DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR LABEL COUNTER MACHINE

DATE OF QUALIFICATION	
SUPERSEDE PROTOCOL No.	**NIL**

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

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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 (WAREHOUSE)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			

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2.0 OBJECTIVE:

- To prepare the Design Qualification document for Label Counter Machine on basis of Design and Specification and information given by Supplier.
- To ensure that all Critical Aspects of Process/Product Requirement, cGMP and Safety have been considered in designing the equipment and are properly documented.

3.0 SCOPE:

- The Scope of this Qualification Document is limited to the Design Qualification of Label Counter Machine to be installed at Receiving Area.
- The equipment shall be operated under the dust free environment and conditions as per the cGMP requirements.

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	• Preparation, Review, Compilation and approval of the Design Qualification Protocol cum Report. • Assist in the verification of Critical Process Parameters as per the Specification. • Review of Qualification Protocol cum Report after Execution. • Co-ordination with Warehouse and Engineering to carryout Design Qualification. • Monitoring of Design Qualification Activity.
Warehouse	• Review of the Design Qualification Protocol cum Report. • Assist in the verification of Critical Process Parameters as per the Specification. • Review of Qualification Protocol cum Report after Execution.
Engineering	• Review of the Design Qualification Protocol cum Report. • To co-ordinate and support the Activity. • To assist in Verification of Critical Process Parameter as per the Specification i.e. • Review of Design Qualification Protocol Cum Report after Execution.

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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 EQUIPMENT DESCRIPTION:

The equipment is an automated means to count label with help of gap sensor it suitable for different size of labels.

Fix the label roll on primary winding plate follow steps by show in schematic diagram. Once the machine is started, the labels are passed throughout gap sensor and rewinding in secondary winding plate.

7.0 EQUIPMENT SPECIFICATION:

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

TABEL TOP MODEL TYPE LABEL COUNTER

- cGMP Model
- SS-304 Constriction.
- Inbuilt Primary winding plate.(Tray)
- In Built A.C. Frequency Drive for Speed Control
- PLC & HMI Touch Screen for Operating Controls
- Suitable for 150 labels per minute
- Output: Up to 150 Labels per minute
  (Dispensing Upon Labels Size)

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8.0 CRITICAL VARIABLES TO BE MET:

8.1 PROCESS/PRODUCT PARAMETERS :

Critical Variables	Acceptance Criteria	Reference
Application: Label Counter Machine is capable to ensure that only authorized person shall access the critical area	Label Counter Machine should meet the requirement to ensure that only authorized person access the critical area	Process Requirement
Working: Working of Label Counter Machine	Machine identified the personnel through the Label Counting identification & Show the reading on PLC Screen and Operate the machine of ON/Off Button.	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
Utility connections should be available as per the manufacturer's specification.		
Motor	0.25 HP , 220 V , AC ,1 Phase	Process Requirement
Electricity	0.5 HP , 220 V , AC ,1 Phase	Process Requirement
Room Condition	Should be able to meet the requirement of clean environment.	cGMP Requirement

8.3 TECHNICAL SPECIFICATIONS/KEY DESIGN FEATURES:

S.No.	Parameters	Acceptance criteria	Reference
1.	Model No.	HMLC-150	Design Requirement
2.	SR.No.	HMLC-150/20-21	Design Requirement
3.	Overall Dimension	750 mm x 500 mm x1200 mm	Design Requirement
4.	Weight (Approx.)	Net Weight 150 Kgs. Gross Weight 200 Kgs.	Design Requirement
5.	Input Specification	1500 mm height and label roll Diameter - 300 mm	Design Requirement
6.	Output	Up to 150 Labels per minute	Design Requirement
7.	Make	H.M. Industries	Design Requirement
8.	Primary winding Plate	Made from Acrylic sheet	Design Requirement

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S.No.	Parameters	Acceptance criteria	Reference
		• To fix label roll for the operating purpose	
9.	Control Panel	• Made out from SS-304 Sheet • Placed inside the machine • A/C Frequency Drive • Gap Sensor • Main/Selector	Design Requirement
10.	Operator Interface	• Made from SS-304 • Machine Start/Stop Selector Switch • HMI-4.3" Delta Make • Emergency Stop	Design Requirement
LIST OF BROUGHT OUT ITEMS			
11.	Machine Motor	Bonvario make	Design Requirement
12.	Machine Gearbox	Bonvario make	Design Requirement
13.	Variable Frequency Drive Machine	Delta	Design Requirement
14.	Gap Sensor	Luize	Design Requirement
15.	Selector Switch	Salzer	Design Requirement
16.	Emergency Button	Salzer	Design Requirement
17.	PLC	Delta	Design Requirement
18.	HMI	Delta	Design Requirement

8.4 Material of Contraction:

S.No.	Parameters	Acceptance criteria	Reference
1.	Machine Body	Machine body made from SS-304 Sheet	Design Requirement
2.	Machine Top plate	Mild Steel cladded with SS-304 Sheet	Design Requirement
3.	Label roll plates	Made from acrylic Sheet	Design Requirement
4.	Finish	Matt finishing	Design Requirement

8.5 SAFETY:

Critical Variables	Acceptance Criteria	Reference
Leveling and balancing	Label Counter Machine should be properly balanced & leveled	Safety Requirement
Electrical wiring	Electrical wiring should be proper	Safety Requirement

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8.6 VENDOR SELECTION:

Critical variables	Acceptance criteria	Reference
Selection of Vendor for supplying the Label Counter Machine	Selection of Vendor is done on the basis of review of vendor. Criteria for review should include vendor background (general/financial), technical knowhow, quality standards, inspection of site, costing, feedback from market (customers already using the equipment)	Process Requirement

Checked By
Engineering
Sign/Date: ……

Verified By
Quality Assurance
Sign/Date: ……

Inference:

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Reviewed By
Manager QA
Sign/Date: ……..

9.0 DOCUMENTS TO BE ATTACHED:

- Any other relevant documents.

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:

cGMP	:	Current Good Manufacturing Practice
DQ	:	Design Qualification
Ltd.	:	Limited
mm	:	Millimeter
LCM	:	Label Counter Machine
AC	:	Alternate Current
HP	:	Horse Power
KW	:	Kilo Watt
V	:	Volts
SS	:	Stainless Steel

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14.0 REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (ENGINEERING)			

DESIGNATION	NAME	SIGNATURE	DATE
OPERATING MANAGER (QUALITY ASSURANCE)			

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (WAREHOUSE)			

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			