INSTALLATION QUALIFICATION

NAME OF THE ITEM: STICKER LABELLING MACHINE

FUNCTIONAL AREA : PRODUCTION

PROTOCOL No. :

CONTENTS

1.0 Protocol Approval:

Prepared By:

Functional area	Name	Signature	Date
Engineering			

Reviewed By:

Functional area	Name	Signature	Date
Engineering			
Production			
Quality assurance			

Approved By:

Functional area	Name	Signature	Date
Head Engineering			
Head Manufacturing			
Head Quality			

2.0 Objective:

The purpose of this document is to provide an outline for the inspection of equipment for static attributes to verify that;

- The system is constructed according to the design specifications described in the Design Qualification.
- The system is installed according to the design specifications and manufacturer's recommendations.
- Each installed sub-component has been checked physically and verified the same in accordance with the approved design and equipment data sheets/ specifications.
- The system meets the current Good Manufacturing Practice (cGMP) & Safety requirements.
- No un-authorised or unrecorded modifications have taken place.

Instructions:

- For each data sheet, record the requested information in black ink.
- In the "Verified" column, indicate that the item is inspected and verified according to pre-laid Specifications. Verification can be by a visual examination referring literature and using a measuring device, etc.
- After each data sheet is completed, put signature and date in the assigned space.
- Where the required information is not available 'Not Available' shall be entered accordingly. A single diagonal line shall be scribed through unused boxes and comments sections and "N/A" meaning "not applicable" entered, along with initials and date of the person who enters the line.
- After installation, check all instruments and components are installed as per the P & ID. Use a copy of this diagram as checklist and after completion of checking, attach this verified copy duly signed and approved along with this report.
- After completion of installation vendor should issue the commissioning report, which has to be authenticated by the engineering department.

3.0 Responsibilities:

In accordance with protocol, following functions shall be responsible for the qualification of equipment regardless of whether such work is performed by own staff or contract / consulting staff. When the work is carried by contract/consulting staff, all the work is to be performed under the oversight of ……...

3.1 Engineering Department

- Prepares the Installation qualification protocol.
- Ensures that the protocol is in compliance with current policies and procedures on equipment Qualification.
- Ensures that the content is sufficient, clearly defined, technically sound and accurate.
- Ensures compliance with design specifications for equipment / system.
- Distributes the draft protocol for review and collates comments.
- Makes any necessary corrections to the protocol and answers queries from the reviewers.
- Distributes the finalized protocol for review and approval signatures.
- Execution of IQ protocol.
- Develop departmental SOPs, log books, where appropriate.
- Review of protocol, the completed qualification data package, and the final report.

3.2 Head/Designee Engineering, production and quality assurance

- Review of protocol and the completed qualification data package, and the final report.
- Assist in the resolution of validation deficiencies.

3.2 Head Engineering, Manufacturing and Quality

- Approval of protocol and the completed qualification data package, and the final report.
- Assist the equipment user in the execution of the protocol.
- Verification that the protocol test requirements are completed and properly documented for approval.
- Assist in the resolution of validation variances.

4.0 Equipment Description & Identification:

4.1 Scope:

For new installation, modification, replacement or relocation of any component of Sticker labeling machine.

Room name	Room No.	Equipment No.
-------	"N/A"	

4.2 Name of the Equipment : STICKER LABELLING MACHINE

4.3 Make /Redesigned by : MAHARSHI UDYOG

4.4 Model No. / TYPE :

4.5 Serial No. :

4.6 Equipment Identification No. :

4.7 Equipment Location :

Remarks (if any)**:** _____

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Verified By & Date:

5.0 List of Reference Documents & Drawings:

S.No.	Name	Document number	Location	Checked by
1	User Requirement Specifications (URS)			
2	Purchase Order			
3	SAT Report			
4	Operating and Maintenance Manual			
5	P & I Diagram			
6	Mechanical Drawing			
7	Electrical Diagram			
8	General Arrangements / schematic line diagram			
9	Utility diagram			
10	Civil layouts			

Remarks (if any)**:** _____

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Verified By & Date:

6.0 Verification of Equipment on Receipt:

S.No.	Title	Observation	Checked by
1.	Purchase Order Number and date		
2.	Was the Machine Properly Protected From Heat, Rain & Dirt Etc.? During Transportation?		
3.	Physical verification of machine and its components for any damage		
4.	Nature of damage, if any		
5.	Corrective action in case of any damage.		
6.	Availability of accessories as per packing list received		

Remarks (if any)**:** _____

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Verified By & Date:

7.0 Verification of Major Components:

The principal components of the machine are listed in the following table. Visually inspect the components as installed and verify that it is as specified in the acceptance criteria.

S.No.	Name of component	Specified	Observation	Checked by Sign/ date
1.	Main Body & Top plate			
a.	Material	S.S. 304 & M.S. duly S.S. 304 Cladded.		
2.	Conveyor Side Channel			
a.	Material	S.S. 304		
3.	Conveyor Slat			
a.	Material	82 / 88 mm. S.S. 304 / Delrin Slat		
4.	Label Release Plate			
a.	Material	S. S. 304		
5.	Dispenser Body			
a.	Material	Engineering Plastic / Aluminium		
6.	Check the Model			
a.	Make	FIXONAME – VSC/VLC-240		
7.	Over all Dimensions			
a.	Dimensions	As Per Dwg		
8.	Labelling head			
A	Check the Labelling head	Servo motor, drive and adjustable label head height		
9.	Product Conveyor			
a.	Check the Product Conveyor	S.S. Chain of 88 mm Wide & length suitable for the machine integration		
10.	Product Separating Device	Alu. Casted 'O' Ring type wheel for Space Creator with Geared DC motor		

S.No.	Name of component	Specified	Observation	Checked by Sign/ date
11.	Label Pressing System			
a.	Material	S.S. 304 & M.S. duly S.S. 304 Cladded.		
12.	Conveyor Side Channel			
a.	Material	S.S. 304		
13.	Conveyor Slat			
a.	Material	82 / 88 mm. S.S. 304 / Delrin Slat		
14.	Label Release Plate			
a.	Material	SS 304		
15.	Dispenser Body			
A	Material	Engineering Plastic/ Aluminum		
16.	Check the Model			
A	Make	FIXONAME – VSC/VLC-240		
17.	Over all Dimensions			
A	Dimensions	As Per Dwg		
18.	Labelling head			
A	Check the Labelling head	Servo motor, drive and adjustable label head height		
19.	Product Conveyor			
a.	Check the Product Conveyor	S.S. Chain of 88 mm Wide & length suitable for the Machine integration		
20.	Product Separating Device	Alu. Casted 'O' Ring type Wheel for Space Creator with Geared DC motor		

S.No.	Name of component	Specified	Observation	Checked by Sign/ date
21.	**Pressing System**			
a	Label Pressing System	Wrap Around System, Label Pressing Pad		
22.	**Labelling Direction**			
a.	Check the label direction	Left to Right		
23.	**Labelling Speed**			
A	Check the Labelling Speed	Up to 240 CPM (depending upon label & Product size)		
24.	**Dispensing Speed**			
A	Check the Dispensing Speed	02 - 60 Mtr./min.		
25.	**Label Release Plate**			
A	Material	S.S. 304 Q		
26.	**Core Dia. of label Stock**			
A	Check the Core Dia. of label Stock	76 mm		
27.	**Midi un-winder Diameter**			
A	Check the Midi un-winder Diameter.	300 mm with suspended spring and automatic paper break with Roll Ending Alarm System		
28.	**Main Drive AC Motor**			
A	Make HP RPM Rating	Megha 0.5 HP 1385 Three phase, 220V input		
29.	**Main Drive Gear Box**			
A	Make Ratio Type	Rotomotive 20 : 1 Box-50		

S.No.	Name of component	Specified	Observation	Checked by Sign/ date
30.	**Check Dispenser Motor**			
A	Make	Fuji Make Small Servo Motor		
31.	**Control panel**			
a.	Check the Control panel	Consist of PLC with micro Processor control panel		
32.	**Operating panel**			
A	Check the Operating panel	Consist of all switch gears		
33.	**Bottle Counting system**			
A	Check the Bottle Counting system	In Built In PLC & Display On LCD		
34.	**Product Sensor**			
A	Make	Wenglor Make Product Sensor		
35.	**Label Sensor**			
A	Check the Label Sensor	Leuze Make Label Sensor		
36.	**Variable AC. Drive For Main Motor**			
A	Check the Variable AC. Drive For Main Motor.	Allen Bradley Make, Power Flex-4M, 0.5 HP		
37.	**Main Drive AC Motor**			
A	Make HP RPM Rating	Megha 0.5 HP 1385 Three phase, 220V input		
38.	**Main Drive Gear Box**			
A	Make Ratio Type	Rotomotive 20 : 1 Box-50		

Remarks (if any)**:** _____

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Verified By & Date:

8.0 Physical Verification of Area:

S.No.	Title	Observation	Checked by
1.	Name of Room and Identification No, where the machine to be installed		
2.	Dimension of the equipment (As per Machine Drawing/ Manual)		
3.	Verify that there is sufficient space for easy movement of man and material after installation		
4.	Verify that foundation arrangement has been made for proper fixing of equipment		
5.	Other provisions: (if any)		
	Equipment lifting and positioning arrangement		
6.	Verify that provisions for required utilities are provided.		
	Electricity		

Remarks (if any)**:** _____

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Verified By & Date:

9.0 Verification of Installation:

S.No.	Description Of Machine Components	Acceptance criteria	Observations	Checked By & Date
1.	A process instruments diagram (P & ID).	All instruments and components shall be installed as per approved P & ID.		
2.	Spirit Level of the Machine	Bubble should be inside the circle		

Remarks:_____

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Verified By & Date:

10.0 Verification of Special Features in the Equipment

10.1 Safety requirements:

S.No.	User requirement	Acceptance criteria	Observations	Checked By & Date
1.	Electrical connection	Connected Properly.		
2.	Alarm / Fault administration	Respective alarm should blow in respective fault.		
3.	Earthing	Touch the tester to body of machine bulb of tester should not glow.		
4.	Emergency switch	Should be stop immediately		

Remarks (If any)**:** _____

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Verified By & Date:

10.2 Automation control and Electrical connections:

S.No.	User Requirement	Acceptance Criteria	Observations	Checked By & Date
1.	Motors	With Calibration Certificate		

Remarks (If any)**:**

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Verified By & Date:

10.3 Location of the Control Panel:

S.No.	User requirement	Acceptance criteria	Observations	Checked By & Date
1.	Assembled in Machine	Should be operational smoothly		

Remarks (If any)**:** _____

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Verified By & Date:

11.0 Material of Construction:

List down and verify that the construction material of equipment components that come into contact with the product are as specified by the Manufacturer and satisfy the User Requirement. All certificates related to material of constriction should be attached.

Component	Specified	Observed	Certificate No.	Acceptable?	
				Yes/No	Initial & Date
Main Body & Top plate	S.S. 304 & M.S. duly S.S. 304 Cladded				
Conveyor Side Channel	S.S. 304				
Conveyor Slat	82 / 88 mm. S.S. 304 / Delrin Slat.				
Label Release Plate	S. S. 304				
Dispenser Body	Engineering Plastic/Aluminum				

Remarks (if any)**:** _____

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Verified By & Date:

12.0 Utilities/ Services Connection Check:

Verify the installed service connections to the component against the supplier's specification.

Utility	Specified	As Found	Confirmed by/ Evidence	Acceptable?	
				Yes/No	Initial & Date
Electricity	220-240 Volts AC, Single Phase, 50 Hz,				

Remarks (if any)**:** _____

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Verified By & Date:

13.0 Manufacturer's Certificates:

Review and attach all manufacturers' certificate(s) as per DQ and also attach any other certificate.

S.No.	Details of Certificate	Remarks	Checked By & Date
1.	Material of Construction		
2.	RPM / HP of Motors		

Remarks (if any)**:** _____

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Verified By & Date:

13.1 Identification of Training Need For Operating Personnel:

S.No.	Training Title	Identified By & Date

Remarks (If any)**:**

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Verified By & Date:

14.0 Deficiency Sheet:

Report any deficiencies from the acceptance criteria or from protocol instructions in the deficiency report form of Appendix 1. Record the total number of deficiencies reported during the installation qualification activities of this Protocol. Record the deficiency number and Title in the Table below. Include all deficiency Report Forms in Appendix 1. Indicate the status of each variance as 'Closed' only when the deficiency is resolved.

Deficiency No.	Deficiency Title	Status

Total No. Of Deficiencies: _____

Remarks (If any)**:**

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Verified By & Date:

15.0 List of Appendix:

Appendix No.	Document Title

Remarks (If any)**:**

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Verified By & Date:

16.0 Deficiency and Corrective Action Report Form

This Deficiency and Corrective Action Report Form shall be completed for each result that does not meet the expected or as designed condition encountered during the execution of the protocol. Each form shall be numbered sequentially and tracked on the Deficiency Sheet within the protocol.

Example Format:

	Deficiency Report Number:
Protocol Section No.:	Date of Test:
Description Of Test Result:	
Immediate Action Taken:	
Corrective Action Taken / Planned:	
Deficiency Reported By:	
Name: Signature:	Date:
Corrective action must be taken prior to approval of IQ or OQ? :	
Head - Engg. Signature	Date:
Head-User dept. signature	Date
QA Signature:	Date:
Corrective Action Implemented:	
Corrective Action Implemented By:	
Name: Signature:	Date:
(Attach comments and supporting documentation as necessary)	
Was a re-test or amendment necessary due to the Deficiency?	Date of re-test:
Is Deficiency Closed (Yes/No):	
QA Signature:	Date:

17.0 Summary & Conclusion:

Prepared By: _____ _____

Name & Department Sign. / Date

18.0 Approval of Installation Qualification:

Functional Area	Name	Signature	Date
Head Engineering			
Head Manufacturing			
Head Quality			