INSTALLATION QUALIFICATION
PROTOCOL CUM REPORT
FOR
STICKER LABELING MACHINE

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

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

PROTOCOL CONTENTS

PHARMA DEVILS	INSTALLATION 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 provide documented evidence for the Installation Qualification of Sticker Labeling Machine.
- 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 (Make: ……)** to be installed in the **Packing Hall**.
- 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.

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 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	• 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	• Review & Pre Approval of Installation Qualification Protocol cum Report. • Co-ordination, Execution and technical support in VLM Installation Qualification Activity. • Responsible for Trouble Shooting (if occurs during execution). • Post Approval of Installation Qualification Protocol cum Report after Execution.

5.0 EQUIPMENT DETAILS:

Equipment Name	Sticker Labeling Machine
Equipment ID.	……
Model	…..
Manufacturer's Name	Maharshi Udyog
Sr.	……
Supplier's Name	Maharshi Udyog
Location of Installation	Packing Hall

6.0 SYSTEM DESCRIPTION:

Model-HLC-100 having Vari-speed Green Endless Belt Conveyor on which Respoules Cassettes 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:

- Executed and approved design qualification document.
- Technical specification of equipment.
- Certificate of material of construction 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.

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.		
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:

……

……

……

……

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

8.2 TECHNICAL SPECIFICATIONS/KEY DESIGN FEATURES:

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
Make	Maharshi Udyog		
Model	HLC-100 (Servo)		
S.No.	……..		
Over all Dimensions (L x W x H)	2000 mm x 610 mm x 2000 mm		
Label Speed	Up to 100 CPM (Depending upon Label /Product Size & Operator Specification)		
Product Conveyor operating Height	900 mm (+ /- 50 Adjustable)		
Case Dimension	2200 mm x 800 mm x 2200 mm(Approx)		
Product ,FFS Respouless Cassette Block	Different size of Respouless cassette block of 3 & 5 Nos. Respouless of 5 to 30 ml.		
Design	Left → Right		
Label Dispenser	New Alu-175 mm Hight		
Dispenser motor	Make : Fuji Type : Small Servo Moter Sr.No. GYB401D6-RC2		
Dispenser Drive	Make : Fuji Type : Alpha 5 Smart Small servo drive Sr.No. 5XBM51A0001F		

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

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
Product Conveyer	100 mm, wide Green endless belt Conveyor, 2000 mm long.		
Label Width (height) Range	08 To 150 mm		
Label Length Range	10 to 300 mm		
Stop Tolerance	+/- 0.5 to 0.75 mm		
Label Stock Roll Dia	300 mm		
Core Dia of Label Stock	76 mm		
Dancing Roll Assy (Medium- Unbinder Dia)	300 mm with Suspended Spring and Automatic Paper break		
Micro Processor base operating Controlled Panel	Feature Touch Keypad operated Micro Processor Control Panel with Servo Motor & Drive. E-Prom No : 139-1 Sr.No: FEI-16222		
Label Pressing System	Sponge Pressure Roller Type: Grove & Nylon Brush		
Main Drive AC Motor	Make : Megha HP : 0.5 HP Phase : 3 Phase 220 V AC Sr.No. 2016043206		
Gear Box	Make : Rotomotive Size : Suitable Size Type : G04161572		

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

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
VFD for Main Motor	Make : Allen Bradly HP : 0.5 HP Type : AB Power Flex-4M		
Product sensor	Make : Leuze, Slot Sensor		
Label Sensor	Make : Leuze, with Reflector		

Checked By
(Production)
Sign/Date:……

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

Inference:

……

……

……

……

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

8.3 MATERIAL OF CONSTRUCTION:

S.No.	PARTS NAME	MOC	OBSERVATION
1.	Main Body & Top plate	SS304	
2.	Conveyer Side Channel	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	
10.	Dispenser Body	Aluminum Die Cast	
11.	Pressure Roller	Aluminum Rubber coated with SS shaft	
12.	Rewinding Roller	Aluminum	
13.	Label Guide Roller	SS304	
14.	Label Web Guide Ring	Nylon	
15.	Label Pressing Spring Patti	SS Spring Steel	
16.	Dispenser other part	Aluminum	
17.	Dancing Roll Assy	SS Shaft Roller & Aluminum Coated Disk	
18.	Modular Rail	Aluminum or MS duly Powder Coated	
19.	Rail Bracket	SS Die cast or CI duly Chrome Plated	
20.	Label Sensor Holding Clamp	Aluminum duly Powder coated or SS	
21.	Label Release Plate	SS304	

Checked By
(Production)
Sign/Date: ……

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

Inference:

……

……

……

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

8.4 SAFETY:

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.		
Machine cannot hurt the Man	Matter Lies with Wastage of Important Inputs and damage of Precious spare part of the Machine.		
Safety Cover	Safety provide for Driving unit		
No Cassettes	No Labeling		
SMPS Power supplier	Protects from Power fluctuation		
Flexibility in Setting	Flexibility in setting like printing position and label dispensing.		
Extra ordinary net Neat & Clean Area	Minimize Noise pollution and thus result into an Increased productivity among the work force.		

Checked By
(Production)
Sign/Date:……

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

Inference:

……

……

……

……

Reviewed By
(Manager QA)
Sign/Date:……

8.5 Utility Connection:

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
Electrical Supply	Voltage : 220/240 V AC Phase : Single Phase (Stabilized, Through 1 KVA CVT = Constant Voltage Transformer) Frequency : 50 HZ		
Earthing	Earthing Connected Properly		

Checked By
(Production)
Sign/Date: ……

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

Inference:

……

……

……

……

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

9.0 REFERENCES:

- Design Qualification of Party Document
- Installation Qualification of Party Document

10.0 DOCUMENTS TO BE ATTACHED:

- Certificate of MOC.
- Any other Relevant Document

11.0 DEVIATION FROM PRE-DEFINED SPECIFICATION IF, ANY:

……

……

……

……

……

……

……

……

12.0 CHANGE CONTROL, IF ANY:

……

……

……

13.0 REVIEW (INCLUSIVE OF FOLLOW UP ACTION, IF ANY):

……

……

……

……

……

14.0 CONCLUSION:

……

……

……

……

……

……

……

……

15.0 RECOMMENDATION:

……

……

……

……

……

……

……

……

……

……

……

16.0 ABBREVIATIONS:

AC	:	Alternating Current
cGMP	:	Current Good Manufacturing Practices
CI	:	Cast Iron
DQ	:	Design Qualification
FFS	:	Form Fill & Seal
HP	:	Horse power
HZ	:	Hertz
IQ	:	Installation Qualification
mm	:	Millimeter
MOC	:	Material of Construction
P & ID	:	Piping & Instrumentation Diagram
PO	:	Purchase Order
SLM	:	Sticker Labeling Machine
SS	:	Stainless Steel
SS	:	Stain less Steel
V	:	Volt
W	:	Watt

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)			