



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

PROTOCOL No.:

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FOR
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MACHINE**

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 prepare the Design Qualification on the basis of URS, Purchase Order and information given by Supplier.
- The purpose of Design qualification is to ensure that all Critical Aspects of Process/Product requirement, cGMP and Safety have been considered in designing the equipment and is properly documented.

3.0 SCOPE:

- The Scope of this Qualification Document is limited to the Design Qualification of Automatic Sticker labeling machine (**Make:** Maharashi), **Model** :..... (With automation) to be installed in ointment Packing Hall.
- The equipment shall be operated under the dust free environment and conditions as per the cGMP requirements.
- The drawings and P & IDs provided by Vendor shall be verified during Design Qualification.

4.0 PROJECT REQUIREMENTS:

- To confirm that safe delivery of the equipment from the supplier site. To ensure that no un-authorized or unrecorded design modification shall take place.
- If at any point in time, any change is desired in the mutually agreed design, change control procedure shall be followed and documented.



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5.0 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 & Compilation of Design Qualification Protocol cum Report. • Review of Design Qualification Protocol cum Report after Execution. • Co-ordination with Production and Engineering to carryout Design Qualification. • Monitoring of Design Qualification Activity. • Review of Design Qualification Protocol cum Report after Execution.
Production	<ul style="list-style-type: none"> • Review & Approval of Design Qualification Protocol cum Report. • Assist in the verification of Critical Process Parameters, Drawings as per the Specification. • Review of Design Qualification Protocol cum Report after Execution.
Quality Control	<ul style="list-style-type: none"> • Review of Design Qualification Protocol cum Report after Execution.
Engineering	<ul style="list-style-type: none"> • Review of Design Qualification Protocol cum Report. • Assist in the Preparation of the Protocol cum Report. • To co-ordinate and support the Activity. • To assist in Verification of Critical Process Parameter, Drawings as per the Specification i.e. <ul style="list-style-type: none"> ➤ GA Drawing. ➤ Specification of the sub-components/bought out items, their Make, Model, Quantity and backup records/ brochures. ➤ Details of utilities. ➤ Material of construction of all components. ➤ Brief Process Description. ➤ Safety Features and Alarms. • Review of Design Qualification Protocol cum Report after Execution.



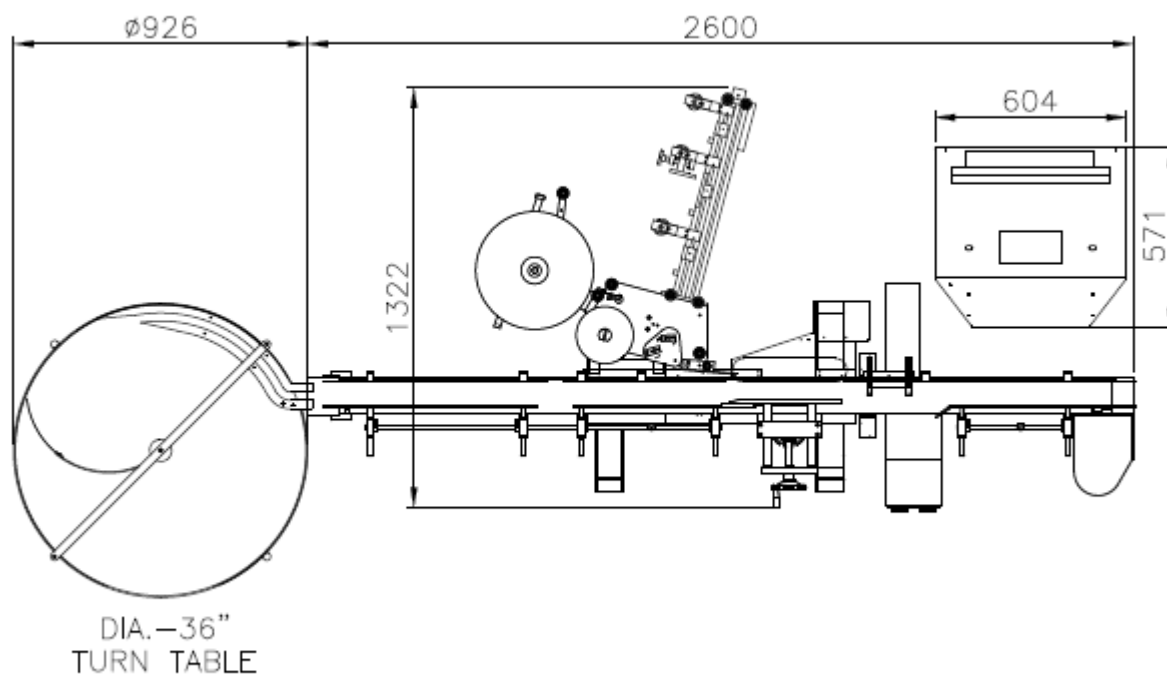
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6.0 BRIEF EQUIPMENT DESCRIPTION:

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 conveyer 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 sticker Labelling machine:





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7.0 EQUIPMENT SPECIFICATION:

Equipment Specifications are based on User Requirement Specification prepared for the manufacturer of equipment ensures complies with User Requirement Specification.

8.0 CRITICAL VARIABLES TO BE MET:

8.1 PROCESS/PRODUCT PARAMETERS:

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
Application: Automatic sticker Labeling machine is designed to Label the Round Objects for different size with over printing in single straight line operation	Should be able to Automatic sticker (Vertical) labeling machine	Process Requirement
Working: <ul style="list-style-type: none">• Machine is suitable for Ø08 mm to Ø150 mm (Vertical Height) & 10mm height to 500mm (Length range).• Machine is suitable for 5 ml to 100 ml Bottle (Ø17mm to Ø65mm) Without Change Parts.	Automatic Sticker labeling machine able to Perform.	Process Requirement
Electrical Control Panel	The system should have Electrical Control Panel.	Design Requirement



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8.2 UTILITY REQUIREMENTS/LOCATION SUITABILITY:

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
Electrical Supply	Voltage : 220/240 V AC Phase : 3 Phase Frequency : 50 HZ(220/240) V AC	Process Requirement
Compressed Air	4 to 6.0 Kg/Cm ²	Process Requirement
Power Requirement	2.5 H.P	Process Requirement

8.3 TECHNICAL SPECIFICATIONS / KEY DESIGN FEATURES:

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
Labeling machine		
Equipment Name	Automatic Sticker Labeling machine	Design Requirement
Make	Servo with automation	Design Requirement
Capacity	Up to 15 CPM	Design Requirement
Label Dispenser	Up to 150 mm	Design Requirement
Equipment Sr. No.	18282	Design Requirement
Equipment model	VSC/VLC-DS-R-150	Design Requirement
Label width (vertical height) range	08 to 150 mm	Design Requirement
Product conveyor	82 mm. (SS Slat chain conveyor of 2500 mm length Approx...	Design Requirement
Label length range	10 to 500 mm	Design Requirement
Stop tolerance / labeling accuracy	+/- 0.5 to 0.75 mm.	Design Requirement
Max label stock (roll) dia.	300 mm.	
Core dia. Of label stock	76 mm	Design Requirement
Dancing roll assay	Suitable for 300 mm , label roll dia . with suspended spring and automatic paper break roll ending alarm system.	Design Requirement



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CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
Product separating device	Nylon twin feed –worn assay (Change part as per bottle/Container size)	Design Requirement
Product holding system	Stabilizing belt hold the product during labeling process	Design Requirement
Label pressing system (for round bottles) & for flat bottles	Wrap around system for round bottle with AC (applicable up to 70% of periphery of round bottle only)	Design Requirement
	Change part for flat bottle	Design Requirement

Parameter	Make	Design Requirement
Motor (main Drive)	Megha	Design Requirement
Main drive Gear box	Rotomotive	Design Requirement
Variable frequency drive (VFD) for main motor	Allen bradley	Design Requirement
Variable frequency drive (VFD) for wrap around assay	Allen bradley	Design Requirement
Label sensor	Luenze, make with sensor	Design Requirement
Product sensor	Leunze , make with reflector	Design Requirement
PLC	fatek	

Other Feature

Touch screen HMI For Operating & Programming	Color touch sreen HMI of 7” screen for operating & programming	Design Requirement
Label roll ending alarm system	P & F, NPN –NO metal proxy sensor using on dancing roll assay . for Low level roll alarm & label roll ending alarm system with machine stop facility & alarm will display on HMI screen.	Design Requirement
Missing label detection with pneumatic rejection system	Panasonic make , 2 nos . color dot sensor for missing label detection & leuze make 2 nd product & rejection sensor ,	Design Requirement



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CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
Tower light	Three color light stack (tower light with buzzer fitted on outside of safety cabinet.	Design Requirement
Emergency stop switch & inching P. B.	S.S box of HMI for stop the machine ; in case of any emergency with inching P.B. for run the machine in inching	Design Requirement

8.4 Alarm system

S.No.	Alarm test	Activity	Action
1.	Roll ending alarm system	Metal proxy sensor provided on both dancing roll assay to check level of label roll, in case of low level or label roll ending	Machine stop & alarm will display on screen of HMI.
2.	Missing label detection with rejection system	Check presence of label on bottle/ container	In case of bottle without label, it will be rejected by pneumatic rejection rejection system and collect in rejection box/ tray.
3.	Emergency stop	In case of emergency switch manually operated by operator	Machine will stop.

Reference: (1) Specifications and Requirements as specified in P.O. and URS.
(2) Operating and service manual

**Verified By
(Quality Assurance)
Sign/Date:.....**

9.0 DOCUMENTS TO BE ATTACHED:

- Technical details for Equipment Requirement with Engineering Drawings.
- Approved Design and Specifications.
- Any other relevant documents.



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

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11.0 ANY CHANGES MADE AGAINST FORMALLY AGREED PARAMETERS:

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12.0 RECOMMENDATION:

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13.0 ABBREVIATIONS:

cGEP	:	Current Good Engineering Practice
cGMP	:	Current Good Manufacturing Practice
CI.	:	Cast Iron
DQ	:	Design Qualification
HP	:	Horse Power
Hr	:	Hour
Hz	:	Hertz
Kg	:	Kilogram
KW	:	Kilo Watt
MCB	:	Miniature circuit breaker
mm	:	Millimeter
MMI	:	Man Machine Interface
MOC	:	Material of Construction
MS	:	Mild Steel
No.	:	Number
P & ID	:	Piping and Instrumentation Diagram
PO	:	Purchase Order
RPM	:	Revolution per minute
SS	:	Stainless steel
URS	:	User requirement specification
VFD	:	Variable Frequency Drive



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14.0 REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (ENGINEERING)			

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY CONTROL)			

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			