

**PHARMA DEVILS**

**INSTALLATION QUALIFICATION  
PROTOCOL CUM REPORT  
FOR  
LABEL COUNTER MACHINE**

**PROTOCOL No.:**

**INSTALLATION QUALIFICATION  
PROTOCOL CUM REPORT  
FOR  
LABEL COUNTER MACHINE**

<b>EQUIPMENT ID. No.</b>	
<b>LOCATION</b>	<b>SECONDARY PACKING MATERIAL STORE</b>
<b>DATE OF QUALIFICATION</b>	
<b>SUPERSEDE PROTOCOL No.</b>	<b>NIL</b>



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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 provide documented evidence for the Installation Qualification of Label Counter 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 Label Counter Machine to be installed at Secondary Packing Material Store.
- This document provides all the relevant information related to specification, installation checks and acceptance criteria to be required to perform installation qualification activity of Label Counter 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:

<b>DEPARTMENTS</b>	<b>RESPONSIBILITIES</b>
<b>Quality Assurance</b>	<ul style="list-style-type: none"> <li>• Preparation, Review, Compilation and approval of the Installation Qualification Protocol cum Report.</li> <li>• Co-ordination with Warehouse and Engineering to carryout Installation Qualification.</li> <li>• Monitoring of Installation Qualification Activity.</li> <li>• Post Approval of Qualification Protocol cum Report after Execution.</li> </ul>
<b>Warehouse</b>	<ul style="list-style-type: none"> <li>• Review of Installation Qualification Protocol cum Report.</li> <li>• To Co-ordinate and support for Execution of Qualification study as per Protocol.</li> <li>• Post Approval of Installation Qualification Protocol Cum Report after Execution.</li> </ul>
<b>Engineering</b>	<ul style="list-style-type: none"> <li>• Review of Installation Qualification Protocol cum Report.</li> <li>• Co-ordination, Execution and technical support in Installation Qualification Activity.</li> <li>• Responsible for Trouble Shooting (if occurs during execution).</li> <li>• Post Approval of Installation Qualification Protocol cum report after Execution.</li> </ul>



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**5.0 EQUIPMENT DETAILS:**

<b>Equipment Name</b>	Label Counter Machine
<b>Equipment ID.</b>	
<b>Manufacturer's Name</b>	
<b>Modal</b>	
<b>SR. No.</b>	
<b>Location of Installation</b>	Secondary Packing Material Store

**6.0 SYSTEM 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.

- **Pressing Roller:** To Rewind label perfectly on another side
- **Counter:** To count label length
- **Main Drive:** Main drive unit is consisting of electric motor and Worm reduction gearboxes to drive rewinding unite.
- **Finish:** All parts are Matt finishing
- **Operator Panel:** SS 304

**7.0 PRE – QUALIFICATION REQUIREMENTS:**

**7.1 Verification of Documents:**

The results of any tests should meet the limits and acceptance criteria specified in the test Documents. Any deviations or issues should be rectified and documented prior to IQ commencing.

S. No.	Document Name	Document/SOP No.	Completed (Yes/No)	Checked By (Engineering) Sign/Date
1.	DQ Protocol Cum Report			

**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.



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**7.1.2 Acceptance Criteria:**

- All the documents should be available, complete and approved by respective authorities.

**8.0 CRITICAL VARIABLES TO BE MET:**

**8.1 Installation Qualification Checklist:**

<b>INSTALLATION CHECKS</b>	<b>ACCEPTANCE CRITERIA</b>	<b>OBSERVATION ( COMPLIES /NOT COMPLIES )</b>	<b>OBSERVED BY (ENGINEERING) SIGN/DATE</b>
<b>Working:</b> 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 Start/Stop Button.		
Horizontal leveling of the equipment	Perfect Horizontal		
Positioning of the equipment	Aligned vertically straight with sufficient space for maintenance		
Balancing of the floor	Floor should be perfectly balanced with no vibrations.		
General Method of electrical wiring	Electrical wiring should be well insulated and there should be no hanging cables It should be located at a safe place protected from water seepage and also at convenient place for operator convenience.		

**Checked By  
 Engineering  
 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 VERIFICATION OF UTILITY REQUIREMENTS:**

<b>CRITICAL VARIABLES</b>	<b>ACCEPTANCE CRITERIA</b>	<b>OBSERVATION ( COMPLIES /NOT COMPLIES )</b>	<b>VARIFICATION SOURCE</b>	<b>OBSERVED BY (ENGINEERING) SIGN/DATE</b>
Utility connections should be available as per the manufacturer's specification.				
Volt	230 V			
Phase	1 Phase			
Frequency	50 Hz			
KW	0.18			
Room Condition	Should be able to meet the requirement of clean environment.			

**Checked By**  
**Engineering**  
**Sign/Date: .....**

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

**Inference:**

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 .....  
 .....

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





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

<b>CRITICAL VARIABLES</b>	<b>ACCEPTANCE CRITERIA</b>	<b>OBSERVATION ( COMPLIES /NOT COMPLIES )</b>	<b>VERIFICATION SOURCE</b>	<b>OBSERVED BY (ENGINEERING) SIGN/DATE</b>
Modal No.	HMLC-150			
SR. No.	HMLC-150/20-21			
Dimension	750 mm x 500 mm x 1200 mm			
MOC	SS-304			

**Checked By**  
**Engineering**  
**Sign/Date:** .....

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

**Inference:**

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



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**8.4 Verification of Basic Installation Specifications:**

**8.6.2 Major Component Verification**

S. No.	Component description	Specification	Method of inspection / Measurement	Observation	Complies / Not Complies	Observed By (Engineering) Sign/Date
1	Machine Motor	Make: Bonvario	Certificate attached & Check visually			
2	Machine Gearbox	Make: Bonvario	Certificate attached & Check visually			
3	VFD	Make: Delta Modal:VFD004 L21A Sr.No.: 19500205	Certificate attached & Check visually			
4	Gap Sensor	Make: luize Modal:GS61/6 Sr.No.: 32009006553	Certificate attached & Check visually			
5	Selector Switch	Make : Salzer	Certificate attached & Check visually			
6	Emergency Button	Make : Salzer	Certificate attached & Check visually			
7	PLC	Make : Delta Modal:DVP12SA 211T Sr.No.: 19350045	Certificate attached & Check visually			
8	HMI	Make: Delta Modal:DOP- 103BQ Sr.No.19300682	Certificate attached & Check visually			
9	SMPS	Modal: LRS-50- 24 Sr.No.: MW01	Certificate attached & Check visually			



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S. No.	Component description	Specification	Method of inspection / Measurement	Observation	Complies / Not Complies	Observed By (Engineering) Sign/Date
10	Encoder	Modal: E50S8-2500-3T-1 Sr.No.: TE16CR	Certificate attached & Check visually			

**Checked By (Warehouse)**  
**Sign/Date:** .....

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

**Inference:**

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**Reviewed By (Manager QA)**  
**Sign/Date:** .....

**8.5 SAFETY FEATURE & ALARM :**

Critical Variables	Acceptance Criteria	OBSERVATION ( Complies /Not Complies )	OBSERVED BY (ENGINEERING) SIGN/DATE
Leveling and balancing	Label Counter Machine should be properly balanced & leveled		
Electrical wiring	Electrical wiring should be proper		

**Checked By Engineering**  
**Sign/Date:** .....

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

**Inference:**

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



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**9.0 REFERENCES:**

- Design Qualification
- Vender Documents

**10.0 DOCUMENTS TO BE ATTACHED:**

- Any other relevant documents.

**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
- mm : Millimeter
- LCM : Label Counter Machine
- AC : Alternate Current
- HP : Horse Power
- KW : Kilo Watt
- V : Volts
- SS : Stainless Steel



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**17.0 PROTOCOL POST- APPROVAL:**

**PREPARED BY:**

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

**REVIEWED BY:**

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

**APPROVED BY:**

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