OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR LABEL COUNTER MACHINE

EQUIPMENT ID. No.	
LOCATION	**Receiving Area**
DATE OF QUALIFICATION	
SUPERSEDES PROTOCOL No.	**Nil**

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

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OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR LABEL COUNTER MACHINE

1.0 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 verify that the equipment operates in accordance with the design and user requirements as defined by set acceptance criteria and complies with relevant cGMP Requirements.
- To verify the Operational features of Label Counter Machine and to ensure that it produces desired Quality & rated output according to manufactures specifications.
- To verify all the Operational features from user point of view of the Equipment, Cleaning Procedure, Startup & Shut down Procedure and Safety Features.

3.0 SCOPE:

- The scope of this Operational qualification protocol cum report is limited to qualification of Label Counter Machine to be installed in the. Receiving Area.
- This Protocol will define the methods and documentation used to perform OQ activity of Label Counter Machine successful, completion of this Protocol will verify that Label Counter Machine meet all acceptance criteria and ready for Daily use.

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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:

DEPARTMENTS	RESPONSIBILITIES
Quality Assurance	• Preparation, Review and Compilation of the Operational Qualification Protocol cum Report. • Co-ordination with Warehouse and Engineering to carryout Operational Qualification. • Monitoring of Operational Qualification Activity. • Post approval of Operational Qualification Protocol Cum Report.
Warehouse	• Review & Pre Approval of Protocol cum Report. • To Co-ordinate and support for Execution of Qualification study as per Protocol. • Post Approval of Qualification Protocol Cum Report.
Engineering	• Review & Pre Approval of Protocol cum Report. • Co-ordination, Execution and technical support in Label Counter Machine Operational Qualification Activity. • Responsible for Trouble Shooting (if occurs during execution). • Post Approval of Qualification Protocol Cum Report.

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5.0 EQUIPMENT DETAILS:

Equipment Name	Label Counter Machine
Equipment ID.	
Manufacturer's Name	
Modal	
SR. No.	
Location of Installation	Receiving Area

6.0 SYSTEM DESCRIPTION:

The equipment is an automated means to count label with help of gap sensor. It is 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 PRE – QUALIFICATION REQUIREMENTS:

7.1 Verification of Documents:

- DQ Protocol Cum Report
- IQ Protocol cum Report
- SOP For Operation and Cleaning of Label Counting Machine.

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8.0 CRITICAL VARIABLES TO BE MET:

8.1 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 OQ commencing.

S. No.	Document Name	Document/SOP No.	Completed (Yes/No)	Checked By (Engineering) Sign/Date
1.	DQ Protocol Cum Report			
2.	IQ Protocol Cum Report			
3.	SOP For Operation and Cleaning of Label Counting Machine.			

Checked By
(Warehouse)
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 Operational and Functional Checks:

Operate the Label Counter Machine as per Manufacturer's Manual/SOP and Check for the following functions of the equipment. The Equipment should function as desired.

S. No	Input	Criterion	Method of Testing	Observation	Discrepancy Yes/No	Checked by (Sign/Date)
1.	Main Switch ON	Indicating HMI display starts				
2.	Main Switch OFF	Indicating HMI display stop				
3.	Press Main Motor Start Button in HMI Display	Main drive should be start without unusual noise.				
4.	Press Main Motor Stop Button in HMI Display	Main drive must be stop				
5.	Counting sensor glowing	Sensor must glowing when label pass from their sensing area				
6.	Suitability	The Machine can be preset for different sizes of labels without need of any change parts.				
7.	Feed the minimum and maximum label counting detail in HMI	Minimum: 0 Maximum: 99999 Nos.				
8.	Feed the minimum and maximum label Length detail in HMI	Minimum: 0 Maximum: 99999.99 m				
9.	After compilation of pre-defined label quantity	Machine should stop automatically				

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S. No	Input	Criterion	Method of Testing	Observation	Discrepancy Yes/No	Checked by (Sign/Date)
10.	Counter verification	Method: Prepare the label roll with predefined label quantity and missing quantity and run the label roll on machine. Label Quantity: Missing Label Quantity: Acceptance Criteria: Counter should displayed the label quantity and missing label quantity as per the predefined quantity.				
11.	Emergency Button	Machine should Stop Immediately				

Checked By
(Warehouse)
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 FUNCTIONING OF SENSOR:

S.No.	Sensor No.	Acceptance Criteria	Observation	Checked By Engineering Sign / Date
1.	Label Counting	Sensor must glowing when label pass from their sensing area than machine should be Run Smoothly.		
2.	Missing Label Counting	Sensor must not glowing when label is not presents		
3.	Maximum numbers of missing label	When the missing label quantity is more than the set limit, then machine should be stop immediately.		

8.4 Power Failure Verification:

Item	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Main Power shut down	Equipment stops in safe and secure condition		
Main Power Restored	Equipment can be restarted with no problems or adverse conditions.		

Checked By
(Warehouse)
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:

The Principle Reference is the following:

- Validation Master Plan.
- Design Qualification
- Installation Qualification
- Vendor Documents

10.0 DOCUMENTS TO BE ATTACHED:

- Any Other Relevant Documents

11.0 DEVIATION FROM PREDEFINED 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
DQ	:	Design Qualification
IQ	:	Installation Qualification
OQ	:	Operational Qualification
Ltd.	:	Limited
QA	:	Quality Assurance
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 POST APPROVAL:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

DESIGNATION	NAME	SIGNATURE	DATE
OPERATING MANAGER (QUALITY ASSURANCE)			
HEAD (ENGINEERING)			
HEAD (WAREHOUSE)			

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			