



PHARMA DEVILS

**INSTALLATION QUALIFICATION PROTOCOL CUM
REPORT
FOR
AUTOMATIC STICKER LABELING MACHINE**

PROTOCOL No.:

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

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)			
HEAD (PRODUCTION)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			



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2.0 OBJECTIVE:

- To provide documented evidence for the Installation Qualification of Automatic 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 Automatic Sticker Labeling machine (**Make:** "Maharshi" to be installed in 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 Automatic External 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, Pre Approval 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	Automatic Sticker Labeling machine
Equipment ID.	
Manufacturer's Name	Maharshi
Machine No.	
Model No.	
Capacity	150 CFM
Supplier's Name	Maharshi
Location of Installation	Packing Hall

6.0 SYSTEM DESCRIPTION:

This machine is designed to give High Output of Labeling on Bottle. (With automation) Model itself indicates the machine the machine identify as a vertical small / large container double side (front& back) labeling machine for standard rated speed up to 150 CPM depending upon the size of the labels & bottles.

This ,machine is compatible to handle various size of flat , rectangular, square , oval & round bottle & its labels back up to 150 mm label width (vertical height) with the help of minimum change parts & additional round bottle attachment (wrap around system) is applicable up to 70% of periphery of round bottle & not fully wrap around labeling. Online coded device can be install on this machine, which is used to print predetermined data such as mfg. date, retail price (MRP) and batch no. etc. on label.

This machine will supply with some additional automation feature i.e. touch screen HMI 'With Fatek' make PLC , Roll ending alarm system with machine stop facility, missing label detection with pneumatic rejection system & lower light show.



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7.0 PRE – QUALIFICATION REQUIREMENTS:

List of below documents which are available at the time of Installation Qualification.

S.No.	Document	Available (Yes/No)	Verified By (QA)
1.	Approved and executed design qualification document		
2.	Operating Instruction Manual		
3.	G.A Drawing		
4.	Wiring Diagram		
5.	Data Sheet of Variable Frequency Drive		
6.	Data Sheet of Sensors		
7.	Material Test Certificate		
8.	Motor & Gear Box Certificate		
9.	PLC back Up Willingness Certificate		

8.0 CRITICAL VARIABLE TO BE MET:-

8.1 MATERIAL OF CONSTRUCTION:-

S.No.	Name of Major Component	Observation		Checked by	Verified by
		Specified	Actual Compiles /Not Compiles		
1.	Main body & top plate	S.S. 304 Sq. pipe base frame & M. S. Top plate duly S.S. 304 Matt finished cladded.			
2.	Conveyor side channel	S.S. 304 Matt finished			
3.	Doors & covers	S.S. 304 Sheet matt finished			
4.	Product conveyor	82 mm., S.S. Slat chain			
5.	Dispenser body	Aluminum Die cast			



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S.No.	Name of Major Component	Observation		Checked by	Verified by
		Specified	Actual Compiles /Not Complies		
6.	Label release plate (Change Part)	S.S. 304, Size: 105 x175 mm. Ht. with 80 cut. & 1 ft. x175 mm. Ht. with 70 cut			
7.	Rejection box	S.S. 304 Sheet Matt finished with lock & key			

8.2 INSTALLATION QUALIFICATION CHECKLIST:

NAME OF COMPONENTS	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
Check the model	VSC/ VLC-DS-R-150 (Servo With Automation)		
Over all dimension	As per Dwg. No. MUA3 2018- 594-R1		
Check the labeling head	Label head with label dispenser having servo motor, Release plate and pillar bracket assy. For adjustment of labeling position on container.		
Check the label dispenser	Aluminium Die cast label dispenser assy. With servo motor, suitable up to 150 mm label Ht.		
Check the product conveyer	S.S. 304 Slant chain of 82 mm wide & length suitable to the machine integration		
Check the product guide	Adjustable S.S. 304 Flat side guide with brackets		
Check the product	Height adjustable top		



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NAME OF COMPONENTS	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
holding system	stabilizing belt Size: 900H x 25 flat (synchronized with conveyor) for hold oriented product during labeling process		
Check the product separating device	Black nylon wheel with ‘o’ ring type space creator with DC. Geared Motor Make: Dynaflux		
	Nylon twin feed- worm assay. (synchronized; change part as per product shape / size) Worm size: Ø60 x 500mm (1set : set supplied)		
Check the label pressing system (for round bottle) & (For flat/ oval/ square/ rectangular battle)	Wrap Around system system for round bottle with AC .Geared motor (applicable up to 70% of periphery of round bottle only) Belt size: 770x 50x 10 mm. Thickness with opposite label pressing sponge , Pad, size: 330 x 80/50 x 10 mm thickness		
	Spring loaded label pressing sponge pressure roller (change part as per label Ht.) for flat/ oval / square bottle. Roller size : Ø120 x 80mm. Ht. (change part)		



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NAME OF COMPONENTS	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
	Nylon brush on release plate for flat / oval / square bottle (change part as per label Ht. Size: 80mm. Ht. (1 set. Change part)		
	Doctor blade on release plate (change part) 80 mm. Ht. (1 set: change part)		
Check the labeling direction	Left to right (from operator side)		
Check the labeling speed	Up to 150 CPM (Depending upon label length & product shape & size		
Check the label width (vertical height) range	08 to 150 mm.		
Check the stop tolerance/ Labeling accuracy	=/-0.5 to 0.75 mm		
Check the label length range (Parameter)	20 to 500 mm		
Check the core diameter of label stock	76 mm		
Check The Max Label Stock (Roll) Diameter	Suitable for 300 mm. label roll diameter with suspended spring and automatic paper break with label roll ending alarm system. Suitable up to 300 mm roll diameter with P+ F make sensor for label roll ending		



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NAME OF COMPONENTS	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
	alarm system		
Check set of change parts received s per container / label size / shape & marked	Feed worm, sponge roller , release plate , nylon brush & D' blade in case of change of bottle / label height / size shape 1 set feed worm & 1 set of sponge roller, release plate, Nylon brush & D' blade supplied as a change part		

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8.3 ELECTRICAL COMPONENT & SPECIFICATION :

NAME OF COMPONENTS	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
Main drive AC Motor	(Inside the machine frame) Make: “ Megha “ HP: 1 HP Rating: 3 Phase AC Motor Serial no: 2019020157		
Main drive Gear Box	(Direct coupled with motor) Make: “ Rotomotive ” Ratio: 20:1 Type : Box – 050, 80 B5 Sr. no.: G01192036		
Check The Dispenser Motor	‘ Fuji ’ make , Alpha 5 smart small servo motor 2 nos,		
Check The Dispenser Drive	‘ Fuji ’ make , Alpha 5 smart small servo motor 2 nos, Sr. no. T86A058A0003F & T84A247A0034F		
Check The Operating & Control Panel	‘ Proface ’ make touch screen HMI with Maharshi make control panel with ‘Fatek’ make PLC Model: FBS-24 MCT2-D24(2 NOS) & FBS-2 DA , servo drive, VFD, MCB, Connector strip etc. Sr. no. FEM/FES 18642/18643 E-PROM NO. SRV-92		
Check the bottle counting system	In built in PLC display On screen of HMI Display on HMI screen		
Check the label sensor	‘ Leuze ’ make , slot Sensor , installed on modular rail (2 nos) Model: GS 63B /6D		



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NAME OF COMPONENTS	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
Check the product sensor	‘ Leuze ’ make, with reflector fitted on top stabilizing belt at labeling station near release plate Model: PRK 3B/6.22		
Check variable drive (VFD) for main motor	Make: Allen Bradley Power Flex – 4M, 1.0 hp. Sr. No.: W-18350213		
Check the space creator motor	Make: ‘ Dynaflux ’ 75 watt, 180 V DC, 35 RPM, DC. Geared motor. Speed pot given on operating panel.		
Check the space creator drive	Make: Multispan DC drive		
Check the motor for wrap around assay	Make: ‘ SPG ’ 90 watt AC. Geared Motor. Speed pot given on operating panel.		
Check variable drive (VFD) for wrap around assy	Make: Allen Bradley Power Flex – 4M, 0.25 hp. Sr. No.: W-18480159		
Other Information	Nameplate, caution & Utility Label Available on M/c		

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8.4 ADDITIONAL ATTACHMENT FOR AUTOMATION:

NAME OF COMPONENT	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING SIGN/ DATE)
Check the touch screen HMI for operation & programming	Make: ' Proface ' Color touch screen HMI of 7" screen for operating & programming. Model : PFXGP-4402WADW Sr. no. 138814B129519		
Check the PLC	Make: ' Fatek ' Model:FBS-24MCT2-D24 (2nos) & FBS-2DA		
Check the missing label detection with Pneumatic rejection system	Make: ' Panasonic ' 2 nos color dot sensor for missing label detection Model: LX101-Z Make: ' Leuze ' 2 nd Product & rejection Sensor, Model: HT3C/2N ' Festo ' make cylinder & solenoid valve for pneumatic rejection system, if label missing on bottle / container, it will rejected by pneumatic rejection system & will collect in S.S. Lockable rejection box.		
Check the label roll ending alarm system (in case of Std. roll diameter.)	' P+F (Pepperl = Fuchs) ' Make: NPN - No metal proxy sensor (02 Nos.) using on both dancing roll assay. For low label roll alarm & roll ending alarm system with machine stop facility & alarm will display on HMI screen.		
Check the tower light	Three color light stack (tower light with buzzer) fitted on outside of safety cabinet.		



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NAME OF COMPONENT	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING SIGN/ DATE)
Check the Emergency stop switch & Inching P. B.	Provide on S.S. box of HMI for stop the machine; In case of any emergency with inching P.B. for run the machine in inching mode.		

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8.5 WIRING INSTALLATION VERIFICATIONS:

S. No.	PROCEDURE STEP	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
1.	Inspect all wires connected to the terminal blocks	The wire numbers are identical to the numbers of the terminals on which they are landed.		
2.	Inspect all wires connected to the control components	The wire numbers are identical to The numbers specified on electrical schematics.		
3.	Inspect all the wires	The size of wire and the color of its insulation is proper		

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8.6 UTILITIES:

TEST	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
Power supply	220/240 V AC, 50 HZ Single phase stabilized, through 3 KVA CVT= Constant Voltage Transformer		
Air supply	4 to 6 kg/cm2 through FRL at Constant Pressure		

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8.7 ELECTRICAL SAFETY FEATURE:

CRITICAL VARIABLE S	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
Electrical connection	Connected properly		
Stabilized power supply	Protect from voltage fluctuation & surge		
Earthing	Proper earthing should be provided.		

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8.8 MACHINE SAFETY FEATURE:

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
No bottles	No bottle, No Labeling (Product Sensor Provided)		
Roll ending alarm system	Metal proxy sensor provided on both dancing roll assy. To check level of label roll, in case of low label or label roll ending Machine stop & display on HMI		
Missing label detection with rejection system	Check presence of label on bottle/ container In case bottle of without label , it will be rejected by pneumatic rejection system & will collected in S.S. lockable rejection		
Emergency stop switch	In Case Of Emergency Switch Press Manually Machine Will Stop.		

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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
- DQ : Design Qualification
- HP : Horse Power
- Hr : Hour
- Hz : Hertz
- IQ : Installation Qualification
- Kg : Kilogram
- mm : Millimeter
- HMI : Human Machine Interface
- MOC : Material of Construction
- 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)			
HEAD (PRODUCTION)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			