



**INSTALLATION QUALIFICATION
PROTOCOL CUM REPORT
FOR
STICKER LABELLING MACHINE**

PROTOCOL No.:

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



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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)			



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2.0 OBJECTIVE:

- To provide documented evidence for the Installation Qualification of Sticker Labeling machine Liquid Line.
- To confirm that the equipment and its components are installed as per the Specifications mentioned in the design qualification document and other requirements given by supplier.

3.0 SCOPE:

- The scope of this installation qualification protocol cum report is limited to qualification of Sticker Labeling machine to be installed in packing hall, Liquid Line.
- This document provides all the relevant information related to specification, installation checks and acceptance criteria to be required to perform installation qualification activity of Sticker Labeling machine



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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	<ul style="list-style-type: none">• Preparation, Review, Authorization and Compilation of the Installation Qualification Protocol cum Report.• Co-ordination with Production and Engineering to carryout Installation Qualification.• Monitoring of Installation Qualification Activity.• Post approval of Installation qualification Protocol cum Report after execution.
Production	<ul style="list-style-type: none">• Review & Pre Approval of Installation Qualification Protocol cum Report.• To Co-ordinate and support for Execution of Qualification study as per Protocol.• Post Approval of Installation Qualification Protocol cum Report after Execution.
Engineering	<ul style="list-style-type: none">• Review & Pre Approval of Installation Qualification Protocol cum Report.• Co-ordination, Execution and technical support in Installation Qualification Activity.• Responsible for Trouble Shooting (if occurs during execution).• Post Approval of Installation Qualification Protocol cum Report after Execution.



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5.0 EQUIPMENT DETAILS:

Equipment Name	Sticker Labeling machine
Equipment ID.	
Manufacturer's Name	
Machine No.	
Model No.	
Capacity	60-80 bottle per Minute
Supplier's Name	Harikrushna machinery Pvt. Ltd.
Location of Installation	Packing Hall

6.0 SYSTEM DESCRIPTION:

Automatic Sticker Labeling Machine Model: HMPL/SSVL is used for Precise Labeling on round shaped pet/glass bottles. The machine Operates at the Speed off 60 to 80 Bottles per Minute. Specific Shape and Size of Containers can be accommodated on the same machine with /without the help of change Parts.

Main Assembly:

1. Dispenser assembly.
2. Conveyer with side guide.
3. Wrapping assembly.
4. Dispenser Unit.
5. Main Electrical Panel with SMPS, VFD, and Operating panel HMI, Emergency Switch & PLCs.
6. HSA jet Micron Printer.

7.0 PRE – QUALIFICATION REQUIREMENTS:

7.1 Verification of Documents:

- Executed and approved design qualification document.
- Technical specification of equipment.
- MOC Certificate of components.

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 IQ Protocol cum Report.



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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 Installation Qualification Checklist:

INSTALLATION CHECKS	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
Grouting and Mounting	Should be properly grouted and mounted.		
Leveling	Should be properly balanced and leveled.		
Edges of parts	Metal parts should be properly ground without any sharp edges.		
Welding of Joints	Welding of joints should be without any welding burrs.		
Place of Installation	Packing Hall Liquid Line		
Room Condition	General Room Conditions.		
Illumination	NLT 300 Lux		
Working space around the Equipment.	Should be sufficient for easy operation, cleaning, sanitation and maintenance.		

Checked By
Production
Sign/Date:

Verified By
Quality Assurance
Sign/Date:

Inference:

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Manager QA
Sign/Date:



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8.2 Technical Specification :

Critical variables	Acceptance criteria	Observation	Checked By Engineering Sign / Date
Make	Harikrushna Machinery Pvt. Ltd.		
Model	HMPL/SSVL		
S.No.		
Dimensions	1537 x 1060 x 1000 mm		
Label Speed	60-80 Bottle per Minute		
Design	Left → Right		
Label Dispenser	Make : Harikrushna Model : DSP-115RH		
Label Dispensing Speed	02- 60 Mtr / Min		
PLC system	Make : Harikrushna Model : HMPL/STND SR. No. : 2017-2018/010417		
Stepper Motor	Make : Harikrushna Model : HMPL/STND/SM-6		
Product Sensor	Make : Leuze Electronics. Model : D-73277 & LV461.1/P2		
Label gap Sensor	Make : Leuze Electronics. Model : GS61/6		
Wrapping Belt	Make : Harikrushna Model : HMPL/WB73510006 Size : 735*100*10		
Wrapping pad	Make : Harikrushna Model : HMPL/WP32510010 Size : 325*100*10		
Separator Pad	Make : Harikrushna Model : HMPL/WP1802510 Size : 180*25*10		



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Critical variables	Acceptance criteria	Observation	Checked By Engineering Sign / Date
VFD	Make : Delta Model : VFD002L21A Kw/HP: 0.18/0.25 Sr. No. : 004L21A6W16380356 004L21A6W16380285 Qty. : 02 Nos.		
Separator Motor	Make : Rotomotive Type : 3 ph induction motor RPM : 1380 Sr. No. : M08164133		
Separator Gear Box	Make : Rotomotive Type : Box 030 PAM : 63B5 Sr. No. : G01171267		
Conveyer motor	Make : Rotomotive Type : 3 ph induction motor RPM : 1380 Sr. No. : M11164352		
Conveyer Gear Box	Make : Rotomotive Type : Box 030 PAM : 63B5 Sr. No. : G02172558		
Wrapping Gear	Spur Gear: 20 teeth-1 nos. Spur Gear: 28 teeth-1 nos.		
Printing Unit	Make : HSAJET micron Unit I/P : 1 P,230 V AC , 50 Hz		
Encoder	Make : Metronix Model : MS50-82500-5-30F-3 mtr. Sr. No. : 2016121505		



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Critical variables	Acceptance criteria	Observation	Checked By Engineering Sign / Date
HMI	Make : Delta Model : TP02G-AS1 Sr. No. : TP02GAS1W16370121		
MCB	Make : Schneider Model : C6 Rating. : 6 Amps.		
Main ON/OFF switch	Make : L & T Rating. : 6 Amps.		
Emergency Switch	Make : Schneider		

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8.3 MATERIAL OF CONSTRUCTION:

S.No.	PARTS NAME	MATERIAL OF CONSTRUCTION	OBSERVATION	CHECKED BY ENGINEERING SIGN/DATE
Main Body & Product Conveyor				
1.	Main Body & Top plate	SS304		
2.	Conveyer Side Chanell	SS304 Matt Sheet Finished		
3.	Top plate	SS304		
4.	Door & Cover	SS304 Matt Sheet Finished		
5.	Conveyor slide chain	SS304		
6.	Sprockets	EN 24 Duly Hardened		
7.	Fixing Space	SS304		
8.	General Nut & Bolt	SS/MS, Duly Chrome Pleated		
9.	Guide Bracket	SS304/ Aluminum /Nylon		
Dispenser Assy				
10.	Dispenser Body	Aluminum Die Cast		
11.	Traction Roller	Aluminum Duly Coated of 115 mm Ht.		
12.	Pressure Roller	Aluminum Rubber coated with SS shaft		
13.	Rewinding Roller	Aluminum		
14.	Label Guide Roller	SS304		
15.	Label Web Guide Ring	Nylon		
16.	Label Pressing Spring Patti	SS Spring Steel		
17.	Dispenser other part	Aluminum		
18.	Dancing Roll Assy	SS Shaft Roller & Aluminum Coated Disk		
19.	Modular Rail	Aluminum or MS duly Powder Coated		
20.	Rail Bracket	CI duly Chrome Plated		



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S.No.	PARTS NAME	MATERIAL OF CONSTRUCTION	OBSERVATION	CHECKED BY ENGINEERING SIGN/DATE
21.	Sensor Holding Clamp	SS Duly Powder Coated		
22.	Label Release Plate	SS304		
Product Separating Device				
23.	Space Creator	Aluminum Coated		
Label Pressing System				
24.	Wrap- Around Massage Belt	Sponge Rubber Belt		
25.	Top & Bottom Plate	Aluminum with SS Sheet cover		
26.	Label Pressing plate	Aluminum lined with Sponge rubber & Covered with SS Sheet		

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Quality Assurance
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Sign/Date:.....



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8.4 Safety Feature:

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
Joints	Welding of joints without any welding burrs.		
Metal Parts	All the metal parts should be properly grounded without any sharp Edges.		
Leveling and Balancing	Equipment should be properly balanced & leveled.		
Earthing	Proper Earthing should be provided.		
Sensor	Sticker Sensor senses the presence of container for labeling. Label Sensor sense the presence of upcoming label for labeling.		
Emergency Switch	For Immediately Stop the machine		
Rotating Parts	Covered with SS cover		

Checked By
Production
Sign/Date:

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

Inference:

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Sign/Date:.....



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9.0 REFERENCES:

- Validation Master Plan
- Design Qualification Documents
- P & ID , Utility , and GA Drawing
- WHO Essential Drugs and Medicines Policy, QA of Pharmaceuticals, Vol-2-Good Manufacturing Practices and Inspection.

10.0 DOCUMENTS TO BE ATTACHED:

- Certificate of MOC.
- Any other Relevant Document

11.0 DEVIATION FROM PRE-DEFINED 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 Practice
- CI. : Cast Iron
- HP : Horse Power
- Hr : Hour
- Hz : Hertz
- IQ : Installation Qualification
- Kg : Kilogram
- KW : Kilo Watt
- mm : Millimeter
- MMI : Man Machine Interface
- MOC : Material of Construction
- MS : Mild Steel
- No : Number
- RPM : Revolution per minute
- SS : Stainless steel
- VFD : Variable Frequency Drive
- 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)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			