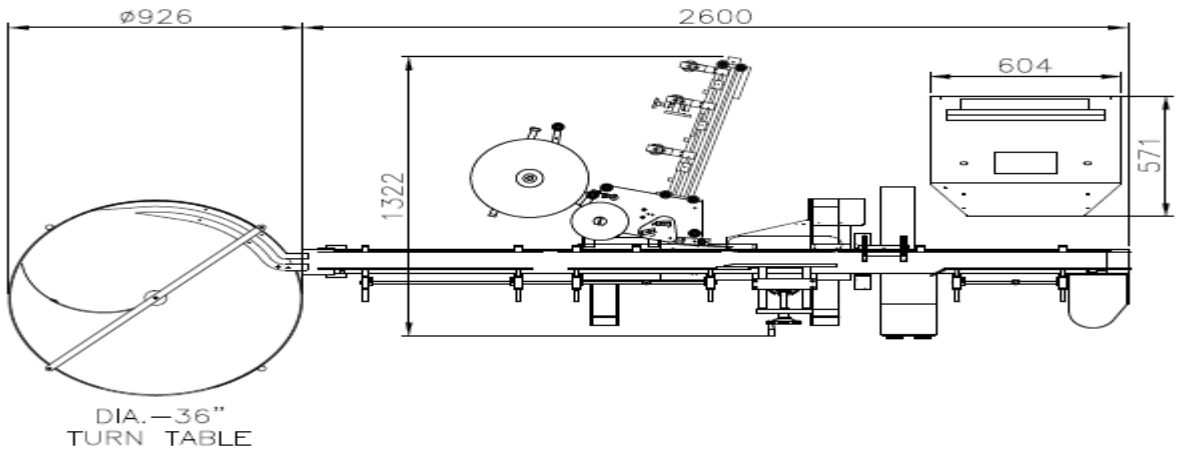
5.0 EQUIPMENT DETAILS:

Equipment Name	Automatic Horizontal Sticker Labeling Machine
Equipment ID.	
Manufacturer's Name	Harikrushna Machinetech Pvt. Ltd.
Machine No.	4486
Model No.	HMPL/BSHL-80
Supplier's Name	Harikrushna Machinetech Pvt. Ltd.
Location of Installation	Packing Hall

6.0 EQUIPEMENT DESCRIPTION:

This machine is designed to give High Output of Labeling on Bottle. After inspection the Bottle are loaded on In-feed turn table. From in feed turn table, Bottle entered in to infeed conveyor belt. Before the discharge the label device is positioned. Label device having a Printer for printing of batch no/mfg. date/expiry date & then camera system to inspect the printing matter OCR, Pharma code, Barcode etc. & once camera inspect the matter & if found any error then same Bottle with Rejected label is collected into a Box provided for rejected Bottle. The label applicator gets activated as soon as Bottle comes in the position of label; it gets sticks on the Bottles. After this, Bottles move toward the pressing belt meant for proper fixing of label. After pressing of the labels, good Bottles are move forward for further process

GA of Automatic Horizontal Sticker Labelling machine:



OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR AUTOMATIC HORIZONTAL STICKER LABELING MACHINE

7.0 PRE - QUALIFICATION REQUIREMENTS:

7.1 Verification of Documents:

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

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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	COMPLETED (YES/NO)	CHECKED BY (ENGINEERING) SIGN/DATE
1.	DQ Protocol cum Report		
2.	IQ Protocol cum Report		
3.	Draft SOP for Operation & Cleaning of Automatic Horizontal Sticker Labeling Machine.		
4.	Draft SOP for Preventive Maintenance of Automatic Horizontal 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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8.2 Functional Checks:

FUCTIONAL CHECK	ACCEPTANCE CRITERIA	OBSERVATIONS	OBSERVED BY (ENGINEERING) SIGN/DATE
Main ON/ Key switch.	To Connect/ disconnect the power supply to the control panel /machine.		
All Function key or Touch key from HMI	As stated in related operating manual.		
Emergency stop push button.	To stop machine in emergency.		
Turn the Knob for desired speed.	Speed will Increase / Decrease.		
Power UP after Power failure	The machine should start smoothly after recovery of Power from power failure		
Timer Check	Time during process should hold same as on power lost.		
Recipe check	Recipe values should be retentive with power		
SYSTEM SETTING			
System start up is OK	Should be Satisfactory		
AUTO Mode entry is ok	Should be Satisfactory		
AUTO Mode entry is ok	Should be Satisfactory		
AUTO Mode Setting is ok	Should be Satisfactory		
All Interlock is clear /OK	Should be Satisfactory		

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8.3 Safety Features, Alarms & Interlock: The equipment shall be provided with safety features as listed below.

TEST	ACCEPTANCE CRITERIA	OBESERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
Vial Jam at Out Feed – Machine Stop	The machine Should gets Automatically stop after Releasing the Vial from out feed machine should run smoothly		
Minimum Vial at in feed Conveyor – Feeder Stop	There is minimum quantity at in feed conveyor the machine should stop and allow to accumulate the Vial in conveyer machine gets restart.		
Rejection Bin full – Machine Stop	If Rejection bin found full the machine Gets stopped and after empty the bin the machine will gets restarted.		
Low Air Pressure – Machine Stop	If air pressure of machine goes below down from 4 kg/cm^2 than machine should stopped.		
Fallen Vial On In-feed Conveyor before labeling	If vial fallen on in-feed conveyer than machine should gets automatically stop		
No Vial at In Feed No Labeling.	If no vial into the in-feed than no label goes on.		

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

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TEST	ACCEPTANCE CRITERIA	OBESERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
Label Roll Empty – Alarm.	If label roll empty machine should not gets started.		
Emergency Stop	Machine should stop after pressing emergency stop button		
Conveyor Drive Fault - Machine Stop	If Conveyer Drive fault alarm generated than should stopped.		
Feeder Drive Fault – Machine Stop	If Feeder Drive fault alarm generated than should stopped.		
Servo Drive Fault – Machine Stop	If Servo Drive fault alarm generated than should stopped.		
Pressing belt Drive Fault – Machine Stop	If Pressing belt Drive fault alarm generated than should stopped.		
Pusher Wheel Drive Fault – Machine Stop	If Pusher wheel Drive fault alarm generated than should stopped.		
Maximum Rejection – Machine Stop	Please check that there is continuous rejection occur and Number of that rejection is more than Set Parameter the machine should get stopped		
Wrong Printing &Without	The machine should not get		

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TEST	ACCEPTANCE CRITERIA	OBESERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
printing Label- Vial Rejected (OCR / 1D & 2D BARCODE & PHARMA CODE)	started if the matter was found wrong		
No label on Vial- Vial Reject	If without label vial found then the machine should reject the vial.		
Camera Stop – Machine Stop	If camera is not in ON condition then machine should not start		
Batch Over-Camera Stop – Machine Stop	In case of completion of batch the camera automatically OFF and machine also should stop.		
Printer Stop - Machine Stop	If Printing is not in ON condition then machine should not start		
Main Star wheel Drive Trip	Machine should Stop		

Checked By
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8.4 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
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Inference:

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8.5 Power Failure Verification:

ITEM	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
Power up after power Failure	Machine should not start automatically with power.		
Main Power Restored	Equipment can be restarted with no problems or adverse conditions by Pressing start button.		
Timer Check	Time during Process should hold same as on power lost.		

Checked By
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Sign/Date: ……

Verified By
Quality Assurance
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Inference:

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8.6 SOFTWARE SYSTEM:

SECURITY	DESCRIPTION	OBSERVATION	CHECKED BY ENGINEERING SIGN /DATE
User Level with User Privileges	Minimum Five Level or as per requirement		
	· Operator Level		
	· Supervisor Level		
	· Manager Level		
	· Administrator Level		
	· Maintenance Level		
Password Length	Alphanumerical and as per client requirement		
Password Change	By Admin Level.		
Alarm History	All Alarms with Time & Date.		
Print Report	Set Parameter & Batch Summary Batch wise & Event Log on line.		
Recipe Management	Should Available.		
Input / Output status and simulation	Should reflect in HMI.		

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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.

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
ID.	:	Identification
IQ	:	Installation Qualification
Kg	:	Kilo Gram
KW	:	Kilo Watt
mm	:	Millimetre
No.	:	Number
OQ	:	Operational Qualification
SOP	:	Standard Operating Procedure
WHO	:	World Health Organization

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17.0 PROTOCOL POST- APPROVAL:

PREPARED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OPERATING MANAGER (QUALITY ASSURANCE)			
HEAD (ENGINEERING)			
HEAD (PRODUCTION)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			