



PHARMA DEVILS

**INSTALLATION QUALIFICATION
PROTOCOL CUM REPORT
FOR
AUTOMATIC SELF ADHESIVE HORIZONTAL LABELING
MACHINE**

PROTOCOL No.:

**INSTALLATION QUALIFICATION
PROTOCOL CUM REPORT
FOR
AUTOMATIC SELF ADHESIVE
HORIZONTAL LABELLING MACHINE**

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



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PROTOCOL No.:

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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 Automatic Self Adhesive Horizontal 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 Self Adhesive Horizontal Labeling machine (**Make:**) 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 Ampoules Washing, Drying & Self Adhesive 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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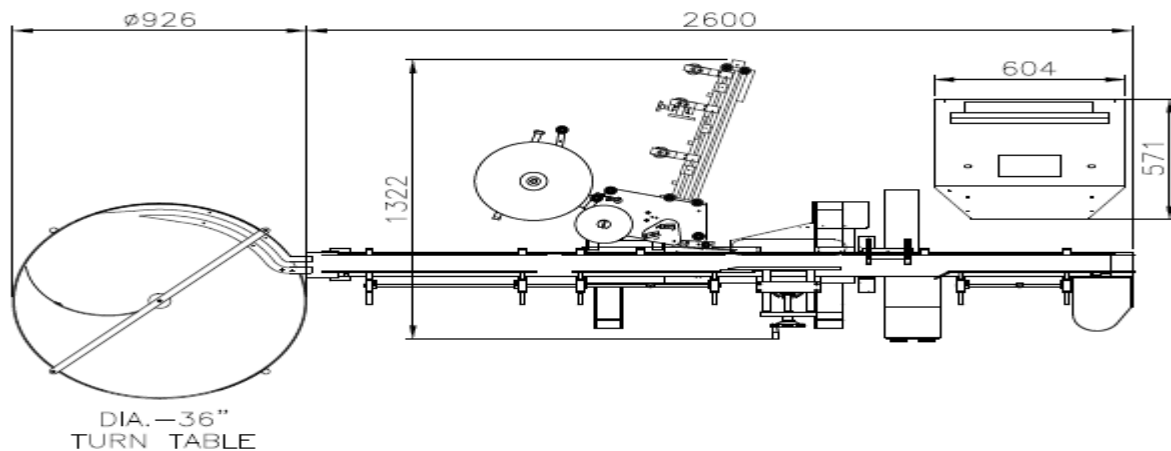
5.0 EQUIPMENT DETAILS:

Equipment Name	Automatic Self Adhesive Horizontal Labeling machine
Equipment ID.	
Manufacturer's Name	
Machine No.	
Model No.	
Capacity	200-250 label per Minute
Supplier's Name	Aseptic Technology inc.
Location of Installation	Packing Hall

6.0 SYSTEM 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 Self Adhesive Horizontal Labelling machine





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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.

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 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.		

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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 Technical Specification :

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
Equipment Name	TURN TABLE		
Make	Aseptic Technology Inc.		
Machine No	TT-103/01/17-18		
Capacity	36"		
MOTOR			
Make	BONFIGLIOLI		
Model	BN71B4		
RPM	1370RPM		
Volts	0.37 Kw		
Sr. No.		
GEAR BOX			
Make	BONFIGLIOLI		
Model	W63UFC1 100 P71B5 B3		
Ratio	100:1		
Sr. No.		
AC DRIVE			
Make	ALLEN-BRADLEY		
Model	22F-A2P5N103		
Specification	0.5HP, 1PH TO 3PH.		
Sr. No.		
MCB			
Make	HAGER		
Model	NCN206N		
Specification	C6		
ACTUATOR			
Make	SCHNEIDER		
Model	BLACK		

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CRITICAL VARIABLES	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
Specification	230VAC		
SPEED POT			
Make	...		
Model	10KΩ		
LABELING MACHINE			
Equipment Name	Automatic Self Adhesive Horizontal Labeling machine		
Make	Aseptic Technology Inc.		
Model	200-250 Label Per Minute		
Capacity	SL-501/02/17-18		
Sr. No.		
MOTOR (Main Conveyer)			
Make	BONFIGLIOLI		
Model	BN63B4		
RPM	1320RPM		
Volts	0.18 kw		
Sr. No.		
GEAR BOX (Main Conveyer)			
Make	BONFIGLIOLI		
Model	VF44F1 28 P63B5B3		
Ratio	28:1		
Sr. No.		
MOTOR (Pressing Belt)			
Make	BONFIGLIOLI		
Model	BN63B4		
RPM	320RPM		
Volts	0.18 kw		
Sr. No.		
GEAR BOX (pressing belt)			

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CRITICAL VARIABLES	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
Make	BONFIGLIOLI		
Model	VF30F1 7 P63B5B3		
Ratio	7:1		
Sr. No.		
MOTOR (feeder)			
Make	PANASONIC		
Model	M8MX25G4YGA		
RPM	1350RPM		
Watts	25 watts		
GEAR BOX (Feeder)			
Make	PANASONIC		
Model	MX8G30B		
Ratio	30:1		
MOTOR (pusher)			
Make	PANASONIC		
Model	M8MX25G4YGA		
RPM	1350RPM		
Watts	25 watts		
GEAR BOX (pusher)			
Make	PANASONIC		
Model	MX8G30B		
Ratio	30:1		
SERVO MOTOR			
Make	ALLEN BRADLEY		
Model	TL-A2540P-BJ32AA		
RPM	0.86KW		
Volts	5000RPM		
Sr. No.		
SERVO GEAR BOX			
Make	SHIMPO		



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CRITICAL VARIABLES	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
Model	VRSF-5C-19DB19		
Ratio	5:1		
AC DRIVE (main conveyor)			
Make	ALLEN BRADLEY		
Model	22F-D2P5N103		
Specification	1HP,3PH TO3PH		
Sr. No.		
AC DRIVE (pressing belt)			
Make	ALLEN BRADLEY		
Model	22F-A2P5N103		
Specification	0.5HP,1PH TO 3PH		
Sr. No.		
AC DRIVE (feeder)			
Make	ALLEN BRADLEY		
Model	22F-A2P5N103		
Specification	0.5HP,1PH TO 3PH		
Sr. No.		
AC DRIVE (pusher wheel)			
Make	ALLEN BRADLEY		
Model	22F-A2P5N103		
Specification	0.5HP,1PH TO 3PH		
Sr. No.		
SERVO DRIVE			
Make	ALLEN BRADLEY		
Model	2071-AP8		
Specification	800WATT.		
Sr. No.		
MODE BUS MODULE WITH 485			
Make	ALLEN BRADLEY		
Model	1763-NC01		



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CRITICAL VARIABLES	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
Specification	24VDC.		
SINK/SOURCE INPUT MODULE			
Make	ALLEN BRADLEY		
Model	1762-IQ8		
Specification	24VDC.		
Sr. No.	217M6HR5LQ		
OUTPUT MODULE			
Make	ALLEN BRADLEY		
Model	1762-OW8		
Specification	24VDC.		
Sr. No.	217M6HN3HI		
SMPS (PLC)			
Make	OMRON		
Model	S8VK-C12024		
Specification	24VDC, 5 AMP.		
SMPS (CAMERA)			
Make	OMRON		
Model	S8FS-C01512J		
Specification	12VDC, 1.3 AMP.		
RELAY CARD (8 CHANNEL)			
Make	PHOENIX		
Model	PC24D08-C0B		
Specification	24VDC		
SSR			
Make	UNISON		
Model	807 PMDD 100 08 01		
Specification	8AMP,		
SSR card			
Make	UNISON		
Model	704-B PMDD 200 05 00		
Specification	5AMP,		



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CRITICAL VARIABLES	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
Actuator	SCHNEIDER		
Emergency stop	SCHNEIDER		
1way box	TEKNIC		
Transformer	KAMO CARE		
Tower light	MENICS		
Air pressure switch	DANFOSS		
Sensor (label roll empty)	PANASONIC		
Sensor (no vial feeder stop)	PANASONIC		
Sensor (vial jam feeder stop)	PANASONIC		
Sensor (rejection bin full)	PANASONIC		
Sensor (fallen vial)	PANASONIC		
Sensor (ref. For rejection)	PANASONIC		
Sensor (no vial no label)	PANASONIC		
Sensor (vial present at rejection station)	PANASONIC		
Sensor (label gap)	LEUZE		
Sensor (printer trigger)	LEUZE		
Sensor (camera trigger)	LEUZE		
Sensor (vial at in feed Rej. Bin)	LEUZE		
Sensor (good vial counting)	BANNER		
Sensor (label detection 1&2)	LEUZE		
ENCODER (REJECTION)			
Make	BAUMER		
Model	EIL580-SC10.5LN.05000.A		



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CRITICAL VARIABLES	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
Specification	5000PPR		
Sr. No.	700001694507		
ENCODER (PRINTER)			
Make	PEPPERL + FUCHS		
Model	RVI 58N-032K5R66N-02500		
Specification	2500PPR		
Sr. No.	4000005/4600603		
CAMERA SYSTEM			
Make	IMAGING SOURCE		
Model	DMK 23G618		
Sr. No.	06710807		
PRINTER			
Make	HSAJET		
Model	TCUF		
Power	100-240VAC		
FRL	SMC		
Buzzer cum flasher	MIMIC		
Valve (rejection)	SMC		
Cylinder (rejection)	SMC		
COMPUTER SYSTEM			
MAKE	DELL		
TYPE	Microsoft windows 7 (32 Bit) professional License OS		
PLC			
Type	PLC with color HMI touch Screen		
Make	ALLEN BRADLEY		
Model	1766-L32BXB		




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CRITICAL VARIABLES	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
Sr. No.	48890633		
Volt	24VDC.		
HMI			
Make	ALLEN BRADLEY		
Model	2711P-T6C20D8		
Power Supply	24VDC.		
Sr. No	2711P-T6C20D8		
Other Feature			
Fault Indication System	Fault is indicated in HMI screen.		
Gear Box	Make Bonfiglioli gear box with motor for machine.		
User Friendly	Machine can be easily set for other size of Bottles.		
Vision System	Vision System for Barcode (1D/2D) / Pharma code / Printed matter like Batch no., Mfg. Date, Exp. Date and MRP (1.2mm Font). (All above mention matter to be check within 50mm x 50mm area).		

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CRITICAL VARIABLES	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
Printer	Ink Jet Printer (HSAJET) (Make : HP) (Window for Batch Printing in case of laminated / Glossy Labels) – For 8 Line Printing, Two head Printer.		
Optional Accessories	Pneumatic Container Rejection Device for Rejecting of Container if BAR CODE / PHARMA CODE / OCR / OCV is not present/wrong.		

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 Production
 Sign/Date:.....**

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 Quality Assurance
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 Manager QA
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8.3 PLC INPUT / OUTPUT SPECIFICATIONS:

INPUT	DESCRIPTION	OBSERVATION	OUTPUT	DESCRIPTION	OBSERVATION
X0	Gap sensor		Y0	Servo enable	
X1	No vial no label sensor		Y1	Rejection solenoid valve	
X2	Camera output		Y2	Servo start indexing	
X3	End of sequence		Y3	Spare	
X4	Encoder a channel		Y4	Servo drive fault reset	
X5	Encoder b channel		Y5	Main conveyor	
X6	Vial at infeed rejection bin sensor		Y6	Pressing belt drive	
X7	Vial jam feeder stop		Y7	Feeder drive	
X8	Power failure		Y8	Hooter	
X9	Spare		Y9	Index 0 select input	
X10	Vial present at rejection station		Y10	Spare	
X11	Air pressure switch		Y11	Inching index 2 select	
X12	Emergency stop		Y12	Spare	
X13	Rejection bin full		Y13	Red light	
X14	Label roll empty		Y14	Yellow light	
X15	Vial present at fallen vial sensor		Y15	Green light	
X16	Fallen vial sensor		Y16	Spare	
X17	Spare		Y17	Spare	
X18	Good vial counting sensor		Y18	Pusher wheel drive	
X19	Spare				
X20	Label detection sensor -1				
X21	Printer stop machine stop				
X22	No vial feeder stop sensor				
X23	Camera stop machine stop				
X24	Spare				
X25	Spare				
X26	Label detection sensor -2				
X27	Reference sensor for rejection				


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8.4 LOGICAL SECURITY SPECIFICATIONS:

S. No.	USER GROUP NAME	RIGHTS & AUTHORIZATION	Observation	OBSERVED BY (ENGINEERING) SIGN/DATE
1	Administrator	All rights		
2	Manager	Change in the process parameters, Operation, Recipe Creation, Deletion & edit, Print reports		
3	Supervisor	Operation, Variable parameters change, Print report, Recipe download, alarm ack.		
4	Maintenance	I/O list		
5	Operator	Operation, print reports alarm acknowledge		


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8.5 MATERIAL OF CONSTRUCTION:


COMPONENT	MOC	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
Machine frame structure	MS. Angle Duly Cladded with SS.304 Sheet		
External cladding	SS 304, (No Painted Surface)		
Star Wheel	Aluminum Casting		
In Feed & Out worm	Delrin		
In Feed Tray	SS 304		
Out Feed Tray	SS 304		

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8.6 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.		

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Inference:


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(Manager QA)
Sign/Date:.....

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8.7 Utility Verification List:

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
Electrical Supply	Voltage : 415 V (± 10 %) Phase : 3 Phase Frequency : 50 HZ		
Compressed Air	4 Kg/Cm ²		
Power Requirement	2.5 H.P		


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Manager QA
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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
- DQ : Design Qualification
- 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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PROTOCOL No.:

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)			