



**PHARMA DEVILS**

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

**PROTOCOL No.:**

**DESIGN QUALIFICATION  
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**DATE OF QUALIFICATION**

**SUPERSEDE PROTOCOL No.**

**NIL**



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**1.0 PROTOCOL PRE – APPROVAL:**

**PREPARED BY:**

<b>DESIGNATION</b>	<b>NAME</b>	<b>SIGNATURE</b>	<b>DATE</b>
<b>OFFICER/EXECUTIVE (QUALITY ASSURANCE)</b>			

**REVIEWED BY:**

<b>DESIGNATION</b>	<b>NAME</b>	<b>SIGNATURE</b>	<b>DATE</b>
<b>OPERATING MANAGER (QUALITY ASSURANCE)</b>			
<b>HEAD (ENGINEERING)</b>			

**APPROVED BY:**

<b>DESIGNATION</b>	<b>NAME</b>	<b>SIGNATURE</b>	<b>DATE</b>
<b>HEAD (PRODUCTION)</b>			



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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 & IDs provided by Vendor shall be verified during Design Qualification.



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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:

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



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**5.0 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.

**6.0 BRIEF PROCESS DESCRIPTION:**

**6.1 Purpose**

Automatic Sticker Labeling Machine Model: HLC-100 itself Indicate the Machine Identified as a Horizontal Cassette Labeling for Standard Rated Speed up to 100 CPM Depending upon the size of Label/ Cassette & Operator Efficiency .the Machine is Compatible to handle Various sizes of Cassette & its Label W/O. change part up to 150 mm label width (height).

**6.2 Design Consideration:**

The Automatic Sticker Labeling machine, Model: HLC-100 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 Cassette Containers & its Labels without Change Parts. Operator requires Minimum Changeover time from one size of Cassette Label to another.

As in Built DIGITAL ELECTRONIC COUNTER provide continuous information of the Total number of Respouless Cassette labeled & Speed of machine.



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### **6.3 Working:**

Model-HLC-100 having Vari-speed Green Endless Belt Conveyor on which Respoules Cassettes are loaded in horizontal position which will carry to an applying station i.e. below release plate, a product sensor sense the presence of Respoules Cassette at applying 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 applying 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.

### **6.4 PLC Features**

Dedicated programmer (PLC) has an in built counter, On-line speed & self-diagnostic LEDs for any fault indication like Power Supply, Label & Product Sensor Signal, and Printer Signal Etc. There is a one-touch operation to increase or decrease the speed of machine.

### **6.5 Testing**

The equipment will be tested continuously for 24 hours at our Plant itself before dispatch. All other Mechanical, Electrical & Electronic Components will be checked by the respective field experts before it will be taken for use. All Fabricated and mechanical parts will also thoroughly checked under strict quality control of our well-equipped QC Department. Quality Checking will include Size, Thickness, and Material of Construction & other unavoidable characteristics of the Spare Parts.

### **6.5 Mounting**

In our equipment, the special attention would not be required for Mounting such as underground earthing (or) any pre-provision of foundation at the actual Site of Equipment Operation. The whole Machine will be **Mounted on Four Adjustable Legs**, which could be adjusted to match the Conveyor Working Height of other On-line connected Machine. The equipment will be free from vibration.

The Equipment will be stood on a fixed pallet until it has to be shifted / adjusted by the Man Power / Pallet truck.



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## **6.6 Paneling**

### **6.6.1 Paneling**

The Main PLC Panel Box is mounted on the Right Hand Side of the Machine from the Operator Side and the Switch Box is in the main panel fixed on Top Plate of the machine. It is easy to Maintain and it will safeguard the Electrical related Problems. The Panel Board is build from SS 304 Matt finished sheet. One Emergency Stop button (Optional) will also be provided on the Main Panel to On or Off the Machine during the Emergency period and it will also save the valuable time of operator during the daily on and off process. The Panel Box consisting of PLC, Mains switch, & Emergency Stop if reqd.

### **6.6.2 Automation System**

HLC-100 is fully Automatic Labelling machine. Machine is equipped with “No Cassette, No Label” Device, Electronic Sensor which sense the Respoules Cassette and allow to release One Label at a time automatically. If there is No Respoules Cassette then not a Single Label will come, Coding (optional) is also automatic which print the data if label is released, otherwise not. There is an in-built counter provided along with speed indication in PLC. Self-diagnostic LEDS are provided on front panel to check function / problems; Dispenser is operated at low voltage.

## **7.0 EQUIPMENT SPECIFICATION:**

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





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**8.0 CRITICAL VARIABLES TO BE MET:**

**8.1 PROCESS/PRODUCT PARAMETERS:**

<b>Critical variables</b>	<b>Acceptance criteria</b>	<b>Reference</b>
<b>Application:</b> 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
<b>Working:</b> 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
<b>Electrical Control Panel</b>	The system should have Electrical Control Panel.	Design Requirement

**8.2 UTILITY REQUIREMENTS/LOCATION SUITABILITY:**

<b>Critical variables</b>	<b>Acceptance criteria</b>	<b>Reference</b>
<b>Electrical Supply</b>	Voltage : 220/240 V AC Phase : Single Phase ( Stabilized, Through 1 KVA CVT = Constant Voltage Transformer ) Frequency : 50 HZ	Process Requirement



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**8.3 TECHNICAL SPECIFICATIONS/KEY DESIGN FEATURES:**

<b>CRITICAL VARIABLES</b>	<b>ACCEPTANCE CRITERIA</b>	<b>REFERENCE</b>
Make	Maharshi Udyog	Design Requirement
Model	HLC-100 (Servo)	Design Requirement
Sr.	15241	Design Requirement
Over all Dimensions ( L x W x H)	2000 mm x 610 mm x 2000 mm	Design Requirement
Label Speed	Up to 100 CPM ( Depending upon Label /Product Size & Operator Specification)	Design Requirement
Product Conveyor operating Height	900 mm (+ /- 50 Adjustable)	Design Requirement
Case Dimension	2200 mm x 800 mm x 2200 mm( Approx)	Design Requirement
Product ,FFS Respouless Cassette Block	Different size of Respouless cassette block of 3 & 5 Nos. Respouless of 5 to 30 ml.	Process Requirement
Design	Left → Right	Design Requirement
Label Dispenser	New Alu-175 mm Hight	Design Requirement
Dispenser motor	Make : Fuji Type : Small Servo Moter Sr.No. : GYB401D6-RC2	Design Requirement
Dispenser Drive	Make : Fuji Sr.No. : 5XBM51A0001	Design Requirement
Product Conveyer	100 mm, wide Green endless belt Conveyer, 2000 mm long.	Design Requirement
Label Width (height ) Range	08 To 150 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 ( Medium- Unbinder Dia)	300 mm with Suspended Spring and Automatic Paper break	Design Requirement



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<b>CRITICAL VARIABLES</b>	<b>ACCEPTANCE CRITERIA</b>	<b>REFERENCE</b>
Micro Processor base operating Controlled Panel	Feathure Touch Keypad operated Micro Processor Control Panel with Servo Motor & Drive.	Design Requirement
Label Pressing System	Sponge Pressure Roller Size : 85 mm Height Size : Ø 130 x 75 mm Height	Design Requirement
	Type: Grove & Nylon Brush on Release Plate Size : 85 mm Height	
Main Drive AC Motor	Make : Megha HP : 0.5 HP Phase : 3 Phase 220 V AC. Input : 220 V AC	Design Requirement
Main Drive Gear Box	Make : Rotomotive Sr.No. G04161572 Size : Suitable Size Ratio : 20 :1 Type : Box-50 71B5	Design Requirement
VFD for Main Motor	Make : Allen Bradly HP : 0.5 HP Type : AB Power Flex-4M Sr.No. : W-15500061	Design Requirement
Product sensor	Make : Leuze, Type : Slot Sensor on Modular Rail Model: GS63 B/6D	Design Requirement
Label Sensor	Make : Leuze, Type : with Reflector Volt :10 30 VC Model : PRK 3B/6.22SB	Design Requirement

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



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**8.4 MATERIAL OF CONSTRUCTION:**

<b>S.No.</b>	<b>PARTS NAME</b>	<b>MATERIAL OF CONSTRUCTION</b>
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.	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	SS Die cast or CI duly Chrome Plated
21.	Label Sensor Holding Clamp	Aluminum duly Powder coated or SS
22.	Label Release Plate	SS304
23.	Label Pressing system	Sponge Pressure Roller (Groove Type ) and Nylon Brush

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



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**8.5 SAFETY:**

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

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







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**13.0 ABBREVIATIONS:**

cGEP	:	Current Good Engineering Practice
cGMP	:	Current Good Manufacturing Practice
CI.	:	Cast Iron
CPM	:	Cassette Per Minute
HP	:	Horse Power
Hr	:	Hour
Kg	:	Kilogram
MCB	:	Miniature circuit breaker
mm	:	Millimeter
MOC	:	Material of Construction
SS	:	Stainless 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:**

<b>DESIGNATION</b>	<b>NAME</b>	<b>SIGNATURE</b>	<b>DATE</b>
<b>HEAD (ENGINEERING)</b>			

<b>DESIGNATION</b>	<b>NAME</b>	<b>SIGNATURE</b>	<b>DATE</b>
<b>HEAD (QUALITY CONTROL)</b>			

<b>DESIGNATION</b>	<b>NAME</b>	<b>SIGNATURE</b>	<b>DATE</b>
<b>HEAD (PRODUCTION)</b>			

<b>DESIGNATION</b>	<b>NAME</b>	<b>SIGNATURE</b>	<b>DATE</b>
<b>HEAD (QUALITY ASSURANCE)</b>			