



**DESIGN QUALIFICATION
PROTOCOL CUM REPORT
FOR
STICKER LABELING MACHINE**

| | |
|-------------------------------|------------|
| DATE OF QUALIFICATION | |
| SUPERSEDE PROTOCOL No. | NIL |



DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR STICKER LABELING MACHINE

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DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR STICKER LABELING MACHINE

1.0 PROTOCOL PRE – APPROVAL:

INITIATED BY:

| DESIGNATION | NAME | SIGNATURE | DATE |
|--|------|-----------|------|
| OFFICER/EXECUTIVE (QUALITY ASSURANCE) | | | |

REVIEWED BY:

| DESIGNATION | NAME | SIGNATURE | DATE |
|-------------------------------|------|-----------|------|
| HEAD (PRODUCTION) | | | |
| HEAD (ENGINEERING) | | | |

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 **Sticker Labeling Machine (Make: M/s)** to be installed in Packing Hall.
- The equipment shall be operated under the dust free environment and conditions as per the cGMP requirements.
- The drawings and P & ID's 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 and 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.• 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 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. |
| 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.➤ Identification of components for calibration.➤ 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:

6.1 Purpose

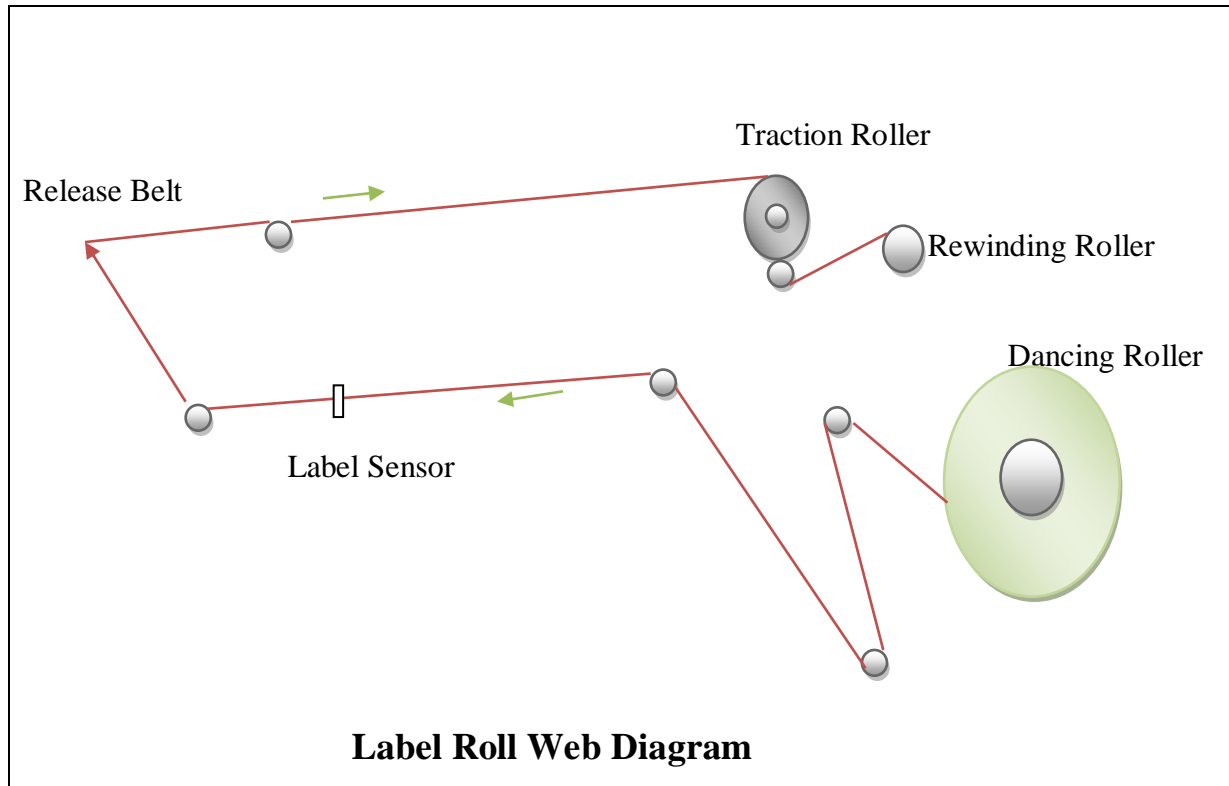
Automatic Sticker Labeling Machine Model: VSC/VLC-200 (With Automation) used to Apply Sticker labels up to 95 mm Label Ht. on vertical Small / Round Container of different diameter without any change parts. For the Standard Rated Speed up to 200 CPM depending upon the size of the Labels & Bottles. The machine Supplied with On-line Coding Device ('Domino' Inkjet Printer), which is used to print predetermined data as Mfg. Date, Retail Price, and Batch No. etc. This machine also Supplied with some additional automation feature; like Touch screen HMI with Fatek PLC, Missing Label detection with Pneumatic Rejection System & Emergency stop switch etc as per client's requirement.

6.2 Design Consideration:

The Automatic Sticker Labelling machine, Model: (With Automation) is rugged, versatile and engineered for reliability and enhances Operation Efficiency, which confirms to High Standard Engineering Design / Workmanship, which comply with all currently applicable Statutory Regulations, prevailing Safety Rules /Code Engineer Standard and Good Manufacturing Practices (GMP). The equipment is designed by the renowned technocrats from the most advanced electronic & mechanical pool of knowledge available in the Modern Age This equipment has a Robust Construction. It is compatible to work in any condition .The equipment can be amended as per the requirement of input as it is Tailor made Machine. The machine is designed in such way that a single machine can handle different size of Round Containers & its Labels without Change Parts. Operator requires Minimum Changeover time from one size of Container or Label to another. Touch Screen HMI will display continuous information of the Total Number of Containers Labeled & Speed of Machine.



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6.3 Working:

FIXONAME Model-VSC/VLC-200 (with Automation) having Vari-speed S.S. Slat Chain conveyor of Approx. 2 Mtr. Length. There is Space creator provided for create space between two containers which travels to applying station i.e. at release plate before wrap around device, a product sensor senses the presence of container at application station and **gives a signal to dispenser motors for dispensing a label.** At the same time a label sensor mounted on modular rail senses the gap between two labels, indicates a completion of one label dispensing for the container and gives signal to stop the dispenser motor and at the same time forward the signal to On-line Coder (**'Domino' Inkjet Printer**), which is used to print necessary details. On-line Coder fixed on modular rail has adjustments in both the directions to adjust the overprinting as per label layout. Now at application station, label is picked up by container due to adhesiveness, goes further to wrap around device, **where in container is rotated to wrap around the label on body and further goes to the discharge end.** There is also provision of Missing Label Detection & Pneumatic Rejection system. If any container without label, sensor will gives signal to PLC and container will rejected by Pneumatic rejection system.



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7.0 EQUIPMENT SPECIFICATION:

Equipment Specifications are based on User Requirement Specification prepared. 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: 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 Label the Stickers. | Process Requirement |
| Working: The machine product sensor sense the presence of container and dispense the label | Dispensing of label should be immediately done as product container reaches, and should stop as there is no container | Process Requirement |
| Electrical Control Panel | The system should have Electrical Control Panel. | Design Requirement |

8.2 UTILITY REQUIREMENTS/LOCATION SUITABILITY:

| Critical variables | Acceptance criteria | Reference |
|--|--|---------------------|
| Electrical Supply | Voltage : 220 V Phase : Single Phase Frequency : 50 HZ | Process Requirement |
| Air Supply (Optional For Pneumatic Rejection System) | 4 To 6 Kgs/Cm ² Thro' FRL at Constant Pressure. | Process Requirement |



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8.3 TECHNICAL SPECIFICATIONS/KEY DESIGN FEATURES:

| CRITICAL VARIABLES | ACCEPTANCE CRITERIA | REFERENCE |
|-------------------------------|--|--------------------|
| Make | Maharshi Udyog | Design Requirement |
| Model | FIXONAME-VSC/VLC-200 (Servo With Automation) | Design Requirement |
| Sr. | 15176 | Design Requirement |
| Dimensions | L 850 mm x W 1000 mm x H 880 mm | Design Requirement |
| Label Speed | Up to 200 CPM | Design Requirement |
| Design | Left → Right | Design Requirement |
| Label Dispenser | New Alu-115 mm Hight | Design Requirement |
| Dispenser motor | Make : Fuji Type : Small Servo Moter | Design Requirement |
| Label Dispensing Speed | 02- 60 Mtr/Min | Design Requirement |
| Max . Pre-Dispensing of Label | 25 mm | Design Requirement |
| Label Widh (height) Range | 08 To 95 mm | Design Requirement |
| Label Length Range | 10 to 300 mm | Design Requirement |
| Stop Tolerance | +/- 0.5 to 0.75 mm | Design Requirement |
| Label Stock Roll Dia | 300 mm | Design Requirement |
| Core Dia of Label Stock | 76 mm | Design Requirement |
| Dancing Roll Assy Dia | 300 mm | Design Requirement |
| Control Panel | | |
| HMI | Make : Proface | Design Requirement |
| PLC | Make: Fetek | Design Requirement |
| Main Drive Unit | | |
| Product Separating Device | Make : Rotomag Type : Alu. Casted Double 'O' Ring Type Space | Design Requirement |
| Label Pressing System | Type : Wrap Around System | Design Requirement |
| Main Drive Motor | Make : Megha HP : 1.0 HP Volt : 220 V Phase : 3 phase AC | Design Requirement |



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| CRITICAL VARIABLES | ACCEPTANCE CRITERIA | REFERENCE |
|-------------------------|---|--------------------|
| Gear Box | Make : Rotomotive Size : Suitable Size | Design Requirement |
| VFD for Main Motor | Make : Allen Bradley HP : 1.0 HP | Design Requirement |
| Drive for Space Creator | Make : Multispam | Design Requirement |
| Product sensor | Make : Leuze | Design Requirement |
| Label Sensor | Make : Leuze, for Transparent label | Design Requirement |
| Printing Trigger Sensor | XV1123199 | |
| On Line Printer | Make : Domino | |



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8.4 MATERIAL OF CONSTRUCTION:

The basic body of the machine is built by the S.S. Squire Pipe frame Structure except M.S. Top Plate duly lined with S.S. Matt finished sheet. Besides Stainless Steel cladding or hard chrome plating of all exposed parts to ensure long life and resistance against corrosion. The Equipment is suitable for wrap around Labelling on round bottles/containers. Basic machine is fitted with universal parts, where in, no change parts are required in case of change of container or label size & additionally On-Line Coder (Optional), Touch screen HMI with Fatek PLC, Missing Label detection with Pneumatic Rejection System & Emergency stop switch etc... as per client requirements

| S.No. | PARTS NAME | MATERIAL OF CONSTRUCTION |
|---|-----------------------------|--|
| Main Body & Product Conveyor | | |
| 1. | Main Body & Top plate | SS304 |
| 2. | Conveyer Side Chanell | 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 |
| Dispenser Assy | | |
| 10. | Dispenser Body | Aluminum Die Cast |
| 11. | Traction Roller | Aluminum Duly Coated of 115 mm Ht. |
| 12. | Pressure Roller | Aluminum Rubber coated with SS shaft |
| 13. | Rewinding Roller | Aluminum |
| 14. | Label Guide Roller | SS304 |
| 15. | Label Web Guide Ring | Nylon |
| 16. | Label Pressing Spring Patti | SS Spring Steel |
| 17. | Dispenser other part | Aluminum |
| 18. | Dancing Roll Assy | SS Shaft Roller & Aluminum Coated Disk |
| 19. | Modular Rail | Aluminum or MS duly Powder Coated |
| 20. | Rail Bracket | CI duly Chrome Plated |
| 21. | Sensor Holding Clamp | SS Duly Powder Coated |



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| | | |
|----------------------------------|---------------------------|---|
| 22. | Label Release Plate | SS304 |
| Product Separating Device | | |
| 23. | Space Creator | Aluminum Coated |
| Label Pressing System | | |
| 24. | Wrap- Around Massage Belt | Sponge Rubber Belt |
| 25. | Top & Bottom Plate | Aluminum with SS Sheet cover |
| 26. | Label Pressing plate | Aluminum lined with Sponge rubber & Covered with SS Sheet |

8.5 SAFETY:

| CRITICAL VARIABLES | ACCEPTANCE CRITERIA | REFERENCE |
|---------------------------|---|--------------------|
| Joints | Welding of joints without any welding burrs. | Safety Requirement |
| Metal Parts | All the metal parts should be properly grounded without any sharp Edges. | Safety Requirement |
| Leveling and Balancing | Equipment should be properly balanced & leveled. | Safety Requirement |
| Earthing | Proper Earthing should be provided. | Safety Requirement |
| Sensor | Sticker Sensor sense the presence of container for labeling. Label Sensor sense the presence of upcoming label for labeling. | Safety Requirement |

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



DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR STICKER LABELING MACHINE

13.0 ABBREVIATIONS:

| | | |
|--------|---|-------------------------------------|
| cGEP | : | Current Good Engineering Practice |
| cGMP | : | Current Good Manufacturing Practice |
| CI. | : | Cast Iron |
| FRL | : | Filter Regulator Lubrication |
| HP | : | Horse Power |
| Hr | : | Hour |
| IB | : | Injection Block |
| Kg | : | Kilogram |
| MCB | : | Miniature circuit breaker |
| mm | : | Millimeter |
| MMI | : | Man Machine Interface |
| MOC | : | Material of Construction |
| MS | : | Mild Steel |
| P & ID | : | Piping and Instrumentation Diagram |
| PO | : | Purchase Order |
| SLM | : | Sticker Labeling Machine |
| SS | : | Stainless steel |
| URS | : | User requirement specification |



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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 ASSURANCE) | | | |