



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

**INSTALLATION QUALIFICATION DOCUMENT 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 qualification document and it is ready for execution. Any changes or modifications to the intent or the acceptance criteria of this qualification document, following approval, requires the generation of an amendment which must be approval prior to execution.

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

The purpose of the Installation Qualification is to provide documented evidence to demonstrate that the PLC system is installed as per the design specifications.

**2.2.0 SCOPE:**

This Installation Qualification will be performed on “**Automatic Vertical Round Bottle Sticker Labelling Machine**” which is located in “Dry Syrup-2”.

This installation qualification document describes the PLC system hardware and software, equipment details, test procedures, documentation, references and acceptance criteria used to establish that “**Automatic Vertical Round Bottle Sticker Labelling Machine**” has been installed 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 Installation 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 installation qualification document from M/S. ....
- Preparation and execution of Installation 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> </ul>	<ul style="list-style-type: none"> <li>➤ Co-ordinate during execution of Qualification activities.</li> </ul>	<ul style="list-style-type: none"> <li>➤ Co-ordinate during execution of Qualification activities.</li> </ul>
<ul style="list-style-type: none"> <li>➤ To provide utilities for Qualification activity.</li> </ul>	<ul style="list-style-type: none"> <li>➤ Provide personnel for facilitating the execution of Qualification activity.</li> </ul>	<ul style="list-style-type: none"> <li>➤ To review and approve the Qualification document.</li> </ul>
<ul style="list-style-type: none"> <li>➤ To review the installation qualification document.</li> </ul>	<ul style="list-style-type: none"> <li>➤ Check that test requirements</li> <li>➤ To Review the installation 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: \_\_\_\_\_

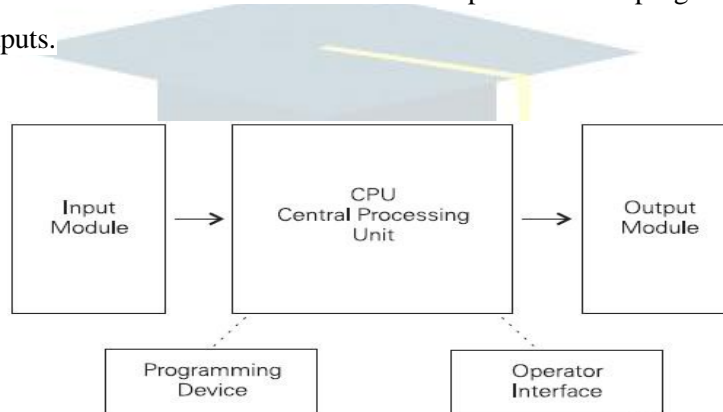


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**2.9.0 PLC DESCRIPTION:**

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.





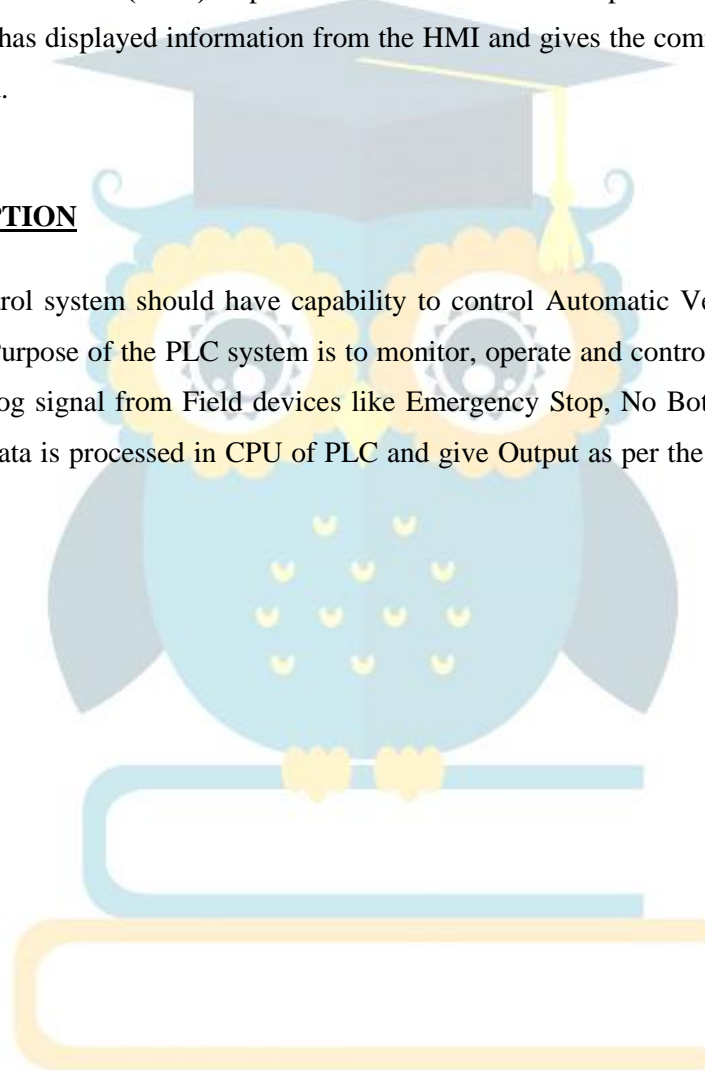
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Digital or discrete input/output has only two states, one is ON and another is OFF. Input and output have light emitting diode (LED) to indicate the state of each input/output. Analog input/output allow to monitor and controlling analog voltage and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

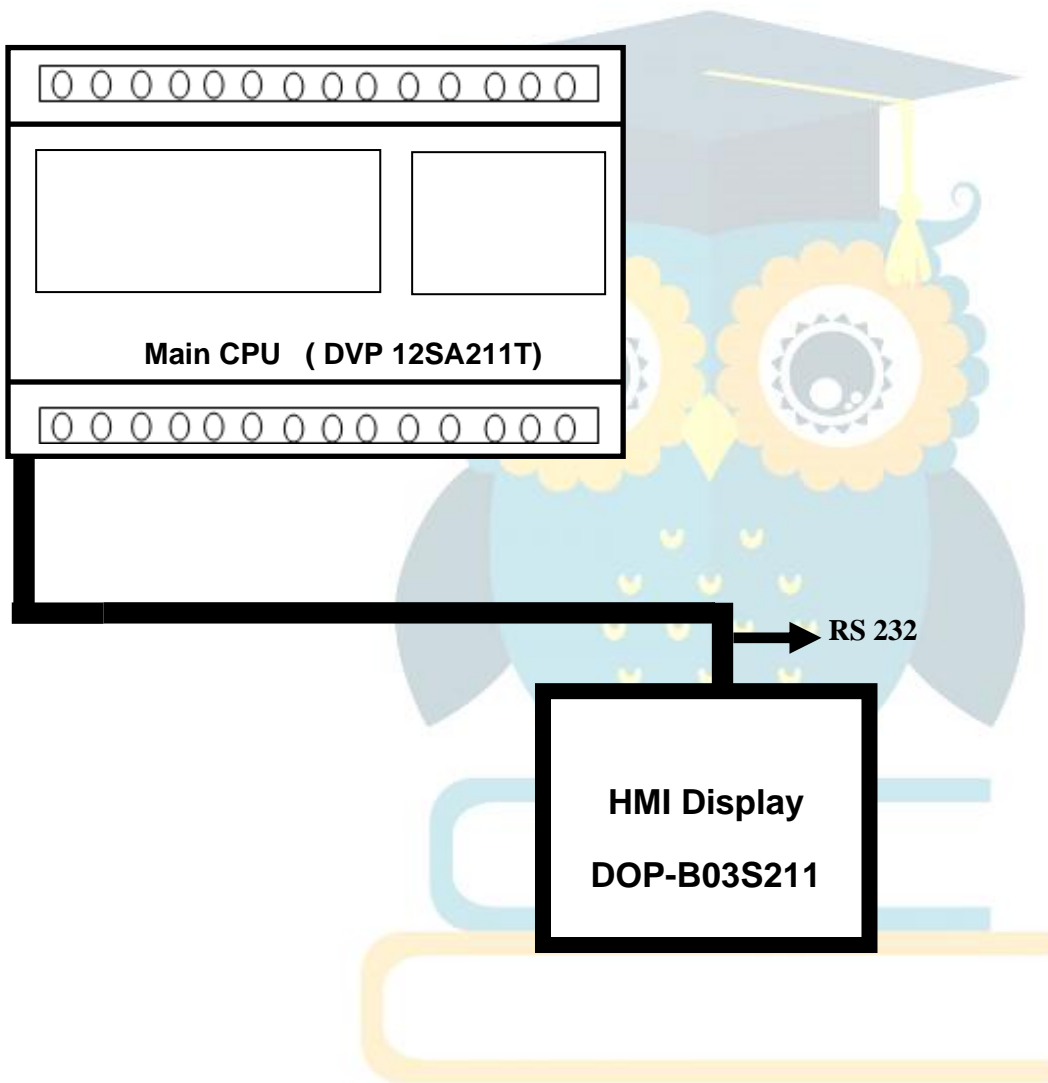




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**2.11.0 PLC SYSTEM SCHEMATIC DIAGRAM**

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 INSTALLATION QUALIFICATION TEST POINTS:**

<b><u>Sr. No.</u></b>	<b><u>Test Details</u></b>
1	IDENTIFY THE SYSTEMS GOING FOR VALIDATION
2	VERIFICATION OF MASTER DOCUMENTATIONS
3	VERIFICATION OF MASTER TEST INSTRUMENTS
4	VERIFICATION OF AMBIENT TEMPERATURE AND HUMIDITY CONDITIONS
5	VERIFICATION OF SCHEMATIC DIAGRAM & ELECTRICAL WIRING DIAGRAM
6	VERIFICATION OF PLC SYSTEM HARDWARE COMPONENTS
7	VERIFICATION OF PLC SYSTEM INPUT/OUTPUT ADDRESS
8	VERIFICATION OF PLC SYSTEM POWER SUPPLY
9	VERIFICATION OF LOGICAL SECURITY / ACCESS CONTROL OF PLC SYSTEM
10	VERIFICATION OF PLC AND HMI SOFTWARE



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**3.1.0 IDENTIFICATION OF THE SYSTEMS GOING FOR VALIDATION**

**Purpose** : This test is specified to illuminate the System going to be validated.

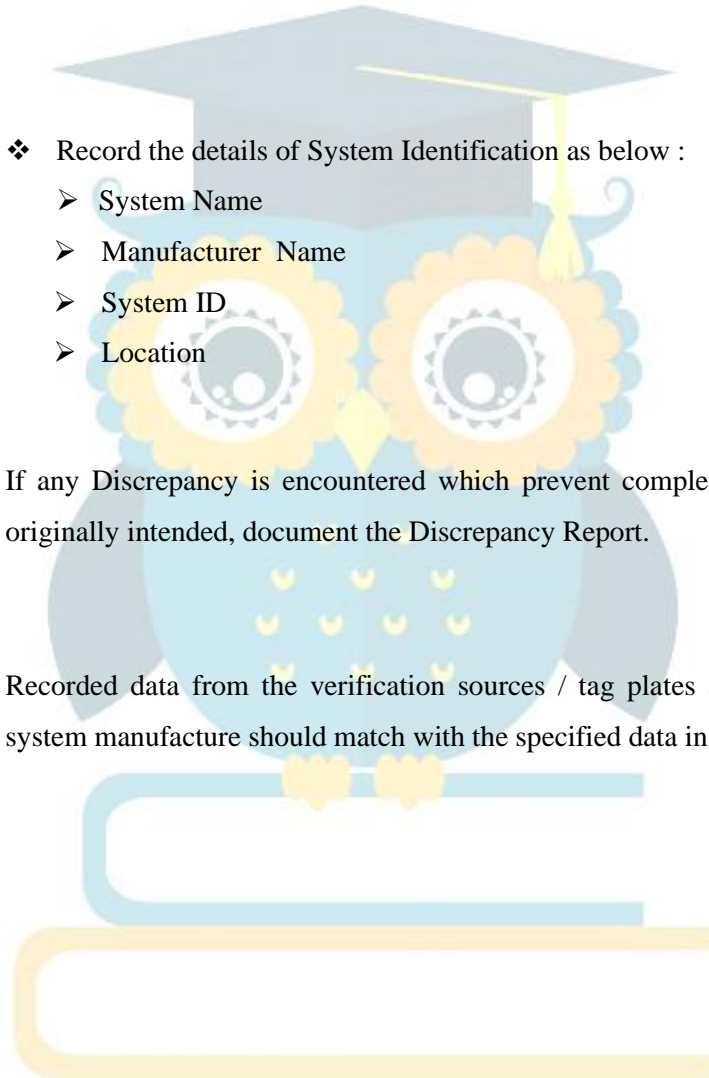
**Scope** : Recording of System details system Name, ID No., Manufacturer and location.

**Procedure** : ❖ Record the details of System Identification as below :

- System Name
- Manufacturer Name
- System ID
- Location

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

**Acceptance Criteria** : Recorded data from the verification sources / tag plates and defined label of system manufacture should match with the specified data in test data table.





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**3.1.1 DATA TABLE OF SYSTEM IDENTIFICATION**

Sr. No	System information	Expected result	Actual result	Meets acceptance criteria	Sign. & date
1	System Name	Automatic Vertical Round Bottle Sticker Labelling Machine		Yes ( ) No ( )	
2	System Manufacturer	Parth Engineering & Consaltant		Yes ( ) No ( )	
3	System ID No.	EQI/PCO/BSL/001		Yes ( ) No ( )	
4	System Location	Dry Syrup-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 MASTER DOCUMENTATIONS**

**Purpose** : This test is to verify and review master document and ensure that system is adequately documented and controlled.

**Scope** : Recording of master document list, location and availability.

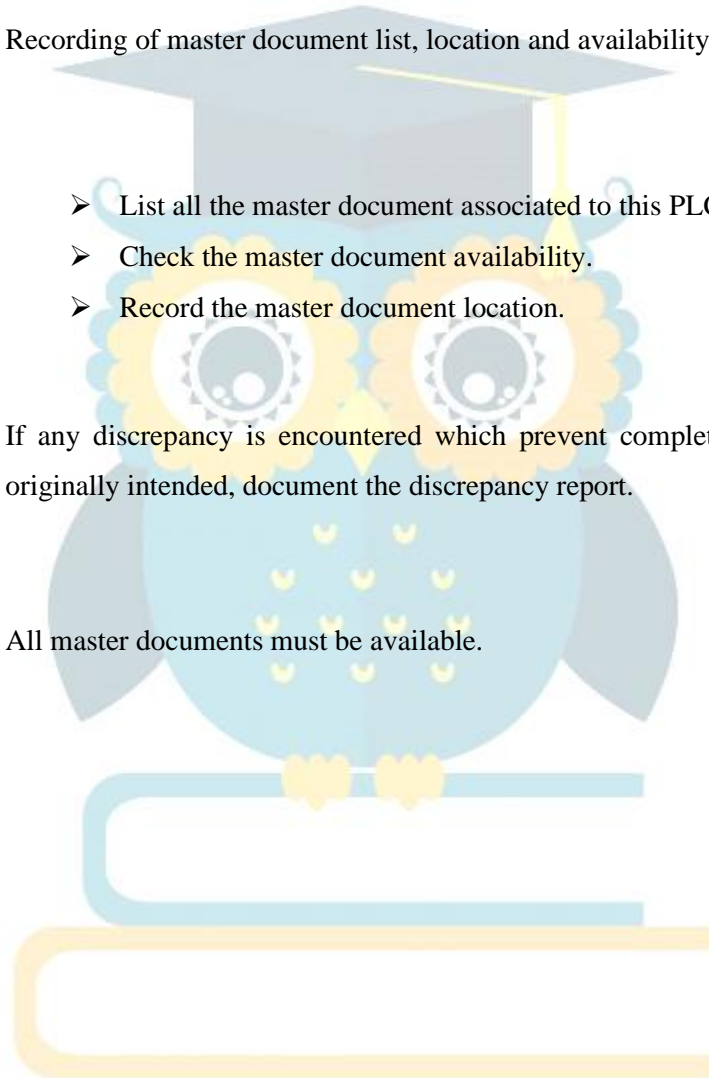
**Procedure** :

- List all the master document associated to this PLC system.
- Check the master document availability.
- Record the master document location.

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

**Acceptance** : All master documents must be available.

**Criteria**





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**3.2.1 DATA TABLE OF MASTER DOCUMENTS**

Sr. No	Master Document Title	Availability Yes/No	Controlled Location	Meets acceptance criteria:	Sign. & date
1	Machine Operation Manual			Yes ( ) No ( )	
2	PLC System Bill of Material			Yes ( ) No ( )	
3	PLC Specification			Yes ( ) No ( )	
4	HMI Specification			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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**3.3.0 VERIFICATION OF MASTER TEST INSTRUMENTS**

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

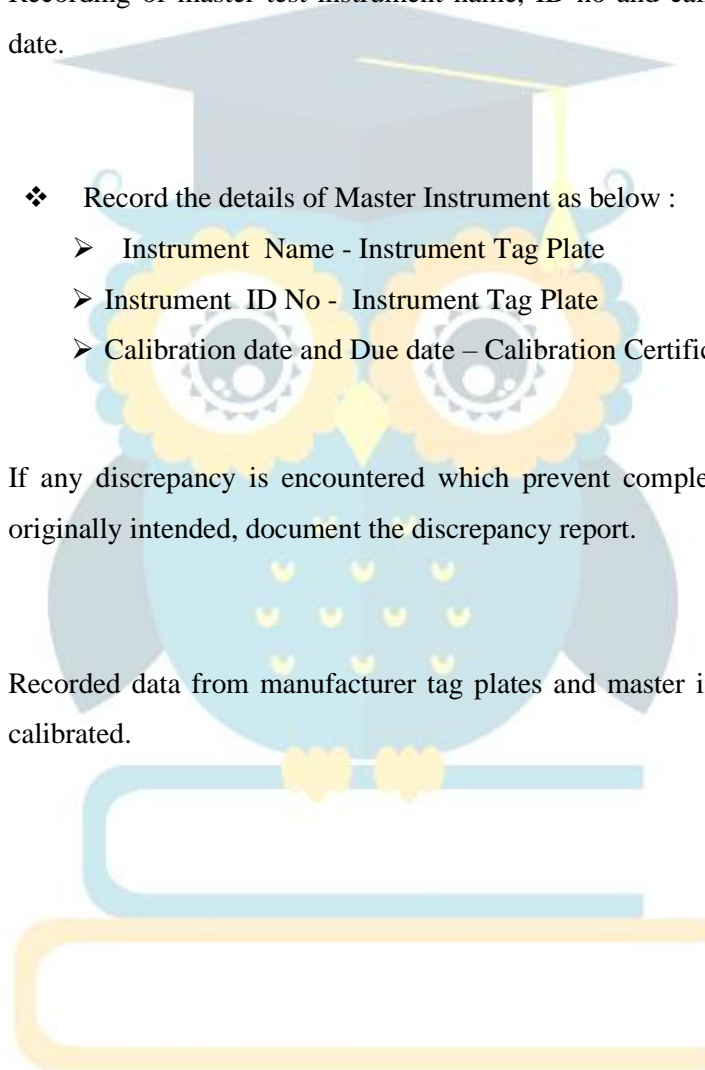
**Scope** : Recording of master test instrument name, ID no and calibration date and due date.

**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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**3.3.1 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	



**INSTALLATION QUALIFICATION DOCUMENT OF PLC SYSTEM  
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**3.4.0 VERIFICATION OF AMBIENT TEMPERATURE AND HUMIDITY CONDITIONS**

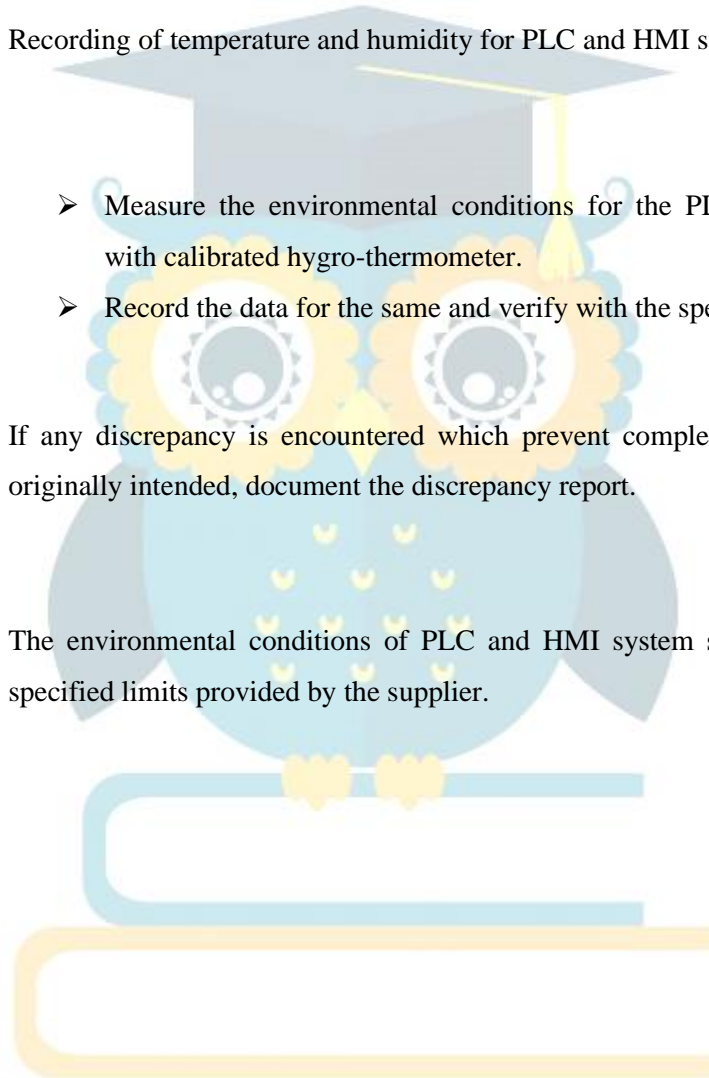
**Purpose** : To verify proper ambient temperature and humidity conditions for PLC and HMI system.

**Scope** : Recording of temperature and humidity for PLC and HMI system.

**Procedure** :  
➤ Measure the environmental conditions for the PLC and HMI system with calibrated hygro-thermometer.  
➤ Record the data for the same and verify with the specified conditions.

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

**Acceptance Criteria** : The environmental conditions of PLC and HMI system should be within the specified limits provided by the supplier.





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**3.4.1 DATA SHEET OF AMBIENT TEMPERATURE AND HUMIDITY CONDITIONS**

❖ **Temperature condition for PLC :-**

Specified temperature range :- 0°C to 55 °C

Field measured temperature :- \_\_\_\_\_

❖ **Temperature condition for HMI :-**

Specified temperature range :- 0°C to 50°C

Field measured temperature :- \_\_\_\_\_

❖ **Relative Humidity condition for PLC :-**

Specified humidity range :- 5% - 95% (without condensation)

Field measured humidity: - \_\_\_\_\_

❖ **Relative Humidity condition for HMI :-**

Specified humidity range :- 5% - 85% (without condensation)

Field measured humidity: - \_\_\_\_\_

**Meets acceptance criteria: 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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**3.5.0 VERIFICATION OF SCHEMATIC DIAGRAM & ELECTRICAL WIRING DIAGRAM**

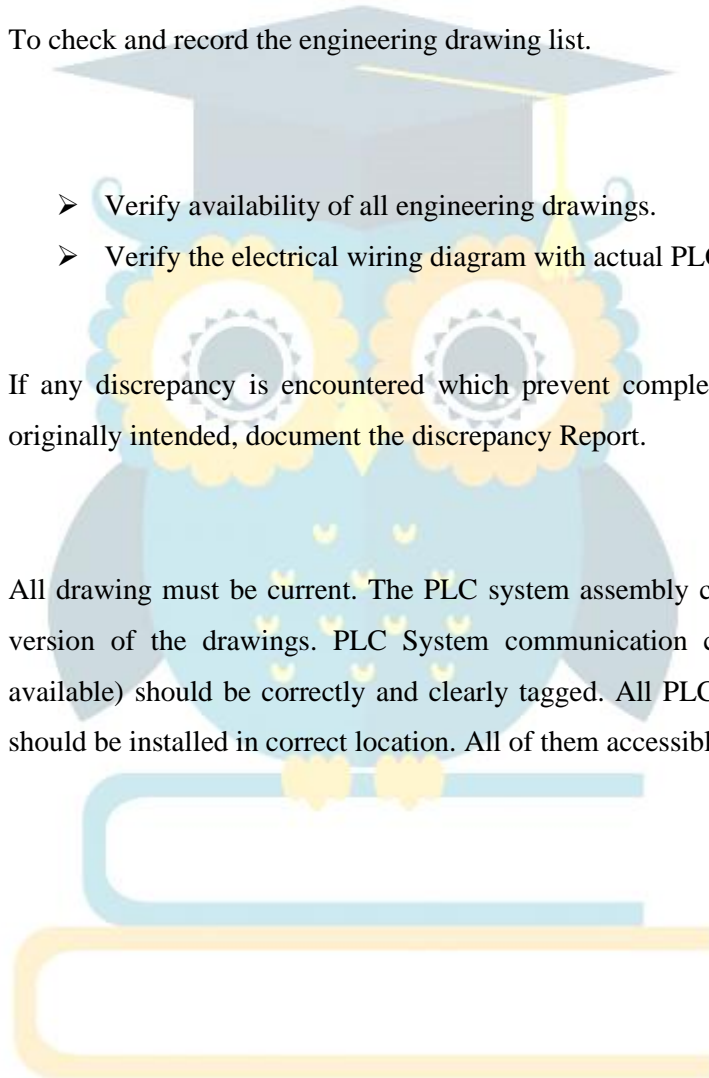
**Purpose** : To verify and check schematic diagram and electrical wiring diagram of PLC system.

**Scope** : To check and record the engineering drawing list.

**Procedure** :  
➤ Verify availability of all engineering drawings.  
➤ Verify the electrical wiring diagram with actual PLC system.

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

**Acceptance Criteria** : All drawing must be current. The PLC system assembly conforms to the latest version of the drawings. PLC System communication cable and printer (if available) should be correctly and clearly tagged. All PLC system components should be installed in correct location. All of them accessible and readable.





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**3.5.1 DATA TABLE OF SCHEMATIC DIAGRAM & ELECTRICAL WIRING DIAGRAM**

Sr. No	Details	Drawing No/ Document Availability Yes/No	Location	Meets acceptance criteria:	Sign. & date
1	Schematic diagram			Yes ( ) No ( )	
2	Electrical wiring diagram			Yes ( ) No ( )	

**Comments/ Remarks:**

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Tested by		Engineering	
Verified by		Engineering	
Reviewed by		QA	



**INSTALLATION QUALIFICATION DOCUMENT OF PLC SYSTEM  
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**3.6.0 VERIFICATION OF PLC SYSTEM HARDWARE COMPONENTS**

**Purpose** : Verify the hardware components of PLC system.

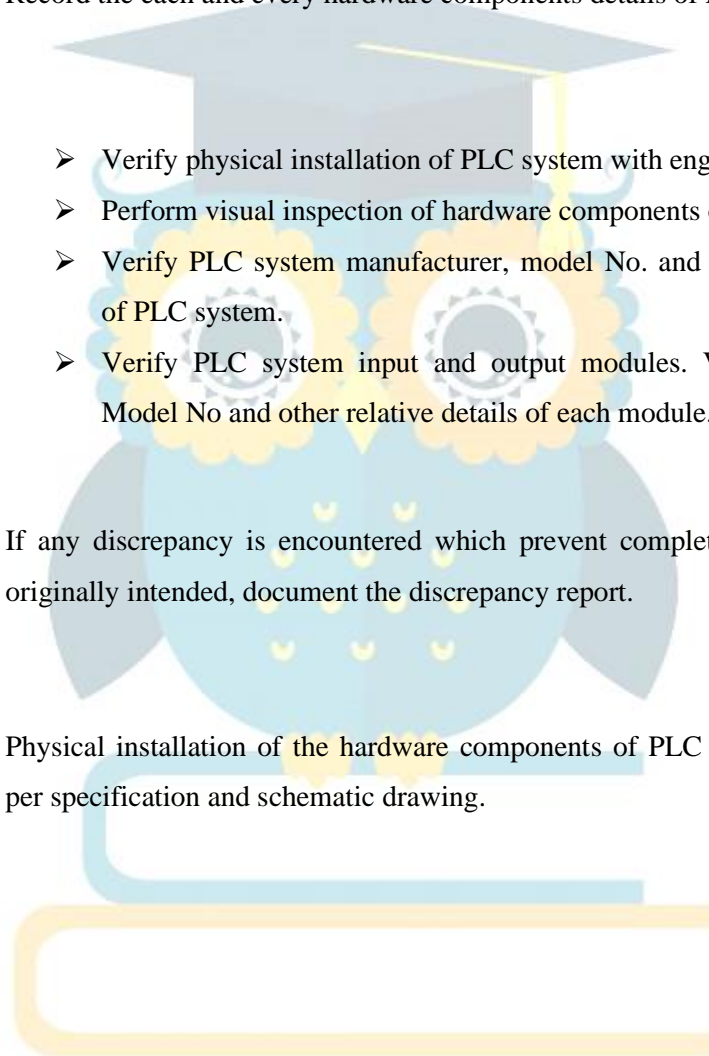
**Scope** : Record the each and every hardware components details of PLC system.

**Procedure** :

- Verify physical installation of PLC system with engineering drawing.
- Perform visual inspection of hardware components of PLC system.
- Verify PLC system manufacturer, model No. and other relative details of PLC system.
- Verify PLC system input and output modules. Verify manufacturer, Model No and other relative details of each module.

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

**Acceptance Criteria** : Physical installation of the hardware components of PLC system should be as per specification and schematic drawing.





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**3.6.1 DATA TABLE OF HARDWARE COMPONENTS**

Description	Manufacturer Specification	Actual Observation	Meets acceptance criteria:	Sign. & date
<b><u>PLC Processor Unit</u></b>				
Manufacturer	Delta		Yes ( ) No ( )	
Model No.	DVP 12SA211T		Yes ( ) No ( )	
No. of digital inputs	07		Yes ( ) No ( )	
No. of digital Outputs	04		Yes ( ) No ( )	
<b><u>HMI Display</u></b>				
Manufacturer	Delta		Yes ( ) No ( )	
Make	DOP-B03S211		Yes ( ) No ( )	
<b><u>Power Supply Unit (SMPS)</u></b>				
Manufacturer	Lubi		Yes ( ) No ( )	
Type	LB-24-045		Yes ( ) No ( )	
<b><u>Communication Cable (PLC to HMI)</u></b>				
Manufacturer	Delta		Yes ( ) No ( )	
Port No.	RS232		Yes ( ) No ( )	



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**Comments/ Remarks:**

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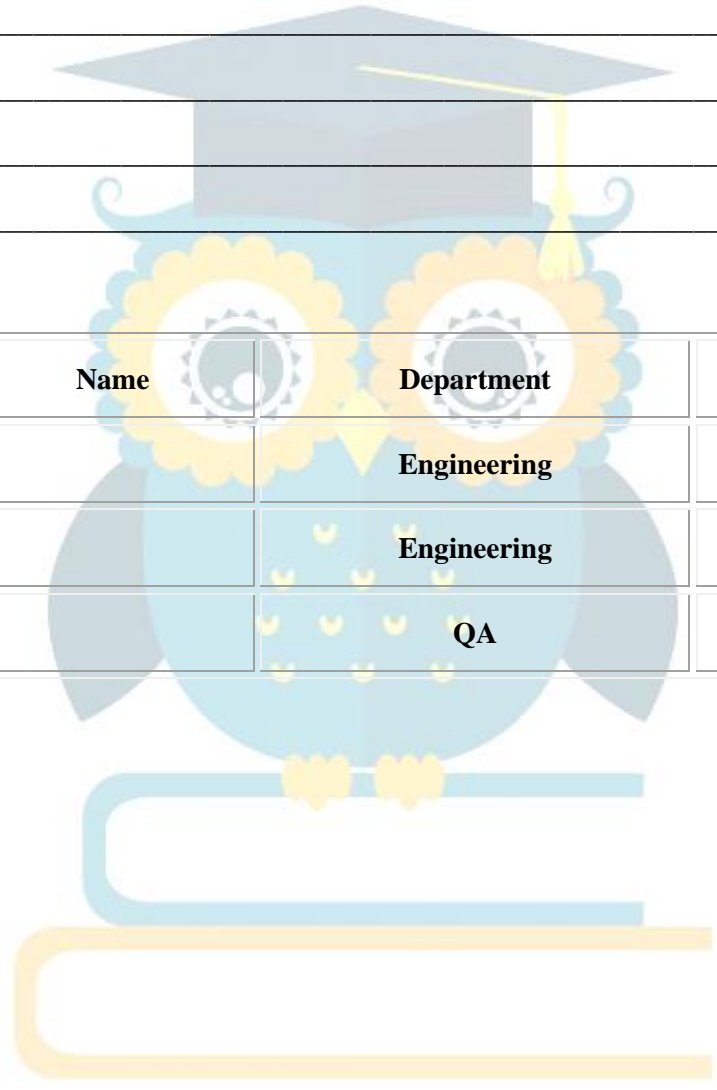
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Verified by		Engineering	
Reviewed by		QA	







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**3.7.0 VERIFICATION OF PLC SYSTEM INPUT/OUTPUT ADDRESS**

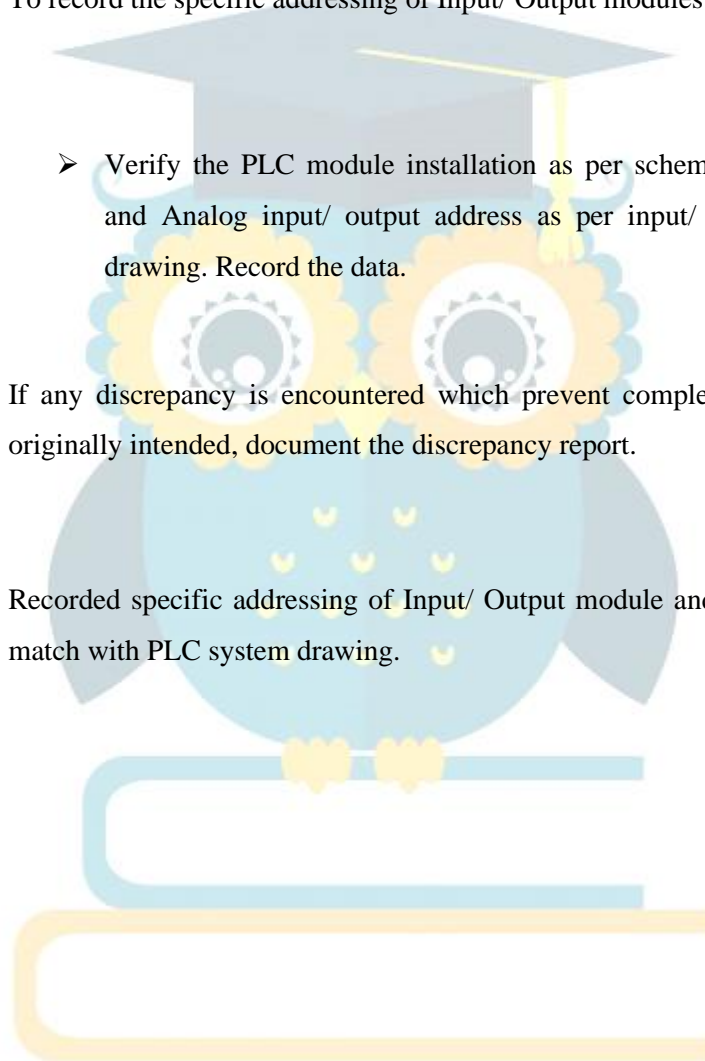
**Purpose** : Verify the Input/ Output address of PLC system.

**Scope** : To record the specific addressing of Input/ Output modules and PLC system.

**Procedure** : ➤ Verify the PLC module installation as per schematic drawing, Digital and Analog input/ output address as per input/ output list and PLC drawing. Record the data.

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

**Acceptance Criteria** : Recorded specific addressing of Input/ Output module and PLC system should match with PLC system drawing.





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**3.7.1 DATA TABLE OF PLC SYSTEM INPUT/ OUTPUT ADDRESS**

Module	Model No.	Addressing	Actual Observation	Meets acceptance criteria:	Sign. & date
Main PLC	DVP-12SA211T	<u>Digital Inputs</u> X0-X6,		Yes ( ) No ( )	
		<u>Digital Outputs</u> Y0-Y3,		Yes ( ) No ( )	

**Comments/ Remarks:**

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



**INSTALLATION QUALIFICATION DOCUMENT OF PLC SYSTEM  
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**3.8.0 VERIFICATION OF PLC SYSTEM POWER SUPPLY**

**Purpose** : Verify the power supply of PLC System.

**Scope** : Measure the power supply of PLC system

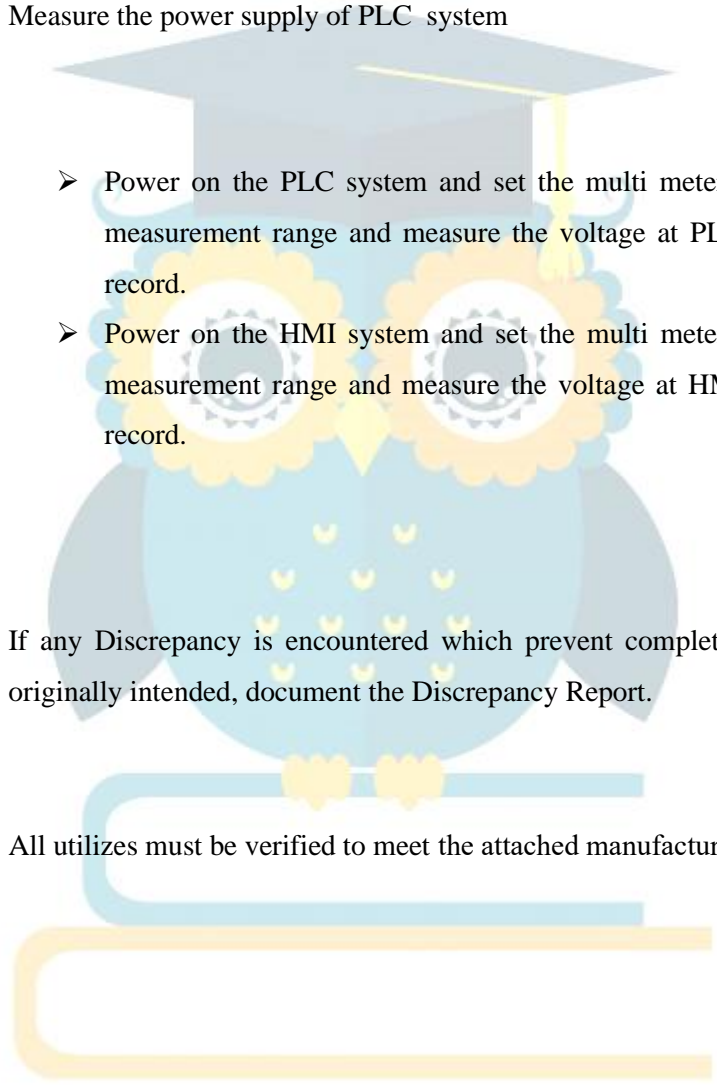
**Procedure** :

- Power on the PLC system and set the multi meter in AC/DC voltage measurement range and measure the voltage at PLC terminal end and record.
- Power on the HMI system and set the multi meter in AC/DC voltage measurement range and measure the voltage at HMI terminal end and record.

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

**Acceptance** : All utilizes must be verified to meet the attached manufacturer's specification.

**Criteria**





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**3.8.1 DATA SHEET OF PLC SYSTEM POWER SUPPLY**

◆ **PLC RATING:-**

Specified Voltage range: 24 VDC Field Measurement Voltage:- \_\_\_\_\_ VAC

◆ **HMI RATING:-**

Specified Voltage range: 24 VDC Field Measurement Voltage:- \_\_\_\_\_ VDC

**Meets acceptance criteria: Yes ( ) No ( )**

**Comments/ Remarks:**

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



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

**3.9.0 VERIFICATION OF PHYSICAL AND LOGICAL SECURITY / ACCESS CONTROL OF PLC SYSTEM**

**Purpose** : Verify the physical and logical security / access control of the PLC system.

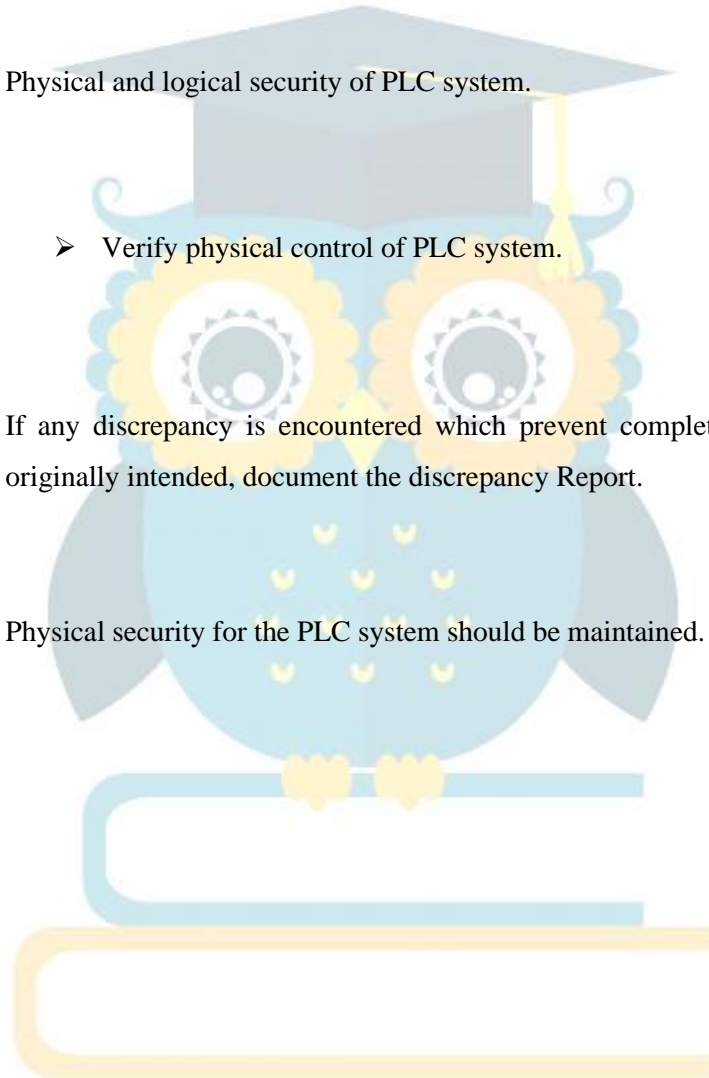
**Scope** : Physical and logical security of PLC system.

**Procedure** : ➤ Verify physical control of PLC system.

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

**Acceptance** : Physical security for the PLC system should be maintained.

**Criteria**





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

**3.9.1 DATA TABLE OF PHYSICAL SECURITY FOR PLC SYSTEM**

Sr. No	System	Physical security available Yes / No	Meets acceptance criteria:	Sign. & date
1	PLC		Yes ( ) No ( )	
2	HMI		Yes ( ) No ( )	

**Comments/ Remarks:**

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



**INSTALLATION QUALIFICATION DOCUMENT OF PLC SYSTEM  
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**3.10.0 VERIFICATION OF PLC AND HMI SOFTWARE**

**Purpose** : Verify the software of PLC and HMI system.

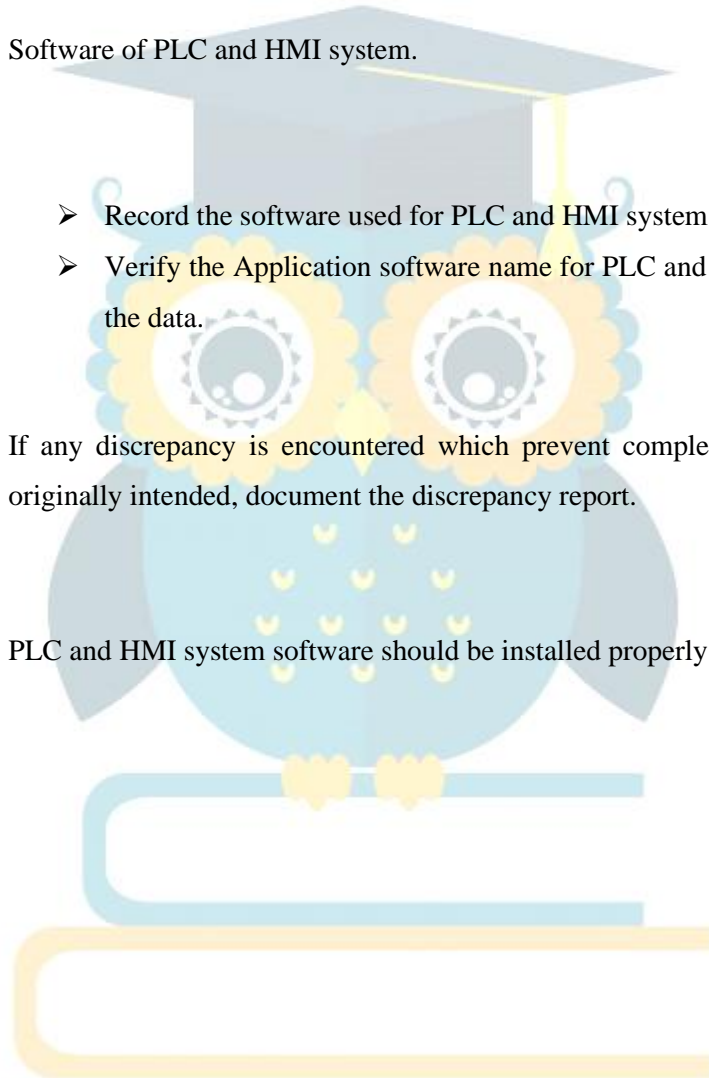
**Scope** : Software of PLC and HMI system.

**Procedure** :  
➤ Record the software used for PLC and HMI system  
➤ Verify the Application software name for PLC and HMI system. Record the data.

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

**Acceptance** : PLC and HMI system software should be installed properly.

**Criteria**





**INSTALLATION QUALIFICATION DOCUMENT OF PLC SYSTEM  
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**3.10.0 DATA TABLE OF PLC AND HMISOFTWARE**

System	Specified	Actual Observation	Meets acceptance criteria:	Sign. & date
<b><u>PLC SYSTEM</u></b>				
Application Software Name	WPL Soft		Yes ( ) No ( )	
Version	2.4.1		Yes ( ) No ( )	
<b><u>HMI SYSTEM</u></b>				
Application Software Name	DOP-B Soft		Yes ( ) No ( )	
Version	1.2		Yes ( ) No ( )	

**Comments/ Remarks:**

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





**INSTALLATION QUALIFICATION DOCUMENT OF PLC SYSTEM  
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**3.11.0 VERIFICATION OF STANDARD OPERATION PROCEDURE**

**Purpose** : Verify the document that the SOP's for the PLC system.

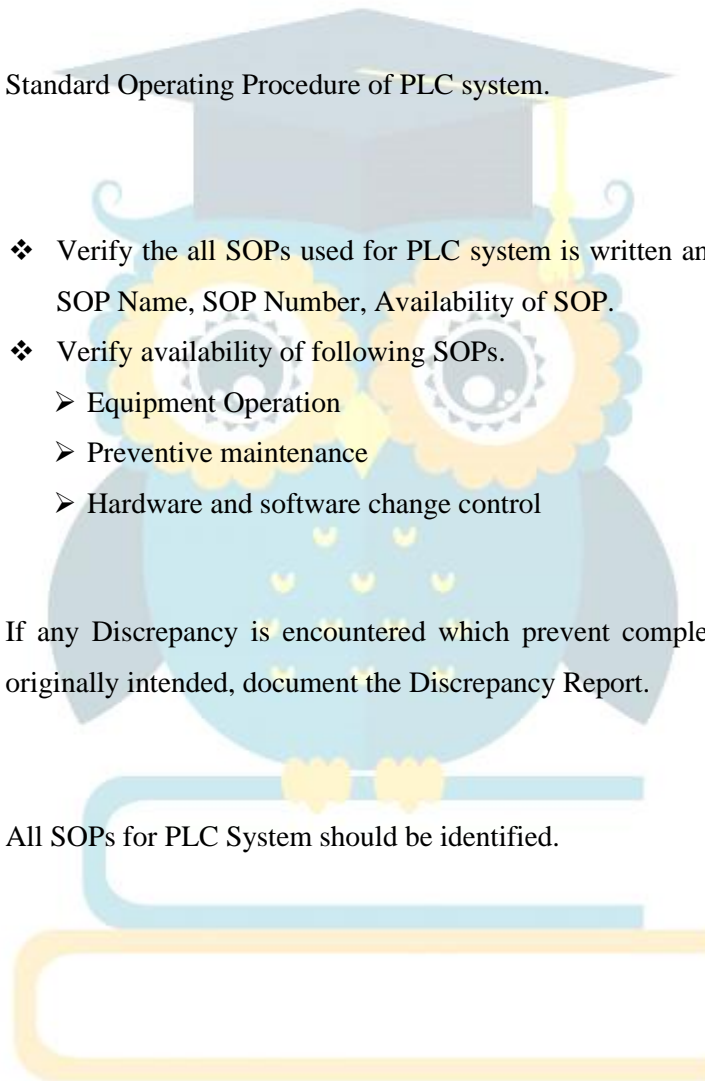
**Scope** : Standard Operating Procedure of PLC system.

**Procedure** :  
❖ Verify the all SOPs used for PLC system is written and currently effective, SOP Name, SOP Number, Availability of SOP.  
❖ Verify availability of following SOPs.  
➤ Equipment Operation  
➤ Preventive maintenance  
➤ Hardware and software change control

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

**Acceptance** : All SOPs for PLC System should be identified.

**Criteria**





**INSTALLATION QUALIFICATION DOCUMENT OF PLC SYSTEM  
FOR  
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**3.11.1 DATA TABLE OF STANDARD OPERATING PROCEDURE**

Sr. No	SOP Name	SOP Number	Availability Yes/No	Meets acceptance criteria:	Sign. & date
1	Equipment Operation Procedure			Yes ( ) No ( )	
2	Preventive Maintenance			Yes ( ) No ( )	
3	Hardware and software change control			Yes ( ) No ( )	

**Comments/ Remarks:**

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



**INSTALLATION 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



**INSTALLATION QUALIFICATION DOCUMENT OF PLC SYSTEM  
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**5.0.0 SUMMARY REPORT**

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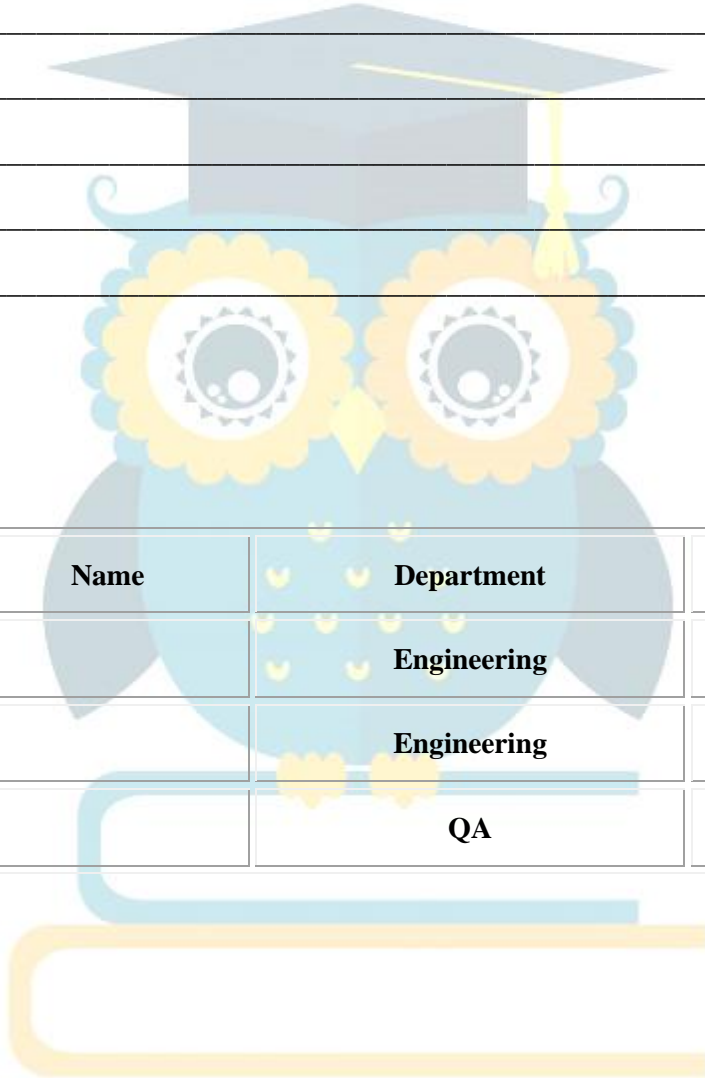
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<b>Function</b>	<b>Name</b>	<b>Department</b>	<b>Sign. &amp; Date</b>
<b>Tested by</b>		<b>Engineering</b>	
<b>Verified by</b>		<b>Engineering</b>	
<b>Reviewed by</b>		<b>QA</b>	





**INSTALLATION QUALIFICATION DOCUMENT OF PLC SYSTEM  
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**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.

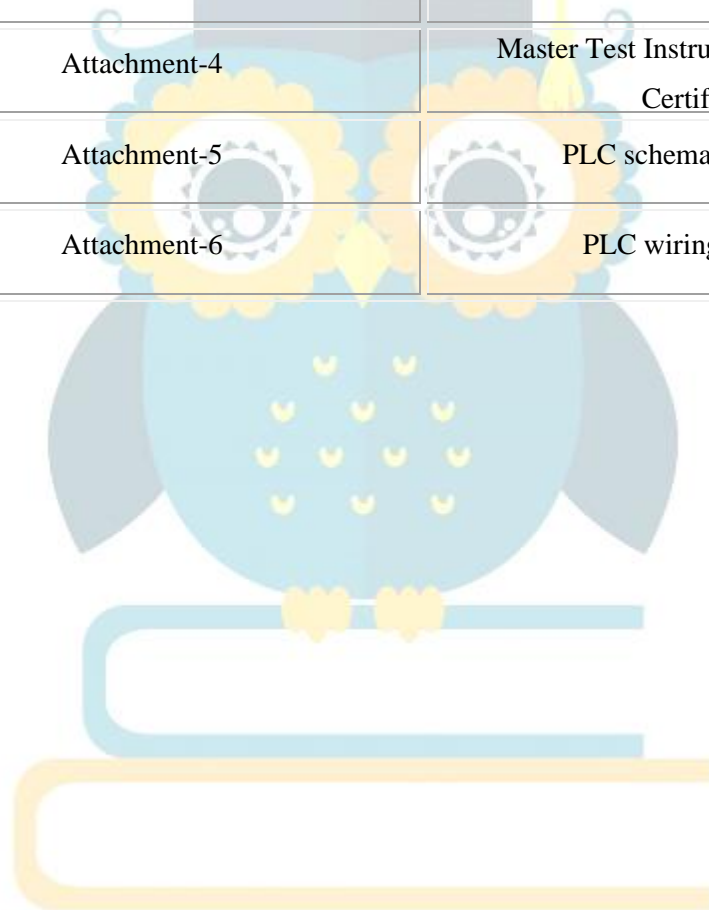
❖ **SOP :Standard Operating Procedure**



**INSTALLATION QUALIFICATION DOCUMENT OF PLC SYSTEM  
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**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	PLC system bill of material
2	Attachment-2	PLC specifications
3	Attachment-3	HMI specifications
4	Attachment-4	Master Test Instrument Calibration Certificate
5	Attachment-5	PLC schematic diagram
6	Attachment-6	PLC wiring diagram





**INSTALLATION 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>IQ</b>	→ <b>I</b> nstallation <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





**INSTALLATION QUALIFICATION DOCUMENT OF PLC SYSTEM  
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**9.0.0 POST APPROVAL SIGNATURES**

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

Function	Name	Department	Designation	Signature/Date
Checked 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	