



**OPERATIONAL QUALIFICATION DOCUMENT OF PLC SYSTEM  
FOR  
AUTOMATIC VERTICAL ROUND BOTTLE STICKER LABELLING MACHINE**

**OPERATIONAL QUALIFICATION OF PLC SYSTEM  
FOR AUTOMATIC VERTICAL ROUND BOTTLE STICKER  
LABELLING MACHINE**

<b>System Name</b>	<b>Automatic Vertical Round Bottle Sticker Labelling Machine</b>
<b>System ID</b>	.....
<b>Location</b>	<b>Dry Syrup</b>
<b>Effective Date</b>	



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**1.0.0 PRE APPROVAL SIGNATURES:**

The signatures below indicate pre approval of this operational qualification document and it is ready for execution. Any changes or modifications to the intent or the acceptance criteria of this operational qualification document, following approval, requires the generation of an amendment which must be approval prior to execution.

**OPERATIONAL QUALIFICATION PRE APPROVAL**

Function	Name	Department	Designation	Signature/Date
Prepared by		Engineering		
Reviewed by		Engineering		
Reviewed by		Production		
Reviewed by		Quality Assurance		

**Final Approval:** Final approval has been given by the following

Function	Name	Designation	Signature/Date
Approved by		Head Quality Assurance	



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**2.0.0 GENERAL:**

**2.1.0 PURPOSE:**

The purpose of this operational qualification document is to verify and document that the PLC system of “Automatic Vertical Round Bottle Sticker Labelling Machine” has been operated and fulfill its intended use when placed in its intended environment.

The purpose of the Operational Qualification is to provide documented evidence to demonstrate that the PLC system is operated and performed as per the manufacturer specifications.

**2.2.0 SCOPE:**

This Operational Qualification will be performed on “Automatic Vertical Round Bottle Sticker Labelling Machine” which is located in “Dry Syrup”.

This operational qualification document describes the PLC system hardware and software, equipment details, test procedures, documentation, references and acceptance criteria used to establish that “Wash Area” has been operated in accordance with the master documentations.

**2.3.0 BACKGROUND:**

The “Automatic Vertical Round Bottle Sticker Labelling Machine” is a new system purchase specifically for use at .....

**2.4.0 REVISION HISTORY:**

Version No.	Effective Date	Reason for Change
00		New Document



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**2.5.0 REFERENCES:**

The test and execution procedure within the scope of the qualification document are consistency with the following reference.

<u>Guideline</u>	<u>Details</u>
GAMP-5	Good Automated Manufacturing Practices
21 CFR Part 210	Code of Federal Regulations, Current Good Manufacturing Practices in Manufacturing Processing, Packing.
21 CFR Part 211	Code of Federal Regulations, Current Good Manufacturing Practices for finished Pharmaceuticals.
EU GMP Annex-11	European Union Good Manufacturing Practices Annexure-11

**2.6.0 VALIDATION TEAM:**

Validation team is responsible for the execution of operational qualification of PLC system. Validation team comprises.

Name	Department	Designation	Sign & Date
	Engineering		
	Production		
	QA		



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**2.7.0 RESPONSIBILITY:**

- Collect all manuals, electrical wiring diagram and documentary or any other data necessary for the preparation, execution of operational qualification document from M/S. ....
- Preparation and execution of Operational Qualification document.
- Initiate Qualification study in coordination with Production, Quality Assurance and Engineering.
- Provide training to the persons, who present during execution, of this study.

<b>Engineering</b>	<b>Production</b>	<b>Quality Assurance</b>
<ul style="list-style-type: none"> <li>➤ Co-ordinate during execution of Qualification activities.</li> <li>➤ To provide utilities for Qualification activity.</li> <li>➤ To review the operational qualification document.</li> </ul>	<ul style="list-style-type: none"> <li>➤ Co-ordinate during execution of Qualification activities.</li> <li>➤ Provide personnel for facilitating the execution of Qualification activity.</li> <li>➤ Check that test requirements</li> <li>➤ To Review the operational qualification document.</li> </ul>	<ul style="list-style-type: none"> <li>➤ Co-ordinate during execution of Qualification activities.</li> <li>➤ To review and approve the Qualification document.</li> </ul>



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**2.8.0 TRAINING RECORD:**

Following persons have been trained on this approved qualification document and will execute/help in execution of this qualification document.

Duration of Training: \_\_\_\_\_

Venue of Training: \_\_\_\_\_ Date of Training: \_\_\_\_\_

Sr. No.	Name of Trainee	Designation of Trainee	Signature of Trainee	Evaluation OK/ To be retrained	Signature of evaluator

**Trainer Details:**

Name: \_\_\_\_\_

Name: \_\_\_\_\_

Designation: \_\_\_\_\_

Designation: \_\_\_\_\_

Signature: \_\_\_\_\_

Signature: \_\_\_\_\_

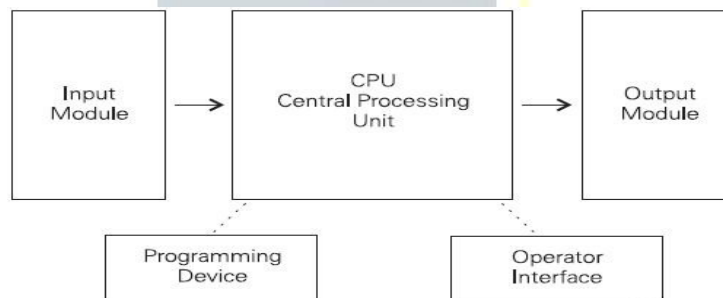


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**2.9.0 PLC DESCRIPTION:**

The dictionary defines automation as “the creation and application of technology to monitor and control the production and delivery of products and services.”

“**Programming Logic Controller**” (PLC) is an industrial computer control system that continuously monitors the state of input devices and makes decisions based upon a custom program, to control the state of devices connected as outputs.



PLC consists of input modules or points, a Central Processing Unit (CPU), and output modules or points. An input accepts a variety of digital or analog signals from various field devices (sensors) and converts them into a logic signal that can be used by the CPU. The CPU makes decisions and executes control instructions based on program instructions in memory.

Output modules convert control instructions from the CPU into a digital or analog signal that can be used to control various field devices (actuators). A programming device is used to input the desired instructions. These instructions determine what the PLC will do for a specific input. An operator interface device allows process information to be displayed and new control parameters to be entered.

The PLC is used many inputs or modules to sense and measure physical quantities of equipment, such as motion, temperature, level, current, voltage, position, and pressure etc. Depending on the status of inputs which sensed by inputs or modules, processor controls various output module to energize or drive the field devices such as valves, motor starters and contactors etc that apply power circuit voltages to the control devices.





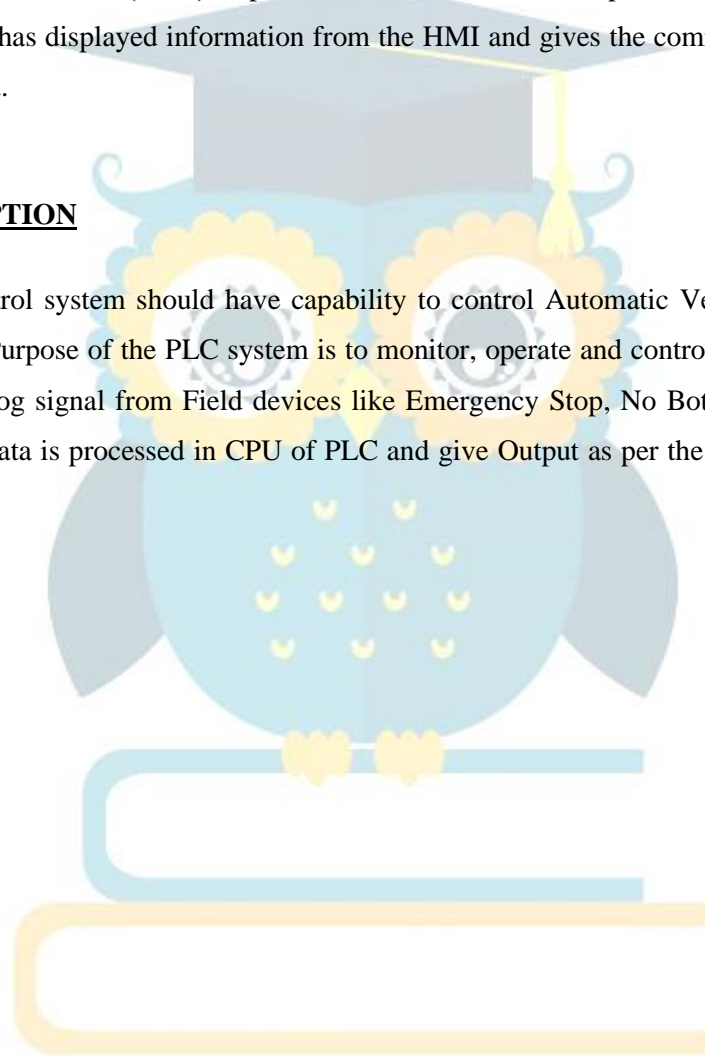
**OPERATIONAL QUALIFICATION DOCUMENT OF PLC SYSTEM  
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Digital or discrete input/output has only two states, one is ON and another is OFF. Input and output have light emitting diode (LED) to indicate the state of each input/output. Analog input/output allow to monitor and controlling analog voltage and control.

“**Human Machine Interface**” (HMI) is platform which is assist the operator to supervise and control the equipment. Operator has displayed information from the HMI and gives the command to PLC then PLC will execute the command.

**2.10.0 SYSTEM DESCRIPTION**

The PLC Based control system should have capability to control Automatic Vertical Round Bottle Sticker Labelling Machine. Purpose of the PLC system is to monitor, operate and control the machine. PLC System gets Digital and analog signal from Field devices like Emergency Stop, No Bottle, Label Gap Sensor, And Other Sensors. The data is processed in CPU of PLC and give Output as per the logics of Servo Pass, Servo Lock and etc.

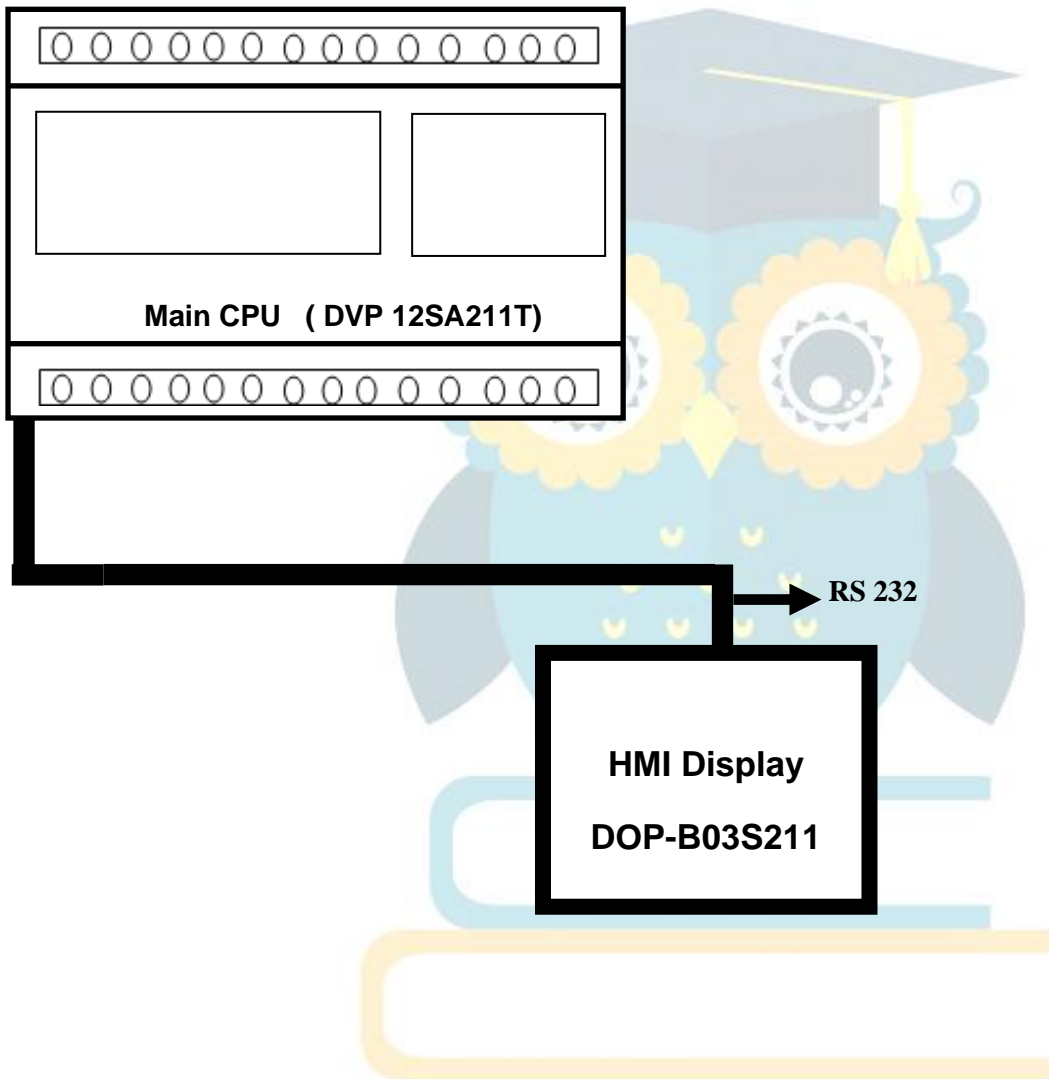




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**2.11.0 PLC SYSTEM SCHEMATIC DIAGRAM**

The PLC system schematic diagram for the “Automatic Vertical Round Bottle Sticker Labelling Machine” automation is given below:





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**3.0.0 OPERATIONAL QUALIFICATION TEST**

<b><u>Sr. No.</u></b>	<b><u>Test Details</u></b>
1	VERIFICATION OF MASTER TEST INSTRUMENTS
2	VERIFICATION OF CALIBRATION CERTIFICATES OF FIELD INSTRUMENTS
3	VERIFICATION OF MAINTENANCE QUALIFICATION DOCUMENTS
4	VERIFICATION OF LED INDICATION OF PLC SYSTEM
5	VERIFICATION OF PLC INPUTS/ OUTPUTS
6	VERIFICATION OF HMI SCREENS
7	VERIFICATION THE RANGE OF SET PARAMETERS
8	VERIFICATION AND TESTING OF POWER LOSS RECOVERY CONDITION
9	VERIFICATION OF COMMUNICATION FAILS RECOVERY CONDITION
10	VERIFICATION OF ALARMS AND INTERLOCKS
11	VERIFICATION OF INTEGRATED CONTROL LOOP



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**3.1.0 VERIFICATION OF MASTER TEST INSTRUMENTS**

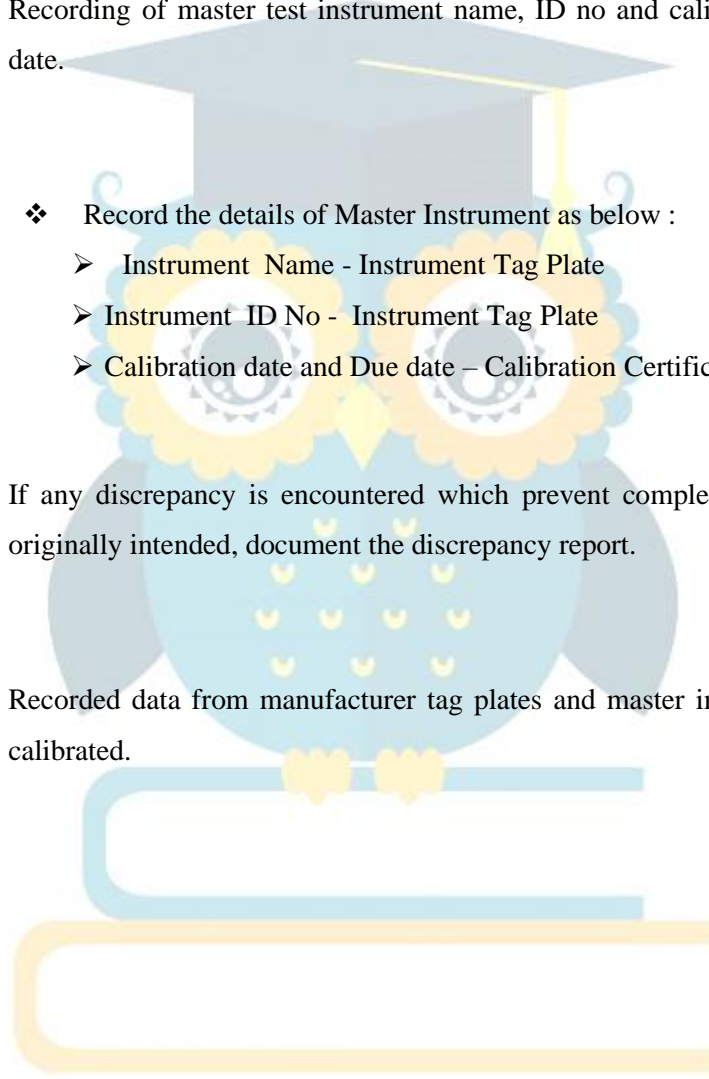
**Purpose** : This test is verified to master instrument which is used for testing.

**Scope** : Recording of master test instrument name, ID no and calibration date and due date.

**Procedure** : ❖ Record the details of Master Instrument as below :  
➤ Instrument Name - Instrument Tag Plate  
➤ Instrument ID No - Instrument Tag Plate  
➤ Calibration date and Due date – Calibration Certificate

**Discrepancy** : If any discrepancy is encountered which prevent completion of the report as originally intended, document the discrepancy report.

**Acceptance Criteria** : Recorded data from manufacturer tag plates and master instruments should be calibrated.





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**3.1.1 DATA TABLE OF MASTER TEST INSTRUMENTS**

Sr. No	Instrument Name	Instrument ID /Make /Model	Calibration Date	Calibration Due Date	Meets acceptance criteria:	Sign. & date
1					Yes ( ) No ( )	
2					Yes ( ) No ( )	

**Comments/ Remarks:**

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Function	Name	Department	Sign. & Date
Tested by		Engineering	
Verified by		Engineering	
Reviewed by		QA	



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**3.2.0 VERIFICATION OF CALIBRATION CERTIFICATES OF SENSORS**

**Purpose** : Verify the calibration certificates of critical sensors in PLC system.

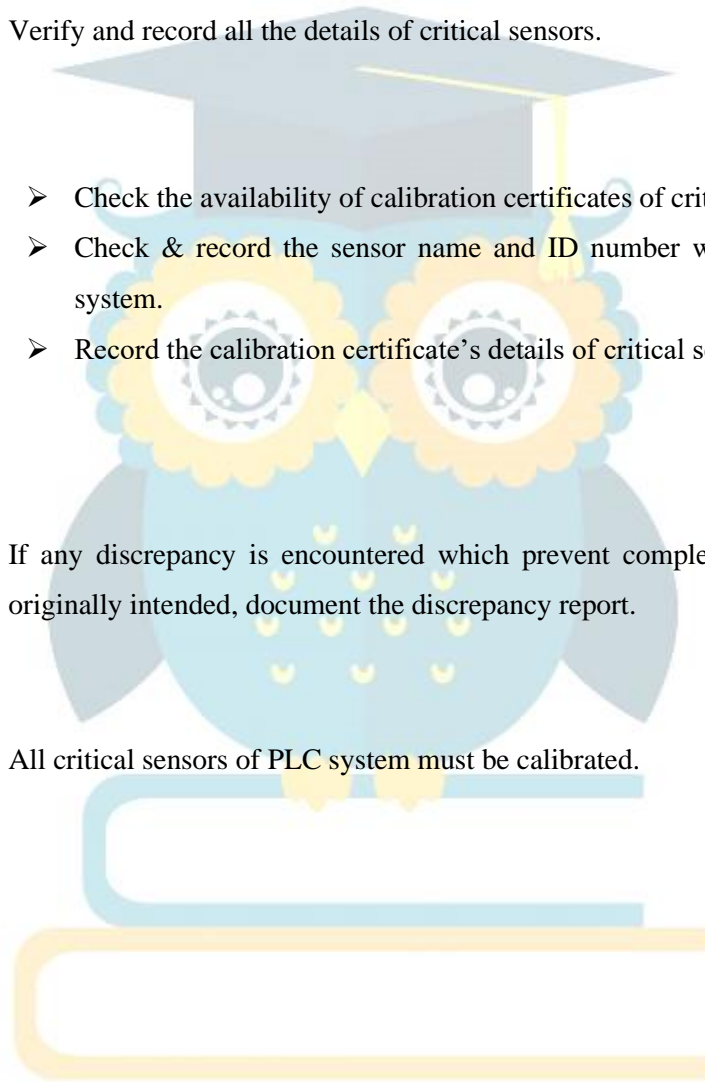
**Scope** : Verify and record all the details of critical sensors.

**Procedure** :  
➤ Check the availability of calibration certificates of critical sensors.  
➤ Check & record the sensor name and ID number which connected PLC system.  
➤ Record the calibration certificate's details of critical sensors.

**Discrepancy** : If any discrepancy is encountered which prevent completion of the report as originally intended, document the discrepancy report.

**Acceptance** : All critical sensors of PLC system must be calibrated.

**Criteria**







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**Comments/ Remarks:**

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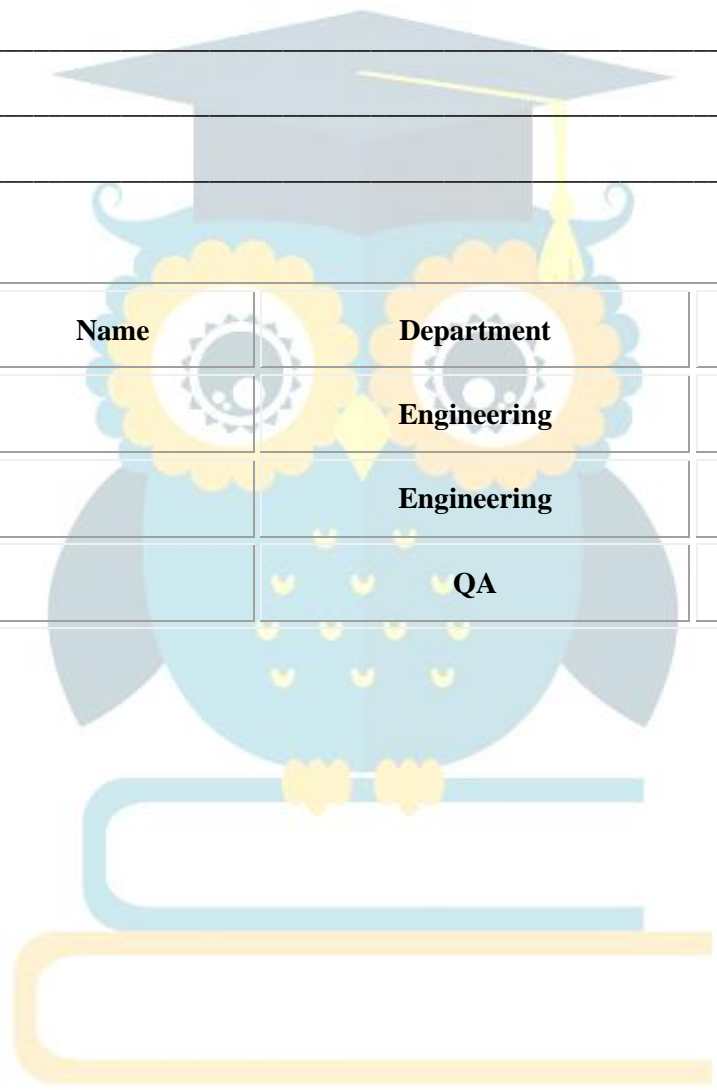
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Function	Name	Department	Sign. & Date
Tested by		Engineering	
Verified by		Engineering	
Reviewed by		QA	







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**3.3.0 VERIFICATION OF MAINTENANCE QUALIFICATION DOCUMENTS**

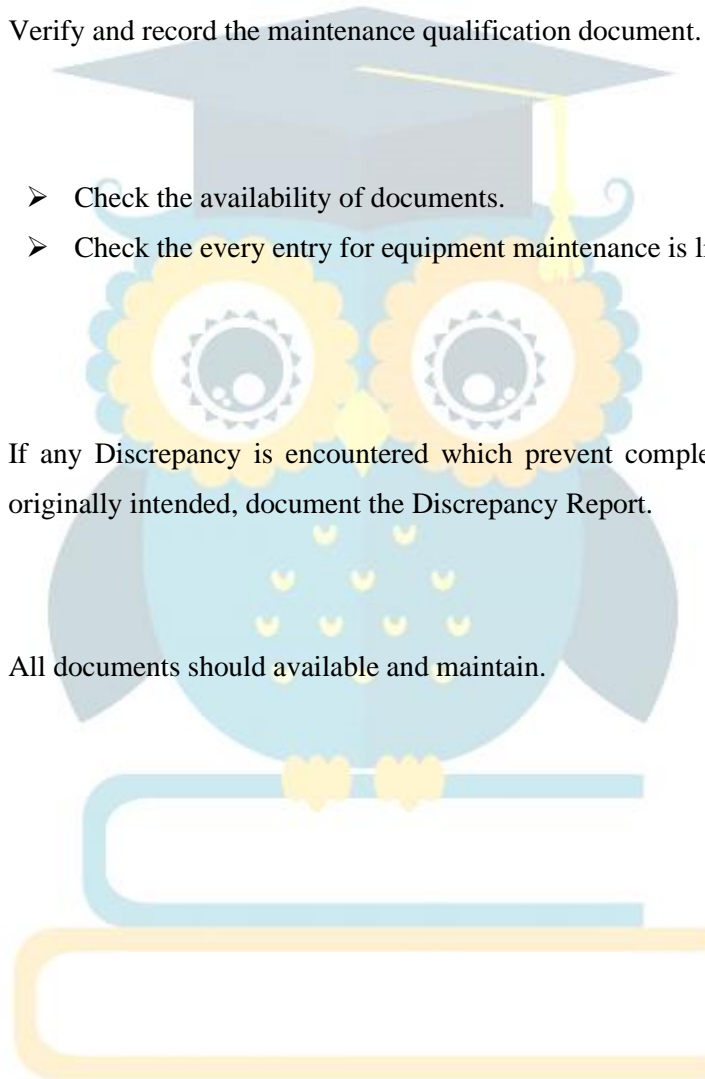
**Purpose** : Verify and review the documents of maintenance.

**Scope** : Verify and record the maintenance qualification document.

**Procedure** :  
➤ Check the availability of documents.  
➤ Check the every entry for equipment maintenance is listed in log-book.

**Discrepancy** : If any Discrepancy is encountered which prevent completion of the report as originally intended, document the Discrepancy Report.

**Acceptance  
Criteria** : All documents should available and maintain.





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**3.3.1 DATA TABLE OF MAINTENANCE QUALIFICATION DOCUMENTS**

Sr. No	Document	Document Available (Yes/ No)	Meet Acceptance Criteria	Sign. & Date
1	Preventive Maintenance Card		Yes ( ) No ( )	
2	Log book of Equipment		Yes ( ) No ( )	

**Comments/ Remarks:**

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Function	Name	Department	Sign. & Date
Tested by		Engineering	
Verified by		Engineering	
Reviewed by		QA	



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**3.4.0 VERIFICATION OF LED INDICATIONS OF PLC SYSTEM**

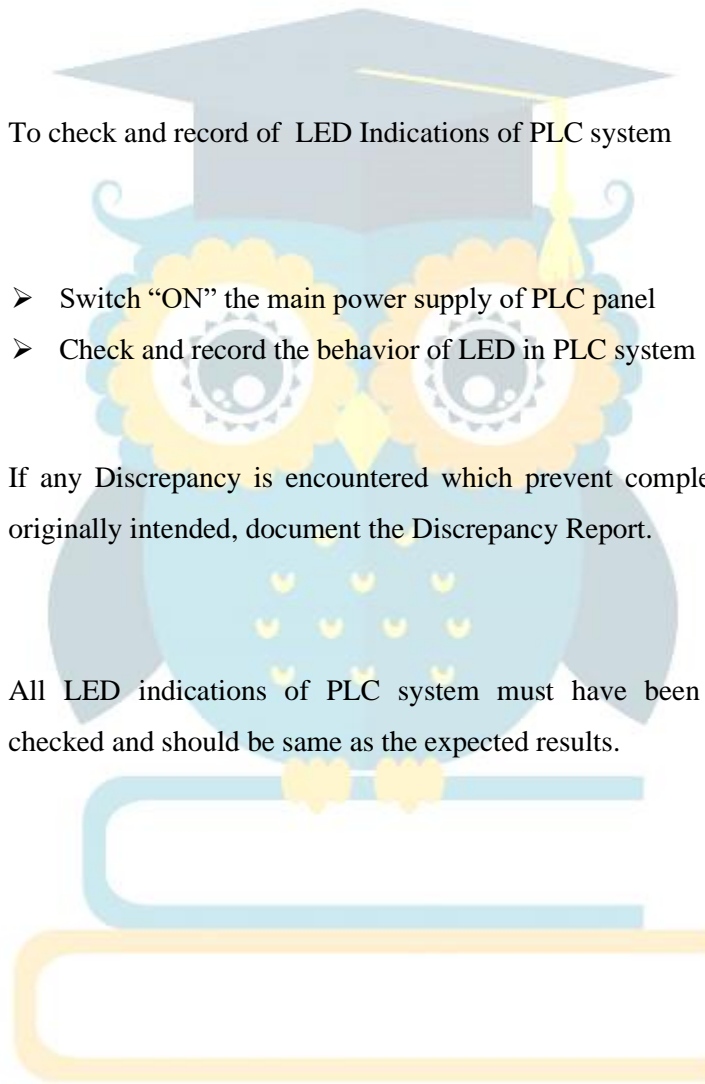
**Purpose** : To verify LED indications of PLC system.

**Scope** : To check and record of LED Indications of PLC system

**Procedure** :  
➤ Switch “ON” the main power supply of PLC panel  
➤ Check and record the behavior of LED in PLC system

**Discrepancy** : If any Discrepancy is encountered which prevent completion of the report as originally intended, document the Discrepancy Report.

**Acceptance Criteria** : All LED indications of PLC system must have been properly visualized, checked and should be same as the expected results.





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**3.4.1 DATA TABLE OF PLC SYSTEM LED INDICATION IN OFF CONDITION**

<b>LED</b>	<b>Expected state of LED</b>	<b>Actual state of LED</b>	<b>Meets acceptance criteria</b>	<b>Sign.&amp; date</b>
<b>PLC PROCESSOR (Mitsubishi FX5U-80MR-ES)</b>				
Power	OFF		Yes ( ) No ( )	
Run	OFF		Yes ( ) No ( )	
Error	OFF		Yes ( ) No ( )	
Comm 1	OFF		Yes ( ) No ( )	

**3.4.2 DATA TABLE OF PLC SYSTEM LED INDICATION IN ON CONDITION**

<b>LED</b>	<b>Expected state of LED</b>	<b>Actual state of LED</b>	<b>Meets acceptance criteria</b>	<b>Sign.&amp; date</b>
<b>PLC PROCESSOR ( Mitsubishi FX5U-80MR-ES )</b>				
Power	ON		Yes ( ) No ( )	
Run	ON		Yes ( ) No ( )	
Error	OFF		Yes ( ) No ( )	
Comm 1	Blink		Yes ( ) No ( )	



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**Comments/ Remarks:**

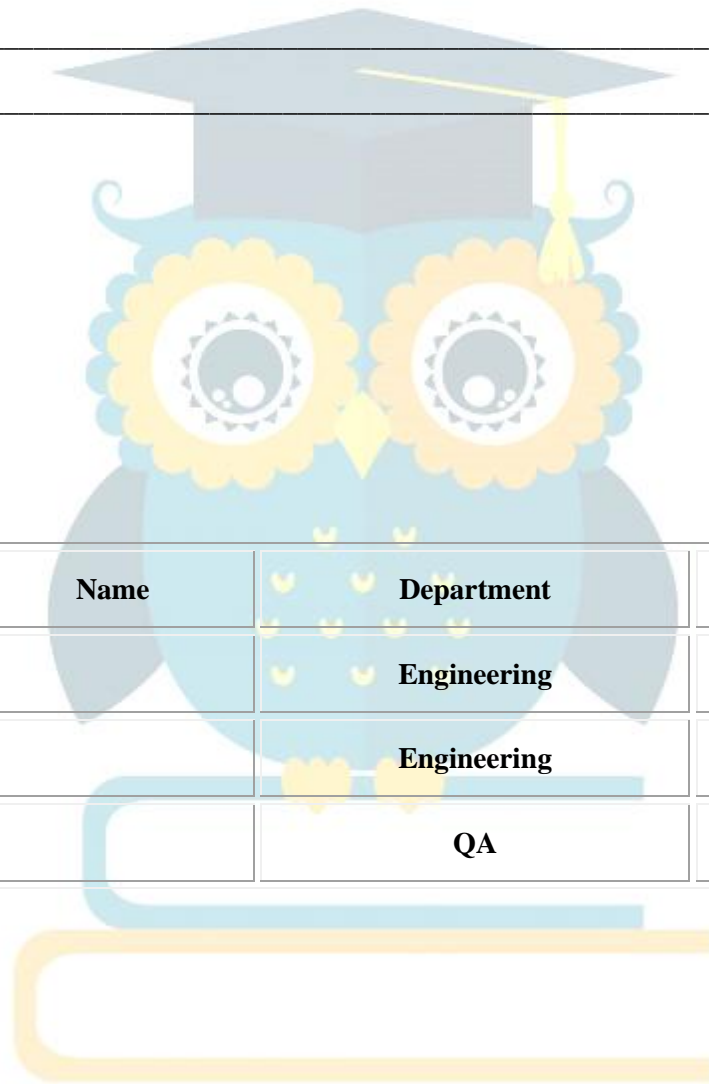
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Function	Name	Department	Sign. & Date
Tested by		Engineering	
Verified by		Engineering	
Reviewed by		QA	



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**3.5.0 VERIFICATION OF PLC INPUTS/ OUTPUTS**

**Purpose** : Verify the entire inputs/outputs of the PLC system, checking the connections to the cards of the PLC system.

**Scope** : To check and record the function of all PLC Inputs and Outputs.

**Procedure** :

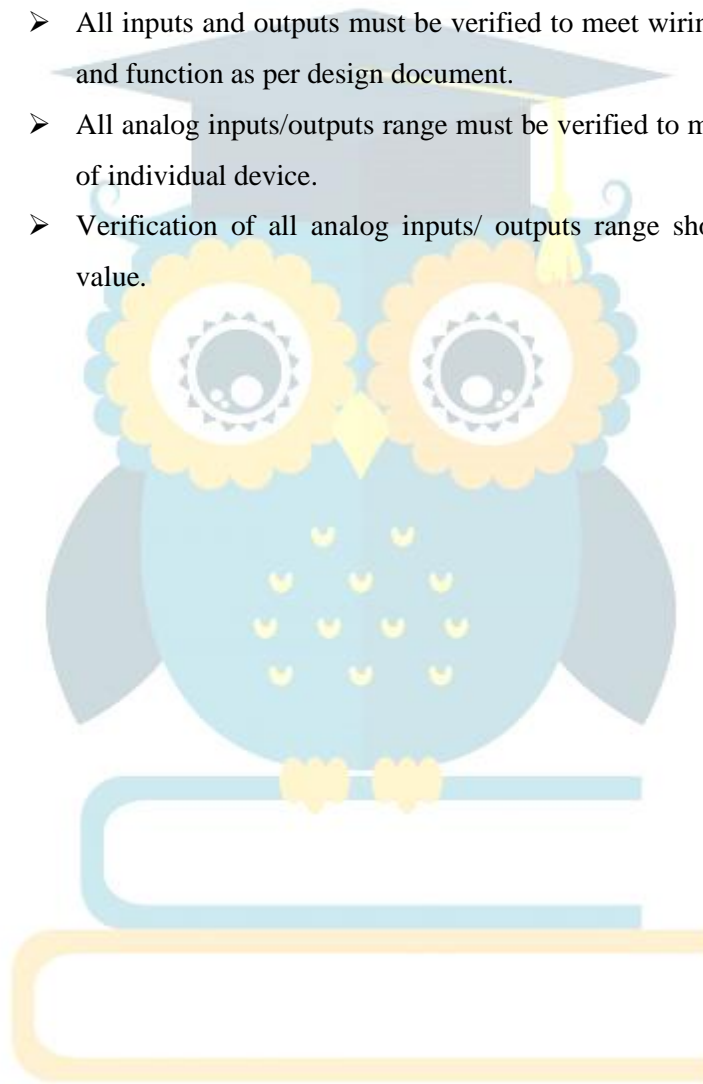
- Digital Inputs
  - Trigger/Force each given digital input from system.
  - Verify and record the status of digital inputs LED indication in PLC system and same time verify the PLC logics in PLC software.
- Digital Outputs
  - Force each digital output ON/OFF.
  - Verify and record the status of digital outputs LED indication in PLC system and same time verify the PLC logics in PLC software.
- Analog Inputs
  - Feed 4-20mA current or appropriate Ohms signal to PLC system using calibrated Universal Calibrator.
- (If Applicable)
  - Simultaneously check the reading in PLC.
  - Verify and record the reading of it.
- Analog Output
  - Measure appropriate current signal from output terminal of PLC system using calibrated universal calibrator.
- (If Applicable)
  - Verify and record the reading of it.



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**Discrepancy** : If any discrepancy is encountered which prevent completion of the report as originally intended, document the discrepancy report.

**Acceptance Criteria** : ➤ All inputs and outputs must be verified to meet wiring diagram of PLC system and function as per design document.  
➤ All analog inputs/outputs range must be verified to meet calibration certificates of individual device.  
➤ Verification of all analog inputs/ outputs range should be within 2% of set value.





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**3.5.1 DATA TABLE OF PLC DIGITAL INPUTS**

PLC Digital Input (DVP 12SA211T)					
PLC Address	Description	Expected state of LED	Actual state of LED	Meets acceptance criteria	Sign. & date
X0	No Bottle	ON		Yes ( ) No ( )	
		OFF		Yes ( ) No ( )	
X1	Label Gap Sensor	ON		Yes ( ) No ( )	
		OFF		Yes ( ) No ( )	
X2	Spare	NA		Yes ( ) No ( )	
X3	SOAP Pump O/L	ON		Yes ( ) No ( )	
		OFF		Yes ( ) No ( )	
X4	Spare	NA		Yes ( ) No ( )	
X5	Spare	NA		Yes ( ) No ( )	
X6	Spare	NA		Yes ( ) No ( )	





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**3.5.2 DATA TABLE OF PLC DIGITAL OUTPUTS**

PLC Digital Outputs (DVP 12SA211T )					
PLC Address	Description	Expected state of LED	Actual state of LED	Meets acceptance criteria	Sign. & date
Y0	Servo Pulse	ON		Yes ( ) No ( )	
		OFF		Yes ( ) No ( )	
Y1	Servo Lock	ON		Yes ( ) No ( )	
		OFF		Yes ( ) No ( )	
Y2	Spare	NA		Yes ( ) No ( )	
Y3	Relay 1	ON		Yes ( ) No ( )	
		OFF		Yes ( ) No ( )	

**Comments/ Remarks:**

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Function	Name	Department	Sign. & Date
<b>Tested by</b>		<b>Engineering</b>	
<b>Verified by</b>		<b>Engineering</b>	



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**Reviewed by**

**QA**

**3.6.0 VERIFICATION OF SECURITY LEVELS**

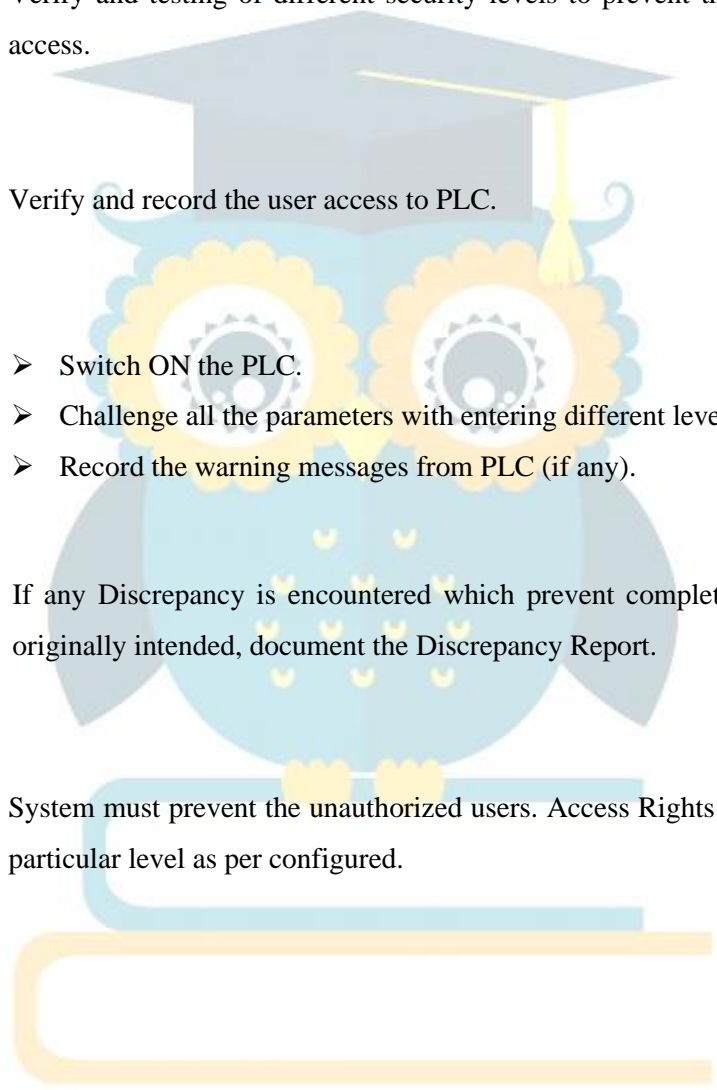
**Purpose** : Verify and testing of different security levels to prevent the unauthorized user access.

**Scope** : Verify and record the user access to PLC.

**Procedure** :  
➤ Switch ON the PLC.  
➤ Challenge all the parameters with entering different level user passwords.  
➤ Record the warning messages from PLC (if any).

**Discrepancy** : If any Discrepancy is encountered which prevent completion of the report as originally intended, document the Discrepancy Report.

**Acceptance Criteria** : System must prevent the unauthorized users. Access Rights should be limited to particular level as per configured.





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**Comments/ Remarks:**

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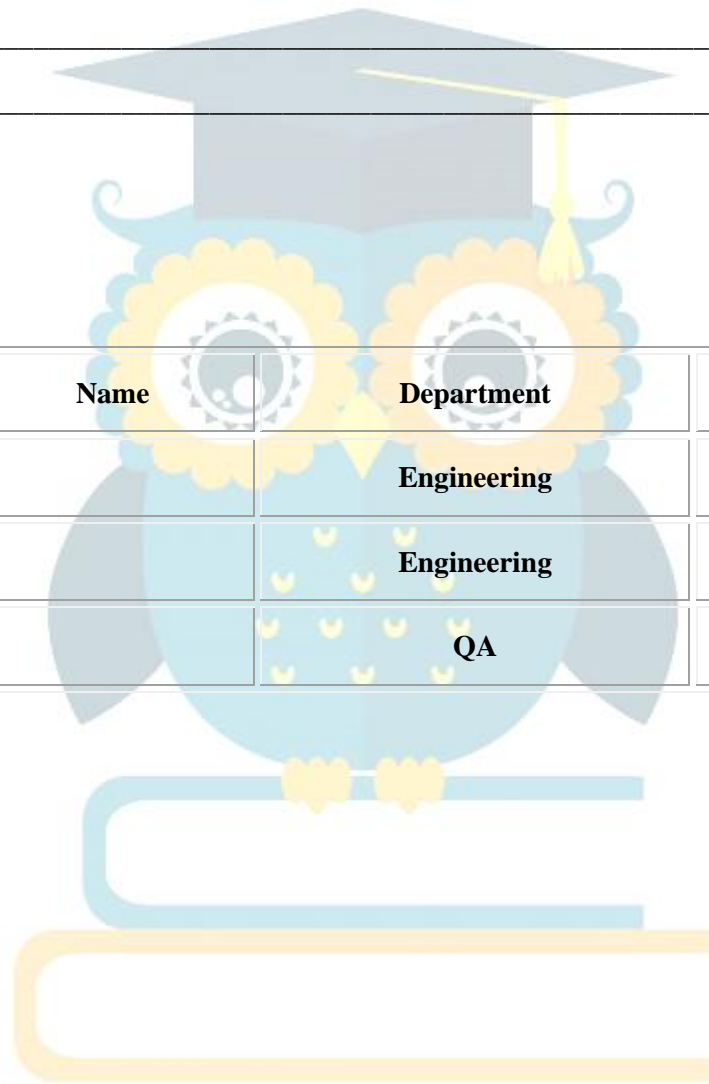
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Function	Name	Department	Sign. & Date
<b>Tested by</b>		<b>Engineering</b>	
<b>Verified by</b>		<b>Engineering</b>	
<b>Reviewed by</b>		<b>QA</b>	





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**3.7.0 VERIFICATION OF HMI SCREENS**

**Purpose** : To verify each function of HMI screens, function keys.

**Scope** : Verify and record all HMI screens and function keys.

**Procedure** :

- Take program backup of HMI and verify with the actual function screens.
- If backup not possible then take screens from manual and verify with the actual function screens.
- Check all programmable function keys for their actual response in each screen. Record the results.
- Check Function Key Command are properly programmed by operating output devices.
- Verify the display on HMI with actual machine conditions and record the actual results.
- Open a screen; check values displayed on HMI for each display object. Record observations.

**Discrepancy** : If any discrepancy is encountered which prevent completion of the report as originally intended, document the discrepancy report.

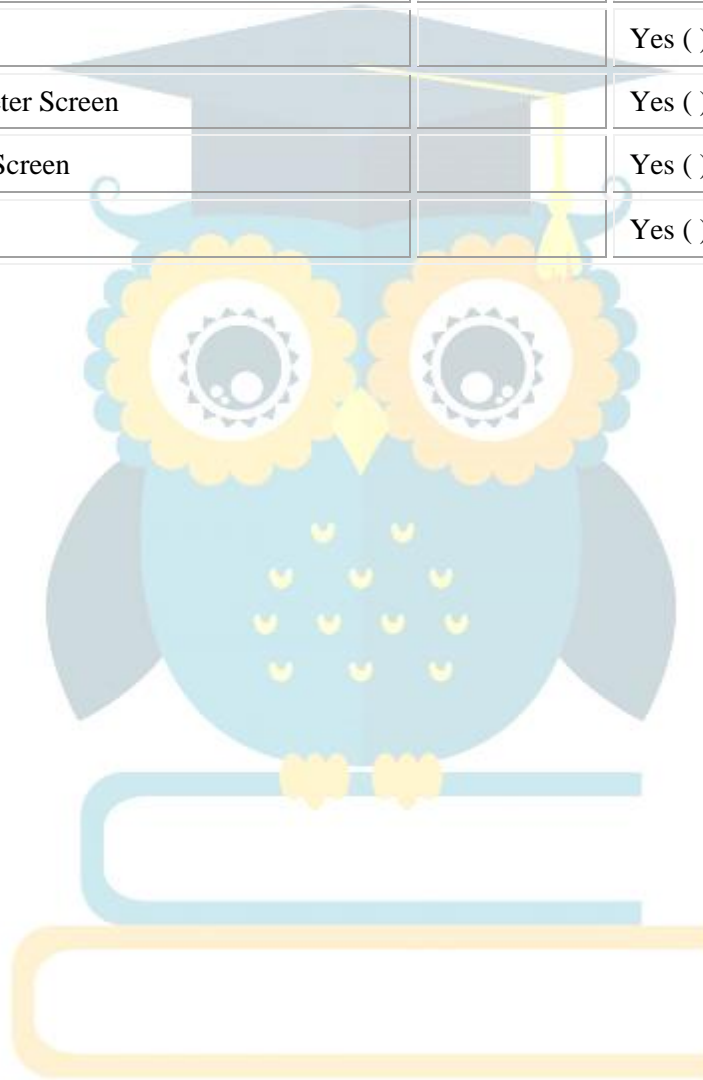
**Acceptance Criteria** : All programmable keys and displays should perform as per define function



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**3.7.1 DATATABLE OF HMI SCREENS**

Sr. No.	Screen Name	Available Yes/No	Meets acceptance criteria	Sign. & date
01	Main Menu Screen		Yes ( ) No ( )	
02	Manual Screen		Yes ( ) No ( )	
03	Setting Parameter Screen		Yes ( ) No ( )	
04	Delay Setting Screen		Yes ( ) No ( )	
05	Auto Screen		Yes ( ) No ( )	





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**3.7.2 DATATABLE OF HMI DISPLAY**

Parameter	Span	Actual Result	Meet Acceptance Criteria	Sign. & Date
<b>Auto Mode Screen</b>				
Machine Speed (BPM)	1 to 200		Yes ( ) No ( )	
Counter	Numeric		Yes ( ) No ( )	
<b>Setting Parameter Screen</b>				
Servo Speed Factor (MPM)	0.01 to 9.99		Yes ( ) No ( )	
<b>Delay Setting Screen</b>				
Delay Time (100ms)	0 to 2000		Yes ( ) No ( )	
On Time (100ms)	0 to 2000		Yes ( ) No ( )	
Label Start (sec)	0.00 to 9.99		Yes ( ) No ( )	
<b>Manual Screen</b>				
Machine Speed (BPM)	1 to 200		Yes ( ) No ( )	
Counter	Numeric		Yes ( ) No ( )	

**Comments/ Remarks:**

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Function	Name	Department	Sign. & Date
Tested by		Engineering	
Verified by		Engineering	
Reviewed by		QA	



**OPERATIONAL QUALIFICATION DOCUMENT OF PLC SYSTEM  
FOR  
AUTOMATIC VERTICAL ROUND BOTTLE STICKER LABELLING MACHINE**

**3.8.0 VERIFICATION OF RANGE OF SET PARAMETERS**

**Purpose** : To check and verify the range of set parameters in HMI screens.

**Scope** : Verify and record the minimum and maximum values of set parameter.

**Procedure** :  
➤ Enter minimum value for the given span and record it.  
➤ Enter maximum value for the given span and record it.  
➤ Enter value above and below the acceptable span and observe the response.  
➤ If value cannot be entered “**above**” maximum and “**below**” minimum then record the message as “**Value cannot be entered**”.

**Discrepancy** : If any discrepancy is encountered which prevent completion of the report as originally intended, document the discrepancy report.

**Discrepancy** : If any discrepancy is encountered which prevent completion of the report as originally intended, document the discrepancy report.

**Acceptance Criteria** : All programmable keys and displays should perform as per define function



**OPERATIONAL QUALIFICATION DOCUMENT OF PLC SYSTEM**

**FOR**

**AUTOMATIC VERTICAL ROUND BOTTLE STICKER LABELLING MACHINE**

**3.8.1 DATATABLE OF HMI SCREENS**

Parameter	Span	Min span	Value is set in system	Max span	Value is set in system	Below Range setting	Value is not set in system	Upper Range setting	Value is not set in system	Meet Acceptance Criteria	Sign. & Date
<b>Auto Mode Screen</b>											
Machine Speed (BPM)	1 to 200		Yes ( ) No ( )		Yes ( ) No ( )		Yes ( ) No ( )		Yes ( ) No ( )	Yes ( ) No ( )	
<b>Setting Parameter Screen</b>											
Servo Speed Factor (MPM)	0.01 to 9.99		Yes ( ) No ( )		Yes ( ) No ( )		Yes ( ) No ( )		Yes ( ) No ( )	Yes ( ) No ( )	
<b>Delay Setting Screen</b>											
Delay Time (100ms)	0 to 2000		Yes ( ) No ( )		Yes ( ) No ( )		Yes ( ) No ( )		Yes ( ) No ( )	Yes ( ) No ( )	
On Time (100ms)	0 to 2000		Yes ( ) No ( )		Yes ( ) No ( )		Yes ( ) No ( )		Yes ( ) No ( )	Yes ( ) No ( )	
Label Start (sec)	0.00 to 9.99		Yes ( ) No ( )		Yes ( ) No ( )		Yes ( ) No ( )		Yes ( ) No ( )	Yes ( ) No ( )	





**PHARMA SCHOLARS**

QUALITY ASSURANCE DEPARTMENT

**PROTOCOL No.:**

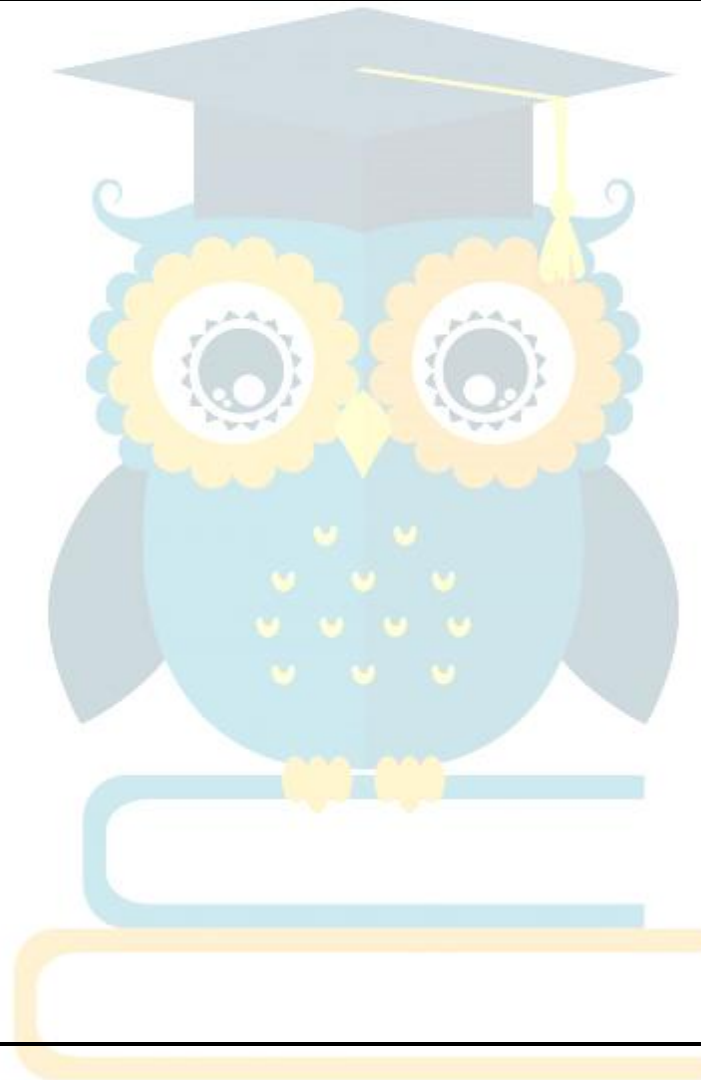
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**REVISION No: 00**

**EFFECTIVE DATE:**

**PAGE No.: 33 of 52**

**OPERATIONAL QUALIFICATION DOCUMENT OF PLC SYSTEM  
FOR  
AUTOMATIC VERTICAL ROUND BOTTLE STICKER LABELLING MACHINE**





**PHARMA SCHOLARS**

QUALITY ASSURANCE DEPARTMENT

**PROTOCOL No.:**

.....

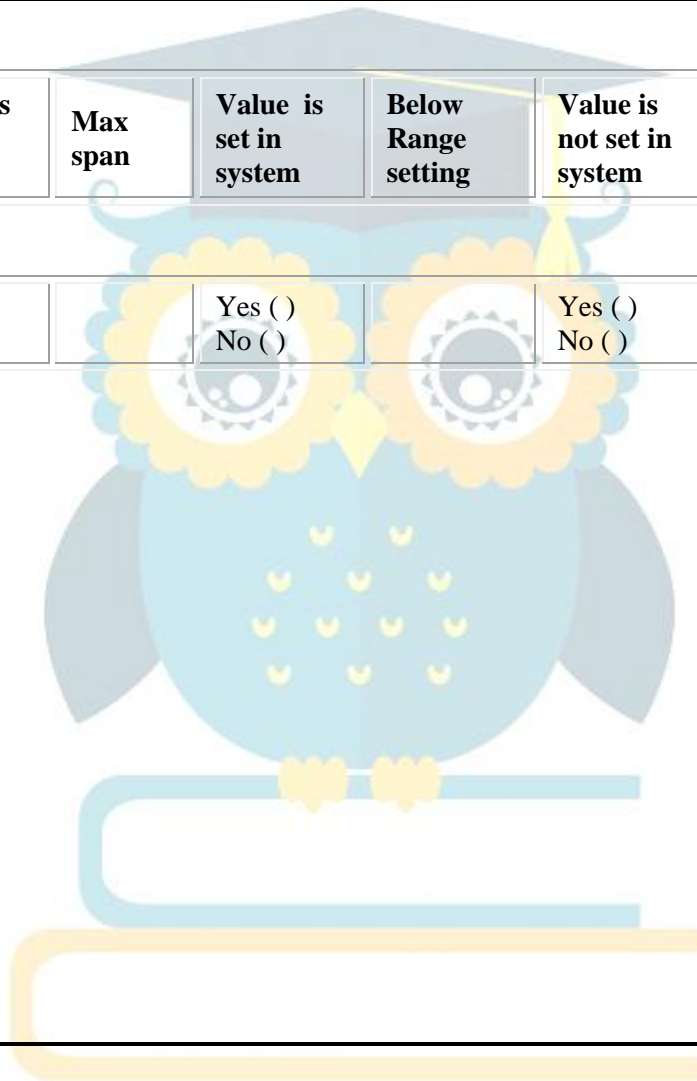
**REVISION No: 00**

**EFFECTIVE DATE:**

**PAGE No.: 34 of 52**

**OPERATIONAL QUALIFICATION DOCUMENT OF PLC SYSTEM  
FOR  
AUTOMATIC VERTICAL ROUND BOTTLE STICKER LABELLING MACHINE**

Parameter	Span	Min span	Value is set in system	Max span	Value is set in system	Below Range setting	Value is not set in system	Upper Range setting	Value is not set in system	Meet Acceptance Criteria	Sign. & Date
<b>Manual Screen</b>											
Machine Speed (BPM)	1 to 200		Yes ( ) No ( )		Yes ( ) No ( )		Yes ( ) No ( )		Yes ( ) No ( )	Yes ( ) No ( )	





**OPERATIONAL QUALIFICATION DOCUMENT OF PLC SYSTEM  
FOR  
AUTOMATIC VERTICAL ROUND BOTTLE STICKER LABELLING MACHINE**

**Comments/ Remarks:**

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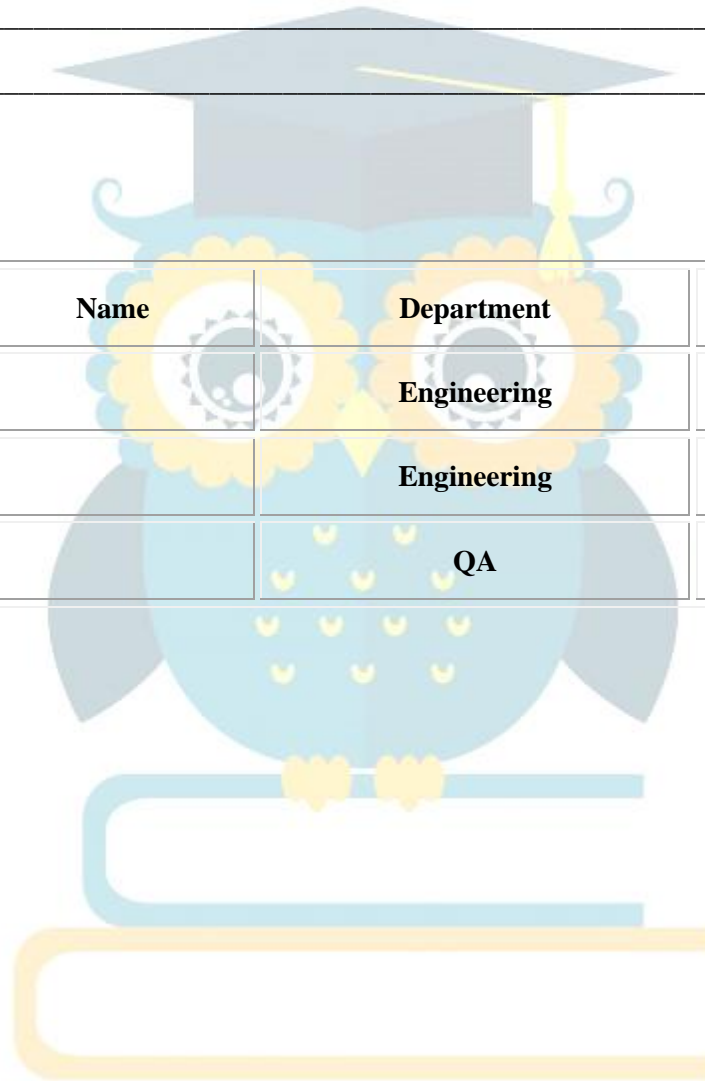
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Function	Name	Department	Sign. & Date
<b>Tested by</b>		<b>Engineering</b>	
<b>Verified by</b>		<b>Engineering</b>	
<b>Reviewed by</b>		<b>QA</b>	





**OPERATIONAL QUALIFICATION DOCUMENT OF PLC SYSTEM  
FOR  
AUTOMATIC VERTICAL ROUND BOTTLE STICKER LABELLING MACHINE**

**3.9.0 VERIFICATION OF POWER LOSS RECOVERY CONDITION**

**Purpose** : Verify and testing of power loss recovery condition.

**Scope** : Record value of process set-parameters after the power fails.

**Procedure** :

- Switch “ON” the PLC system.
- Enter value in set parameter field in HMI screen and record it.
- Start the machine.
- Cut power supply during machine is in “ON” condition.
- Restore power supply after 240 seconds.
- Restart the machine and again record the value which is entered before.
- Ensure that machine should not start unless and until start command is given.

**Discrepancy** : If any Discrepancy is encountered which prevent completion of the report as originally intended, document the Discrepancy Report.

**Acceptance** : ➤ After Power restore the value of process set-parameter should not changed.

**Criteria**

- The process time should start from previous value when the power loss.
- The machine should not start without command by user when power failure condition occurs.
- Machine works normally after Power loss recovery condition.



**OPERATIONAL QUALIFICATION DOCUMENT OF PLC SYSTEM  
FOR  
AUTOMATIC VERTICAL ROUND BOTTLE STICKER LABELLING MACHINE**

**3.9.1 DATA TABLE OF POWER LOSS RECOVERY CONDITION**

<b>Parameter Description</b>	<b>Value Before power loss</b>	<b>Value after power recovery</b>	<b>Expected Result</b>	<b>Meets acceptance criteria</b>	<b>Sign. &amp; date</b>
<b>Auto Mode Screen</b>					
Machine Speed (BPM)			Value remains same	Yes ( ) No ( )	
<b>Setting Parameter Screen</b>					
Servo Speed Factor (MPM)			Value remains same	Yes ( ) No ( )	
<b>Delay Setting Screen</b>					
Delay Time (100ms)			Value remains same	Yes ( ) No ( )	
On Time (100ms)			Value remains same	Yes ( ) No ( )	
Label Start (sec)			Value remains same	Yes ( ) No ( )	
<b>Manual Screen</b>					
Machine Speed (BPM)			Value remains same	Yes ( ) No ( )	



**OPERATIONAL QUALIFICATION DOCUMENT OF PLC SYSTEM  
FOR  
AUTOMATIC VERTICAL ROUND BOTTLE STICKER LABELLING MACHINE**

**Comments/ Remarks:**

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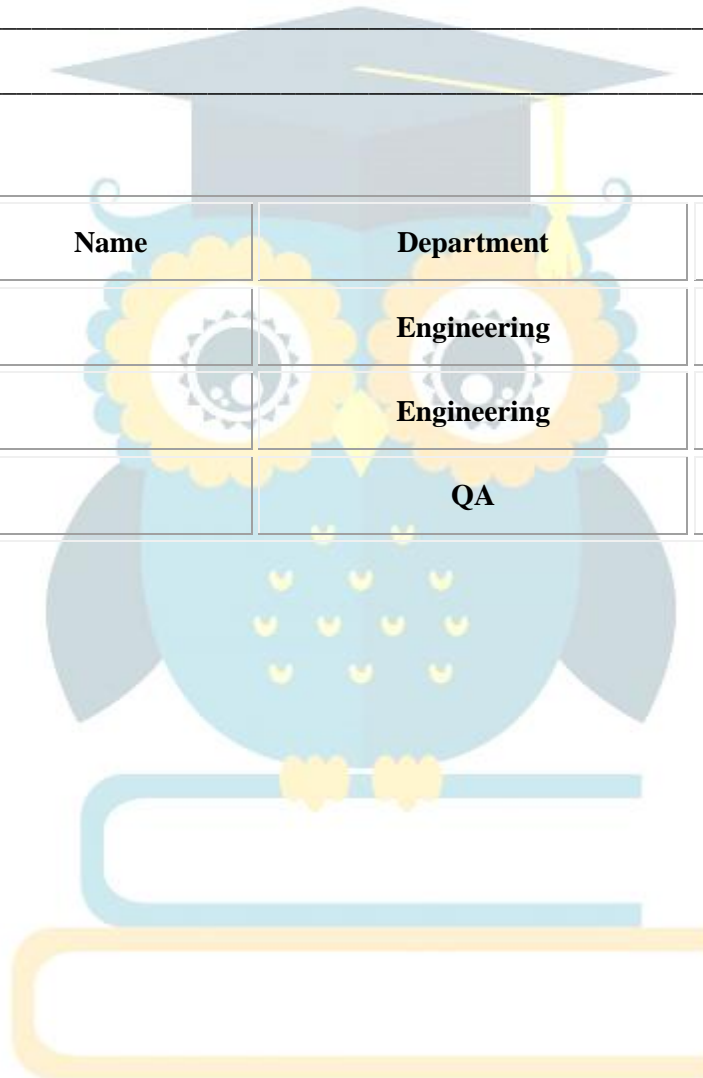
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Function	Name	Department	Sign. & Date
Tested by		Engineering	
Verified by		Engineering	
Reviewed by		QA	





**OPERATIONAL QUALIFICATION DOCUMENT OF PLC SYSTEM  
FOR  
AUTOMATIC VERTICAL ROUND BOTTLE STICKER LABELLING MACHINE**

**3.10.0 VERIFICATION OF COMMUNICATION FAILS RECOVERY CONDITION**

**Purpose** : Verify and testing of communication fails recovery.

**Scope** : Record the value of process set-parameter after communication fails.

**Procedure** :

- Switch “ON” the PLC system.
- Enter value in set parameter field in HMI screen and record it.
- Start the machine in auto mode.
- While the machine is in running condition, unplug the communication link cable between PLC and HMI.
- Take a screen shot or photograph of communication link failure message.
- Try to change recipe in HMI screen.
- Records the result or error message, if no message appears then write “recipe cannot be changed”.
- Reconnect the communication link cable after 240 seconds.
- Record the values again.

**Discrepancy** : If any Discrepancy is encountered which prevent completion of the report as originally intended, document the Discrepancy Report.

**Acceptance Criteria** :

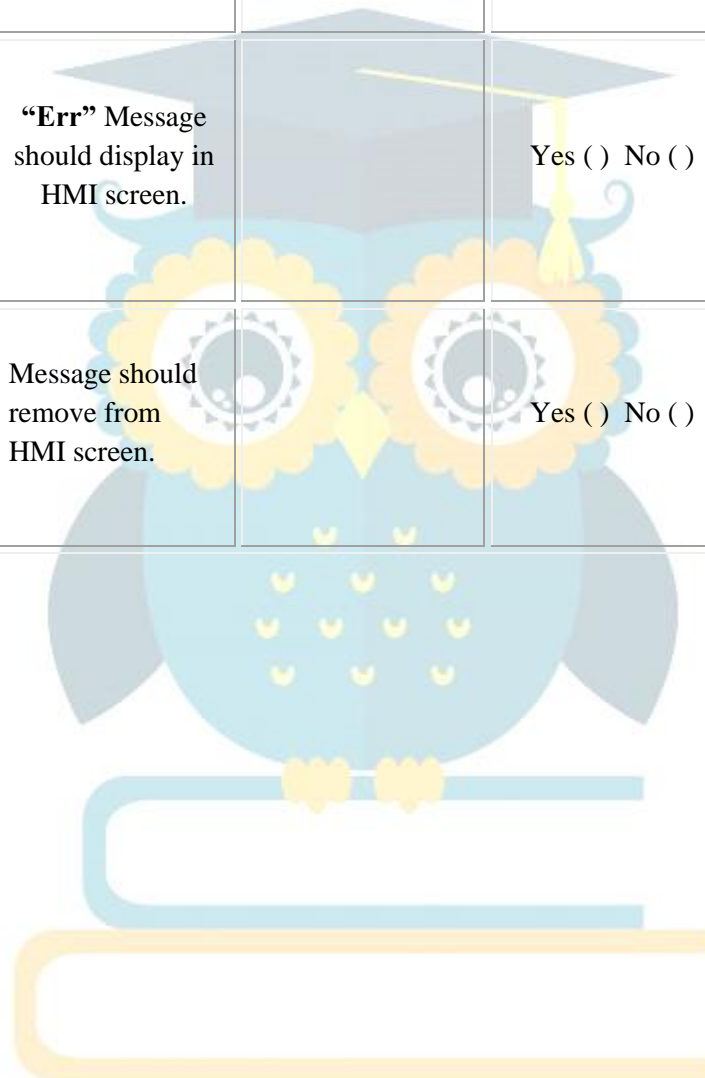
- In communication link failure condition, message must appear in HMI screen.
- When communication link fails the recipe should not be changed or saved.
- After communication link reconnect, the set-parameters should not be changed.
- Machine works normally after communication failure condition.



**OPERATIONAL QUALIFICATION DOCUMENT OF PLC SYSTEM  
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**3.10.1 DATA TABLE OF COMMUNICATION FAILURE CONDITION**

<b>Procedure</b>	<b>Expected result</b>	<b>Actual Result</b>	<b>Meets acceptance criteria</b>	<b>Sign. &amp; date</b>
Start the system in auto mode and disconnect the PLC – HMI communication cable	“Err” Message should display in HMI screen.		Yes ( ) No ( )	
Reconnect the PLC – HMI communication cable	Message should remove from HMI screen.		Yes ( ) No ( )	







**OPERATIONAL QUALIFICATION DOCUMENT OF PLC SYSTEM**

**FOR**

**AUTOMATIC VERTICAL ROUND BOTTLE STICKER LABELLING MACHINE**

Parameter Description	Value Before Communication on unplug	Value after Communication link reconnect	Expected Result	Meets acceptance criteria	Sign. & date
<b>Auto Mode Screen</b>					
Machine Speed (BPM)			Value remains same	Yes ( ) No ( )	
<b>Setting Parameter Screen</b>					
Servo Speed Factor (MPM)			Value remains same	Yes ( ) No ( )	
<b>Delay Setting Screen</b>					
Delay Time (100ms)			Value remains same	Yes ( ) No ( )	
On Time (100ms)			Value remains same	Yes ( ) No ( )	
Label Start (sec)			Value remains same	Yes ( ) No ( )	
<b>Manual Screen</b>					
Machine Speed (BPM)			Value remains same	Yes ( ) No ( )	

**Comments/ Remarks:**

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Function	Name	Department	Sign. & Date
Tested by		Engineering	
Verified by		Engineering	
Reviewed by		QA	



**OPERATIONAL QUALIFICATION DOCUMENT OF PLC SYSTEM  
FOR  
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**3.11.0 VERIFICATION OF ALARMS AND INTERLOCKS**

**Purpose** : Verify that all alarms and interlocks of the PLC system and its functions.

**Scope** : Check and record the alarms and interlocks.

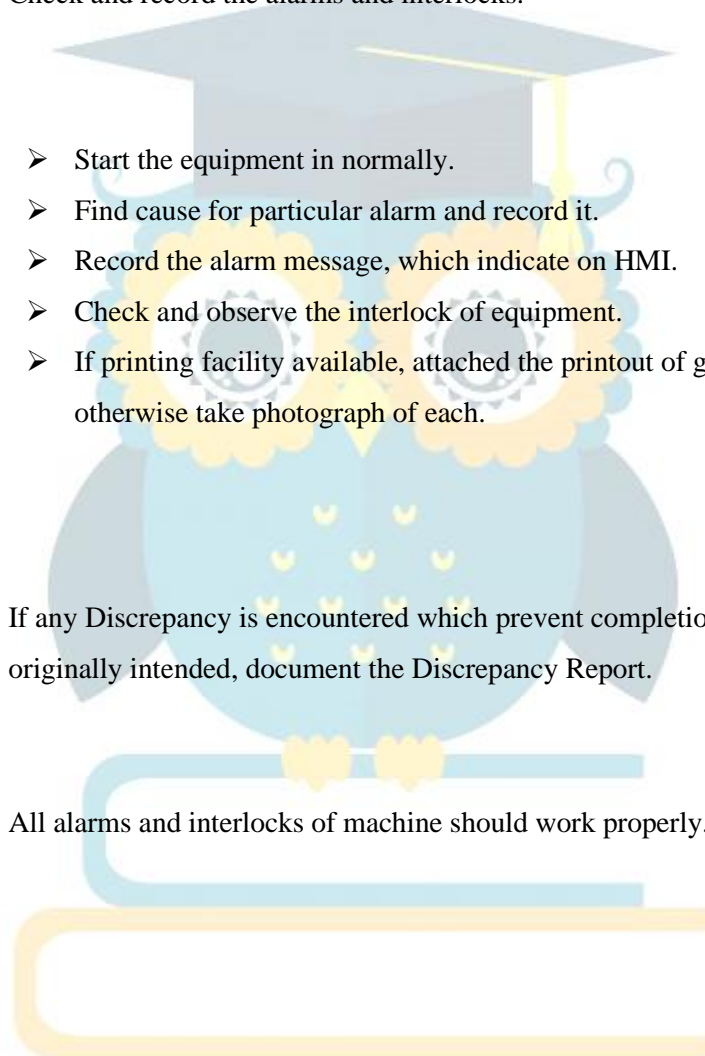
**Procedure** :

- Start the equipment in normally.
- Find cause for particular alarm and record it.
- Record the alarm message, which indicate on HMI.
- Check and observe the interlock of equipment.
- If printing facility available, attached the printout of generated alarms otherwise take photograph of each.

**Discrepancy** : If any Discrepancy is encountered which prevent completion of the report as originally intended, document the Discrepancy Report.

**Acceptance** : All alarms and interlocks of machine should work properly.

**Criteria**





**OPERATIONAL QUALIFICATION DOCUMENT OF PLC SYSTEM  
FOR  
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**3.11.1 DATA TABLE OF ALARMS AND INTERLOCKS**

<b>Cause</b>	<b>Expected Result</b>	<b>Actual Result</b>	<b>Correction</b>	<b>Meets acceptance criteria</b>	<b>Sign. &amp; date</b>
<b>Emergency Switch Operated</b>					
If emergency push button is pressed	<b>“Emergency Switch Operated”</b> alarm message should display in HMI screen and Auto Cycle Deactivated And The Total System Should Go In Hold Mode.		Release the emergency push button	Yes ( ) No ( )	



**OPERATIONAL QUALIFICATION DOCUMENT OF PLC SYSTEM  
FOR  
AUTOMATIC VERTICAL ROUND BOTTLE STICKER LABELLING MACHINE**

**Comments/ Remarks:**

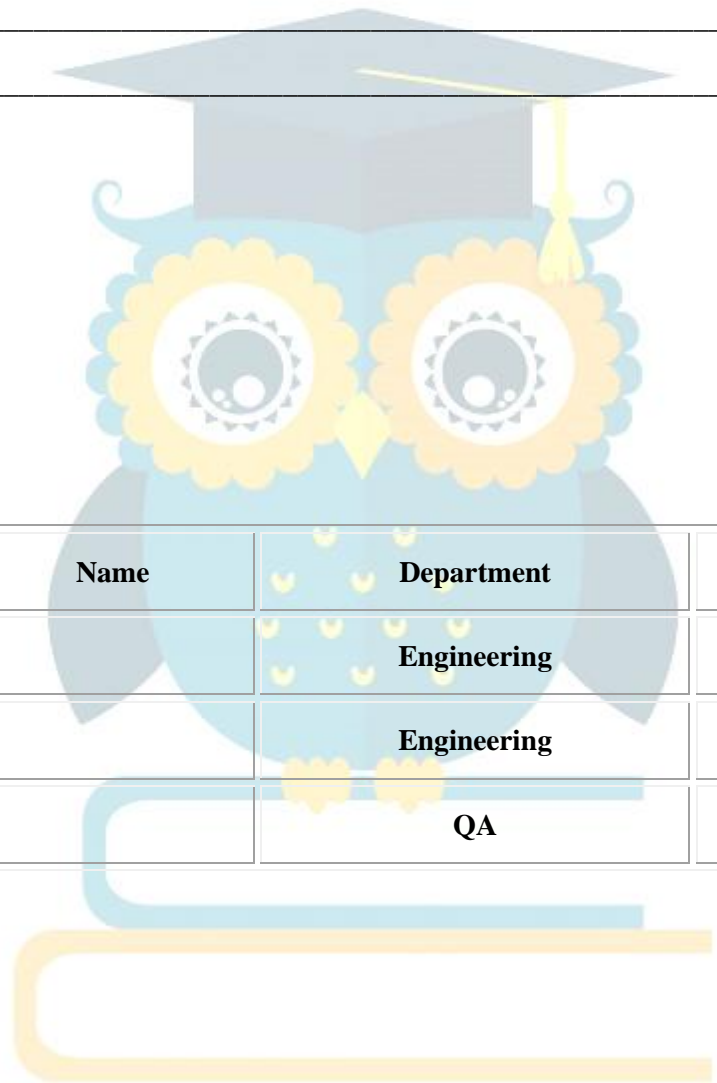
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Function	Name	Department	Sign. & Date
<b>Tested by</b>		<b>Engineering</b>	
<b>Verified by</b>		<b>Engineering</b>	
<b>Reviewed by</b>		<b>QA</b>	



**OPERATIONAL QUALIFICATION DOCUMENT OF PLC SYSTEM  
FOR  
AUTOMATIC VERTICAL ROUND BOTTLE STICKER LABELLING MACHINE**

**3.12.0 VERIFICATION AND RECORD AN INTEGRATED CONTROL LOOP TEST**

**Purpose** : Verify the performance of integrated PLC system.

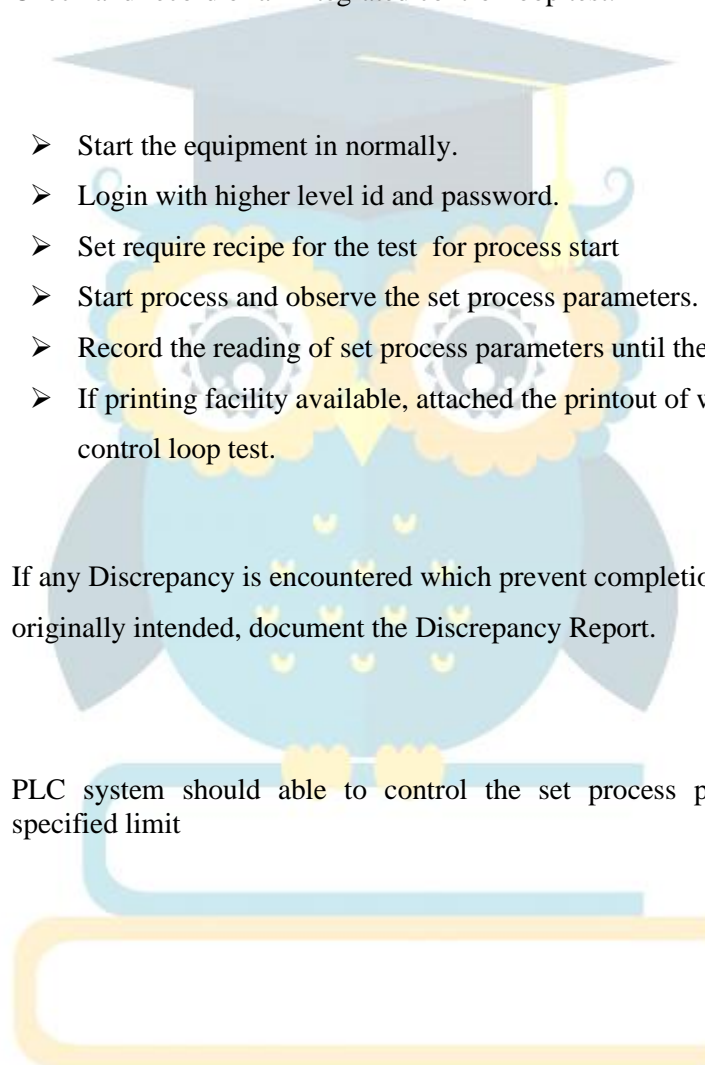
**Scope** : Check and record of an integrated control loop test.

**Procedure** :

- Start the equipment in normally.
- Login with higher level id and password.
- Set require recipe for the test for process start
- Start process and observe the set process parameters.
- Record the reading of set process parameters until the completion of process
- If printing facility available, attached the printout of whole integrated control loop test.

**Discrepancy** : If any Discrepancy is encountered which prevent completion of the report as originally intended, document the Discrepancy Report.

**Acceptance Criteria** : PLC system should able to control the set process parameter within the specified limit





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**3.12.1 DATA TABLE OF CONTROL LOOP TEST**

<u>Set Parameters</u>	<u>Set Value</u>
Machine Speed (RPM)	

<b>Sr. No</b>	<b>Specified</b>	<b>Actual Observation</b>	<b>Meet Acceptance Criteria</b>
1	Process Should start as per set parameter		Yes ( ) No ( )

**Comments/ Remarks:**

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<b>Function</b>	<b>Name</b>	<b>Department</b>	<b>Sign. &amp; Date</b>
<b>Tested by</b>		<b>Engineering</b>	
<b>Verified by</b>		<b>Engineering</b>	
<b>Reviewed by</b>		<b>QA</b>	



**OPERATIONAL QUALIFICATION DOCUMENT OF PLC SYSTEM  
FOR  
AUTOMATIC VERTICAL ROUND BOTTLE STICKER LABELLING MACHINE**

**4.0.0 DEVIATION REPORT AND DISCREPANCY REPORT**

Description of deficiency and its classification*		
Sr.No.	Deficiency	Category

Recommended corrective action, Responsible person			
Sr. No.	Recommended corrective action	Responsibility	Assigned date

Provisional approval to proceed further (For Category B Deficiencies):	
_____	_____
Engineering (Sign and date)	Quality Assurance (Sign and date)

Corrective actions taken (For Category C deficiency)			
Sr.	Corrective action taken	Sign	Date

Closure remarks: Allowed / Not allowed to proceed further
Reviewed and approved by Engineering:
Reviewed and approved by Quality Assurance:

Follow-up Compliance (For category C deficiency):

Recommended corrective actions taken (Action taken within stipulated period)			
Sr.	Corrective action taken	Sign	Date

Closure remarks:
Reviewed and approved by Engineering:

\*Category A: Equipment/instrument/system accepted with deficiency

Category B: Conditional acceptance of equipment, deficiency to be corrected within stipulated period

Category C: Deficiency to be rectified before proceeding further



**OPERATIONAL QUALIFICATION DOCUMENT OF PLC SYSTEM  
FOR  
AUTOMATIC VERTICAL ROUND BOTTLE STICKER LABELLING MACHINE**

**5.0.0 SUMMARY REPORT**

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Function	Name	Department	Sign. & Date
Tested by		Engineering	
Verified by		Engineering	
Reviewed by		QA	





**OPERATIONAL QUALIFICATION DOCUMENT OF PLC SYSTEM  
FOR  
AUTOMATIC VERTICAL ROUND BOTTLE STICKER LABELLING MACHINE**

**6.0.0 TERMINOLOGIES**

❖ **Access security :**

For protection that ensures system access only to authorized persons on their assigned access level.

❖ **Automated system :**

A system that automatically, without human intervention, controls or monitors a specific set of sequential activities; such as a plant process, laboratory function, or data processing operation.

❖ **Installation Qualification (IQ) :**

Document evidence that verify the equipment and its sub-system has been installed properly as per the specification.

❖ **Operational Qualification (OQ) :**

Document evidence that the equipment related system or subsystem has been operated properly as per specification.

❖ **Validation :**

Documented evidence which provides a high degree of assurance that a specific process will consistently produce a product meeting its predetermined specifications and quality attributes.

❖ **PLC :**

PLC is an industrial computer control system that continuously monitors the state of input devices and makes decisions based upon a custom program, to control the state of devices connected as outputs.

❖ **CPU :**

The **central processing unit (CPU)** is the portion of a computer system that carries out the instructions of a computer program, to perform the basic arithmetical, logical, and input/output operations of the system.

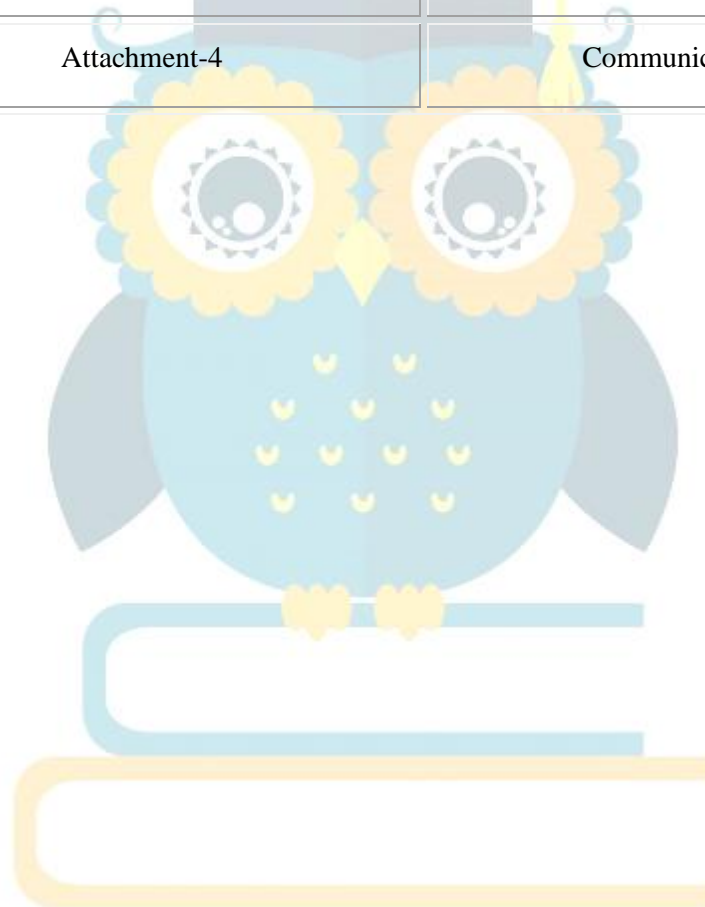
❖ **SOP :Standard Operating Procedure**



**OPERATIONAL QUALIFICATION DOCUMENT OF PLC SYSTEM  
FOR  
AUTOMATIC VERTICAL ROUND BOTTLE STICKER LABELLING MACHINE**

**7.0.0 LIST OF ATTACHMENTS**

<b><u>Sr. No.</u></b>	<b><u>Reference</u></b>	<b><u>Description Of Attachment</u></b>
1	Attachment-1	Master Test Instrument Calibration Certificate
2	Attachment-2	Field Instrument Calibration Certificate
3	Attachment-3	HMI Screen
4	Attachment-4	Communication Fail





**OPERATIONAL QUALIFICATION DOCUMENT OF PLC SYSTEM  
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**8.0.0 LIST OF ABBREVIATIONS**

<u>Acronym</u>	<u>Description</u>
<b>CPU</b>	→ <b>C</b> entral <b>P</b> rocessing <b>U</b> nit
<b>CGMP</b>	→ <b>C</b> urrent <b>G</b> ood <b>M</b> anufacturing <b>P</b> ractices
<b>GAMP</b>	→ <b>G</b> ood <b>A</b> utomated <b>M</b> anufacturing <b>P</b> ractices
<b>GMP</b>	→ <b>G</b> ood <b>M</b> anufacturing <b>P</b> ractices
<b>ID</b>	→ <b>I</b> dentification <b>N</b> umber
<b>IO</b>	→ <b>I</b> nput <b>O</b> utput
<b>RQ</b>	→ <b>R</b> e- <b>Q</b> ualification
<b>PLC</b>	→ <b>P</b> rogrammable <b>L</b> ogic <b>C</b> ontroller
<b>SOP</b>	→ <b>S</b> tandard <b>O</b> perating <b>P</b> rocedure
<b>UPS</b>	→ <b>U</b> ninterruptible <b>P</b> ower <b>S</b> upply
<b>VAC</b>	→ <b>V</b> olts <b>A</b> lternating <b>C</b> urrent
<b>VDC</b>	→ <b>V</b> olts <b>D</b> irect <b>C</b> urrent
<b>VMP</b>	→ <b>V</b> alidation <b>M</b> aster <b>P</b> lan
<b>HMI</b>	→ <b>H</b> uman <b>M</b> achine <b>I</b> nterface





**OPERATIONAL QUALIFICATION DOCUMENT OF PLC SYSTEM  
FOR  
AUTOMATIC VERTICAL ROUND BOTTLE STICKER LABELLING MACHINE**

**9.0.0 POST APPROVAL SIGNATURES**

The signatures below indicate post approval of this Operational Qualification document and it is executed properly. All variations or discrepancies have been satisfactorily resolved.

Function	Name	Department	Designation	Signature/Date
Executed by		Engineering		
Reviewed by		Engineering		
Reviewed by		Production		
Reviewed by		Quality Assurance		

**Final Approval:** Final approval has been given by the following

Function	Name	Designation	Signature/Date
Approved by		Head Quality Assurance	