



**INSTALLATION QUALIFICATION DOCUMENT OF PLC SYSTEM FOR DOUBLE SIDE
ROTARY TABLET COMPRESSION M/C 45 STN (ACCURA PRESS IV)**

**INSTALLATION QUALIFICATION DOCUMENT OF PLC
SYSTEM FOR DOUBLE SIDE ROTARY TABLET
COMPRESSION M/C 45 STN (ACCURA PRESS IV)**

System Name	DOUBLE SIDE ROTARY TABLET COMPRESSION M/C 45 STN (ACCURA PRESS IV)
System ID
Location	COMPRESSION
Effective Date	



**INSTALLATION QUALIFICATION DOCUMENT OF PLC SYSTEM FOR DOUBLE SIDE
ROTARY TABLET COMPRESSION M/C 45 STN (ACCURA PRESS IV)**

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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	



INSTALLATION QUALIFICATION DOCUMENT OF PLC SYSTEM FOR DOUBLE SIDE ROTARY TABLET COMPRESSION M/C 45 STN (ACCURA PRESS IV)

2.0.0 GENERAL:

2.1.0 PURPOSE:

The purpose of this qualification document is to verify and document that the PLC system of “**Double Side Rotary Tablet Compression M/C 45 STN (Accura Press IV)**” 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 “**Double Side Rotary Tablet Compression M/C 45 STN (Accura Press IV)**” which is located in “Compression-1”.

This installation qualification document describes the PLC system hardware and software, equipment details, test procedures, documentation, references and acceptance criteria used to establish that “**Double Side Rotary Tablet Compression M/C 45 STN (Accura Press IV)**” has been installed in accordance with the master documentations.

2.3.0 BACKGROUND:

The “**Double Side Rotary Tablet Compression M/C 45 STN (Accura Press IV)**” 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.

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



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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: _____

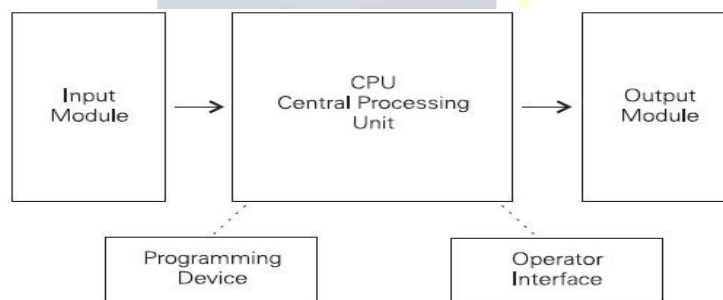


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2.9.0 PLC DESCRIPTION:

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

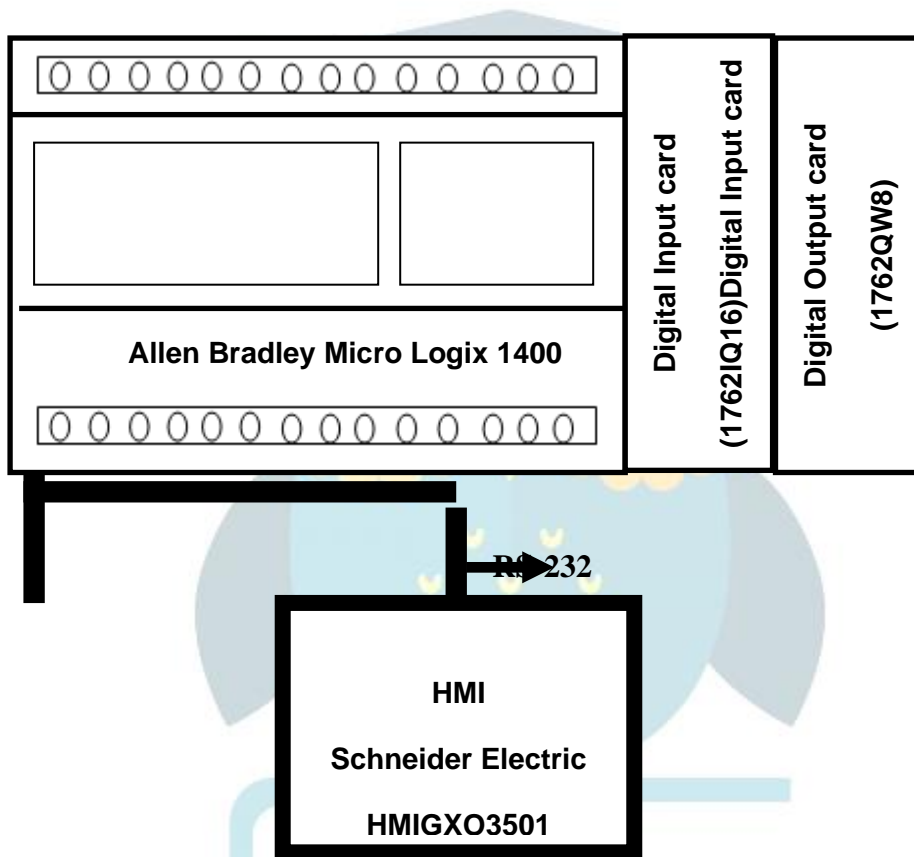
The PLC Based control system should have capability to control Double Side Rotary Tablet Compression M/C 45 STN (Accura Press). Purpose of the PLC system is to monitor, operate and control the machine. PLC System gets Digital signal from Field devices like Servo O/P signal, Proxy, HYD. Trip, VFD1 trip, VFD2 trip, F1 O/L, F2 O/L, E. Stop, LHS main Press OK, RHS Main Press OK, LHS Guard, RHS Guard, Lub. Oil level ok, Hyd. Press switch, LH PWD level, RH PWD level, Dust EXT., LHS Dozzer Present, RHS Dozzer Present, LHS Pre Press OK, RHS Pre Press OK, Front Guard, Rear Guard, LH MIN, LH MAX, RH MIN, RH MAX. The data is processed in CPU of PLC and give Output as per the logics of Control like SER 1 80, SER 1 81, SER 1 82, SER 1 83, VFD1, Clutch , F1, F2, HYD., DEC Valve , LUB. Valve buzzer etc



INSTALLATION QUALIFICATION DOCUMENT OF PLC SYSTEM FOR DOUBLE SIDE ROTARY TABLET COMPRESSION M/C 45 STN (ACCURA PRESS IV)

2.11.0 PLC SYSTEM SCHEMATIC DIAGRAM

The PLC system schematic diagram for the “Double Side Rotary Tablet Compression M/C 45 STN (Accura Press IV)” automation is given below:





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INSTALLATION QUALIFICATION TEST POINTS:

<u>Sr. No.</u>	<u>Test Details</u>
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
11	VERIFICATION OF STANDARD OPERATION PROCEDURE



INSTALLATION QUALIFICATION DOCUMENT OF PLC SYSTEM FOR DOUBLE SIDE ROTARY TABLET COMPRESSION M/C 45 STN (ACCURA PRESS IV)

3.0.0 IDENTIFICATION OF THE SYSTEMS GOING FOR VALIDATION

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

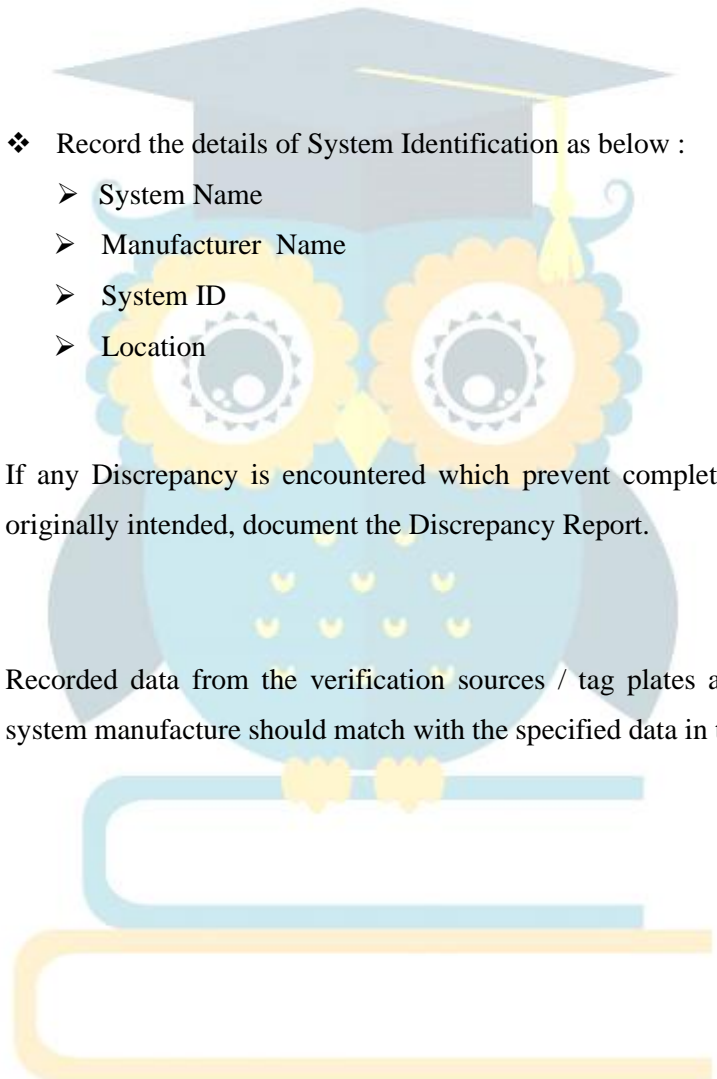
Scope : Recording of System details system Name, ID No., Manufacturer and location.

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	Double Side Rotary Tablet Compression M/C 45 STN (Accura Press IV)		Yes () No ()	
2	System Manufacturer	Fluidpack		Yes () No ()	
3	System ID No.		Yes () No ()	
4	System Location	Compression-1		Yes () No ()	

Comments/ Remarks:

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



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3.1.0 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.

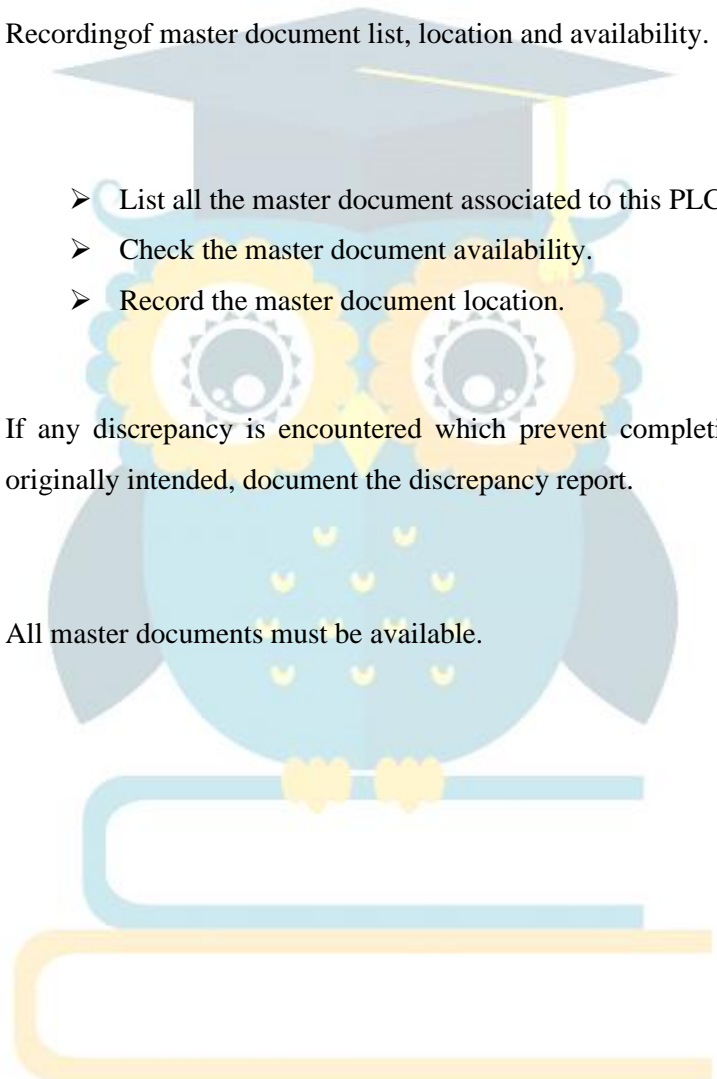
Procedure :

- 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





INSTALLATION QUALIFICATION DOCUMENT OF PLC SYSTEM FOR DOUBLE SIDE ROTARY TABLET COMPRESSION M/C 45 STN (ACCURA PRESS IV)

3.1.1 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:

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



**INSTALLATION QUALIFICATION DOCUMENT OF PLC SYSTEM FOR DOUBLE SIDE
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3.2.0 VERIFICATION OF MASTER TEST INSTRUMENTS

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

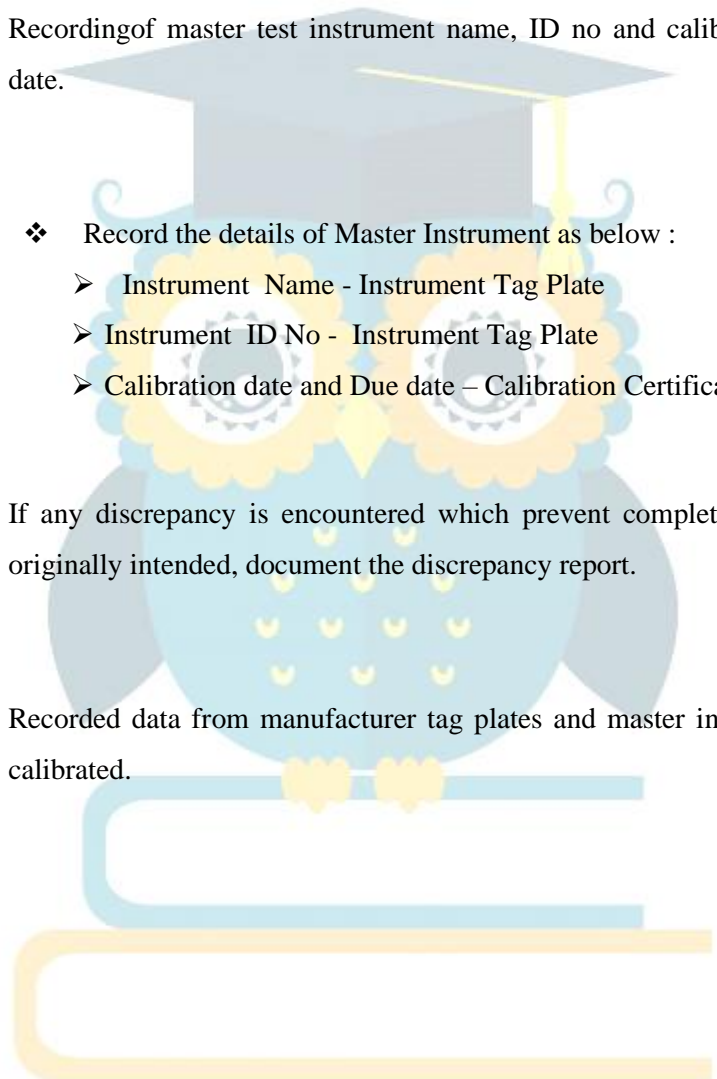
Scope : Recording of master test instrument name, ID no and calibration date and due date.

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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3.2.1 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:

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



**INSTALLATION QUALIFICATION DOCUMENT OF PLC SYSTEM FOR DOUBLE SIDE
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3.3.0 VERIFICATION OF AMBIENT TEMPERATURE AND HUMIDITY CONDITIONS

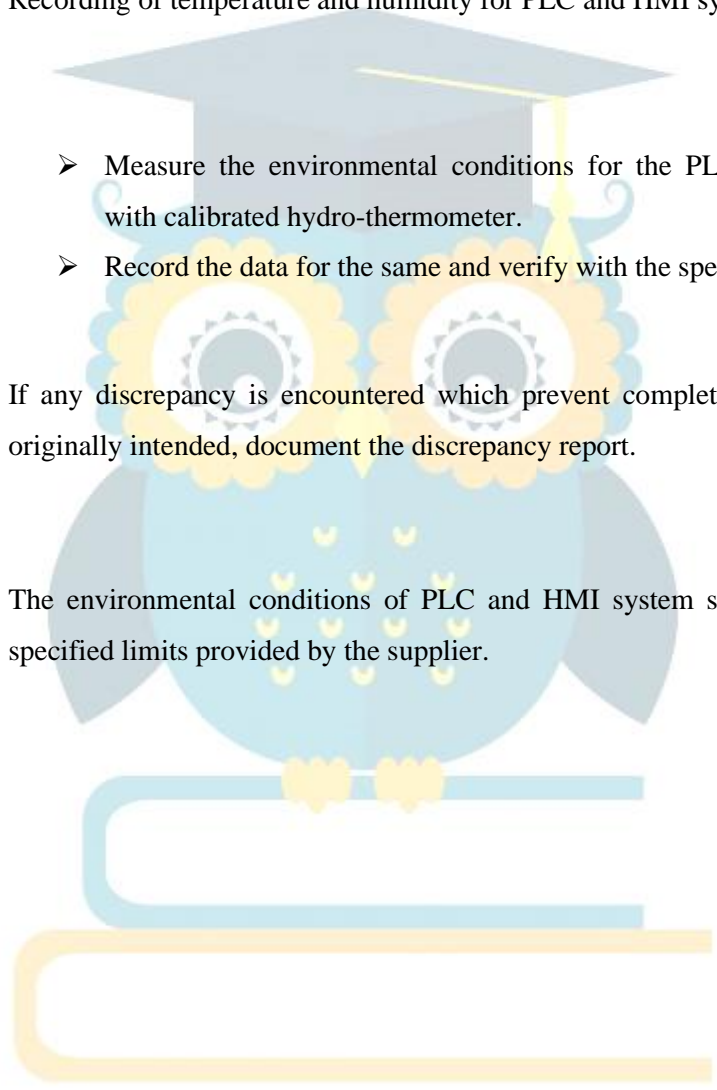
Purpose : To verify proper ambient temperature and humidity conditions for PLC and HMI system.

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

Procedure :
➤ Measure the environmental conditions for the PLC and HMI system with calibrated hydro-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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3.3.1 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 :-10% - 85% (without condensation)

Field measured humidity: - _____

Meets acceptance criteria: Yes () No ()

Comments/ Remarks:

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



INSTALLATION QUALIFICATION DOCUMENT OF PLC SYSTEM FOR DOUBLE SIDE ROTARY TABLET COMPRESSION M/C 45 STN (ACCURA PRESS IV)

3.4.0 VERIFICATION OF SCHEMATIC DIAGRAM & ELECTRICAL WIRING DIAGRAM

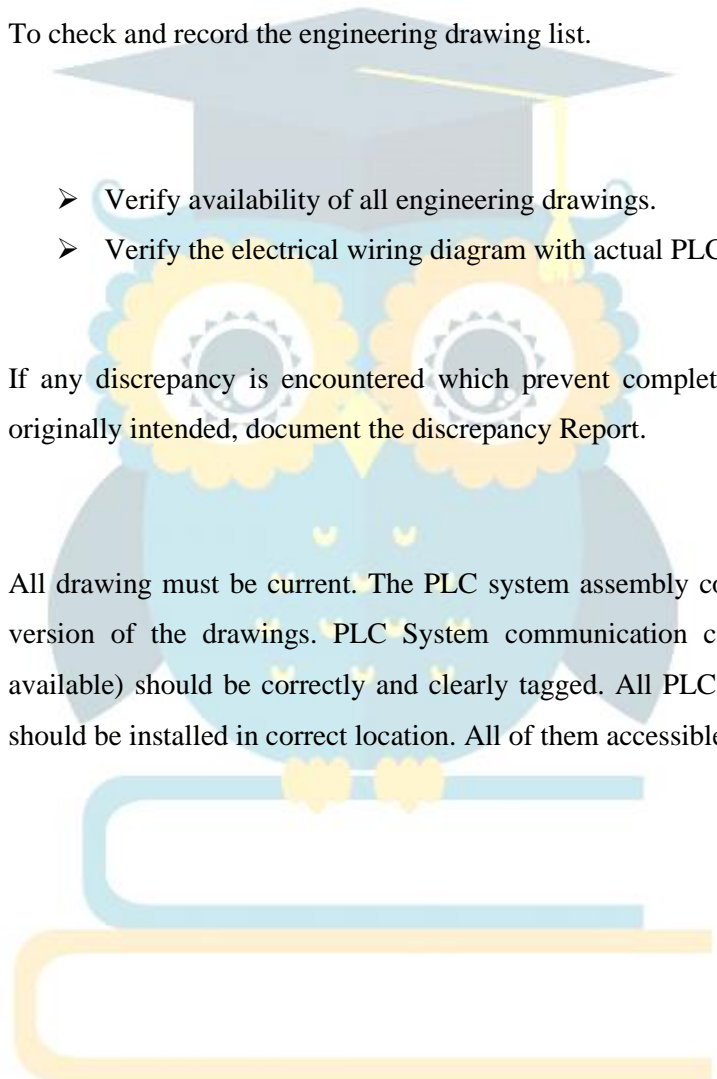
Purpose : To verify and check schematic diagram and electrical wiring diagram of PLC system.

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.





INSTALLATION QUALIFICATION DOCUMENT OF PLC SYSTEM FOR DOUBLE SIDE ROTARY TABLET COMPRESSION M/C 45 STN (ACCURA PRESS IV)

3.4.1 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:

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



**INSTALLATION QUALIFICATION DOCUMENT OF PLC SYSTEM FOR DOUBLE SIDE
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3.5.0 VERIFICATION OF PLC SYSTEM HARDWARE COMPONENTS

Purpose : Verify the hardware components of PLC system.

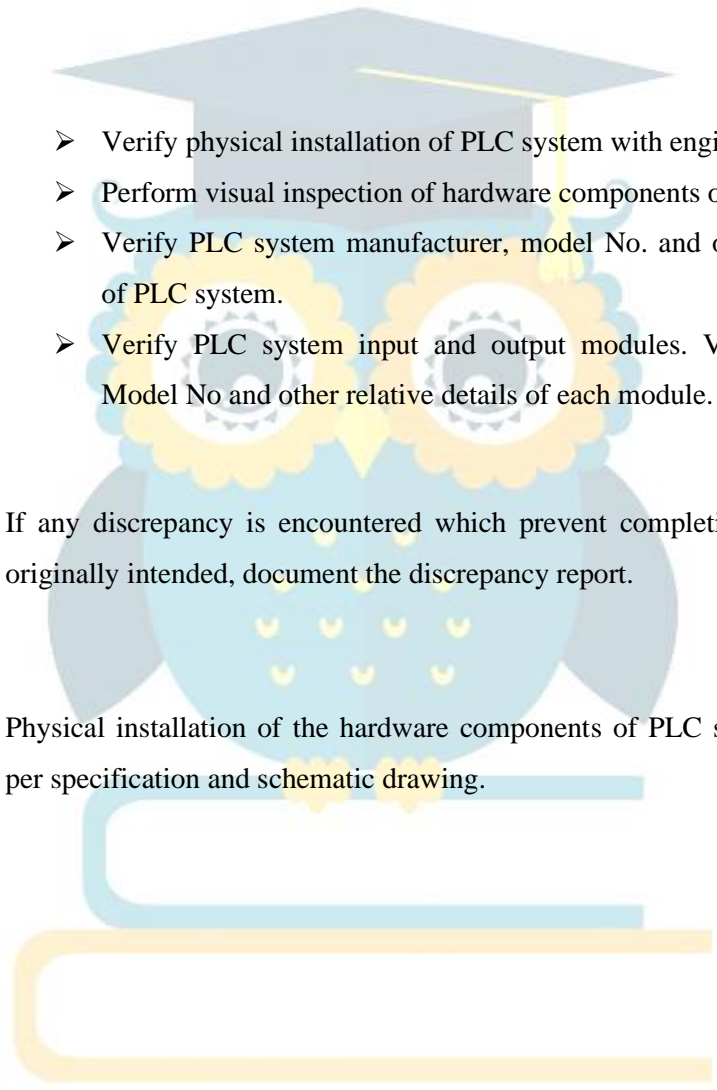
Scope : Record the each and every hardware components details of PLC system.

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.





INSTALLATION QUALIFICATION DOCUMENT OF PLC SYSTEM FOR DOUBLE SIDE ROTARY TABLET COMPRESSION M/C 45 STN (ACCURA PRESS IV)

3.5.1 DATA TABLE OF HARDWARE COMPONENTS

Description	Manufacturer Specification	Actual Observation	Meets acceptance criteria	Sign. & date
PLC Processor Unit				
Manufacturer	Allen Bradley		Yes () No ()	
Model No.	Micro Logix 1400		Yes () No ()	
No. of Digital Inputs	20		Yes () No ()	
No. of Digital Outputs	12		Yes () No ()	
No. of Analog Inputs	04		Yes () No ()	
No. of Analog Outputs	02		Yes () No ()	
Digital Input Card				
Manufacturer	Allen Bradley		Yes () No ()	
Model No.	1762 IQ 16		Yes () No ()	
No. of Digital Inputs	16		Yes () No ()	
Digital Output Card				
Manufacturer	Allen Bradley		Yes () No ()	
Model No.	1762 QW8		Yes () No ()	
No. of Digital Output	08		Yes () No ()	



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Description	Manufacturer Specification	Actual Observation	Meets acceptance criteria	Sign. & date
Analog Input & Output Card				
Manufacturer	Allen Bradley		Yes () No ()	
Model No.	1762 IF2OF2		Yes () No ()	
No .of Analog Input	02		Yes () No ()	
No. of Analog Output	02		Yes () No ()	
HMI				
Manufacturer	Schneider Electric		Yes () No ()	
Model No.	HMIGX03501		Yes () No ()	
PLC-HMI Communication cable				
Manufacturer	Allen Bradley		Yes () No ()	
Type	RS232		Yes () No ()	
Power Supply				
Manufacturer	Mean well		Yes () No ()	
Model No.	PR-120-24		Yes () No ()	



PHARMA SCHOLARS

QUALITY ASSURANCE DEPARTMENT

PROTOCOL No.:

.....

REVISION No: 00

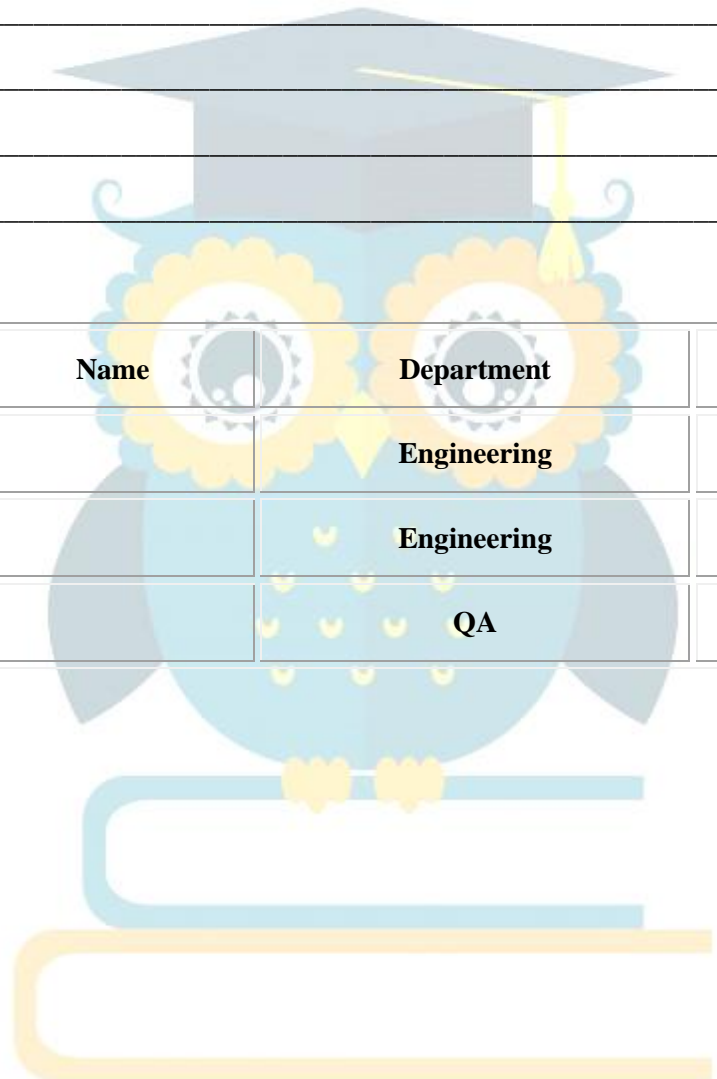
EFFECTIVE DATE:

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Comments/ Remarks:

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





**INSTALLATION QUALIFICATION DOCUMENT OF PLC SYSTEM FOR DOUBLE SIDE
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3.6.0 VERIFICATION OF PLC SYSTEM INPUT/OUTPUT ADDRESS

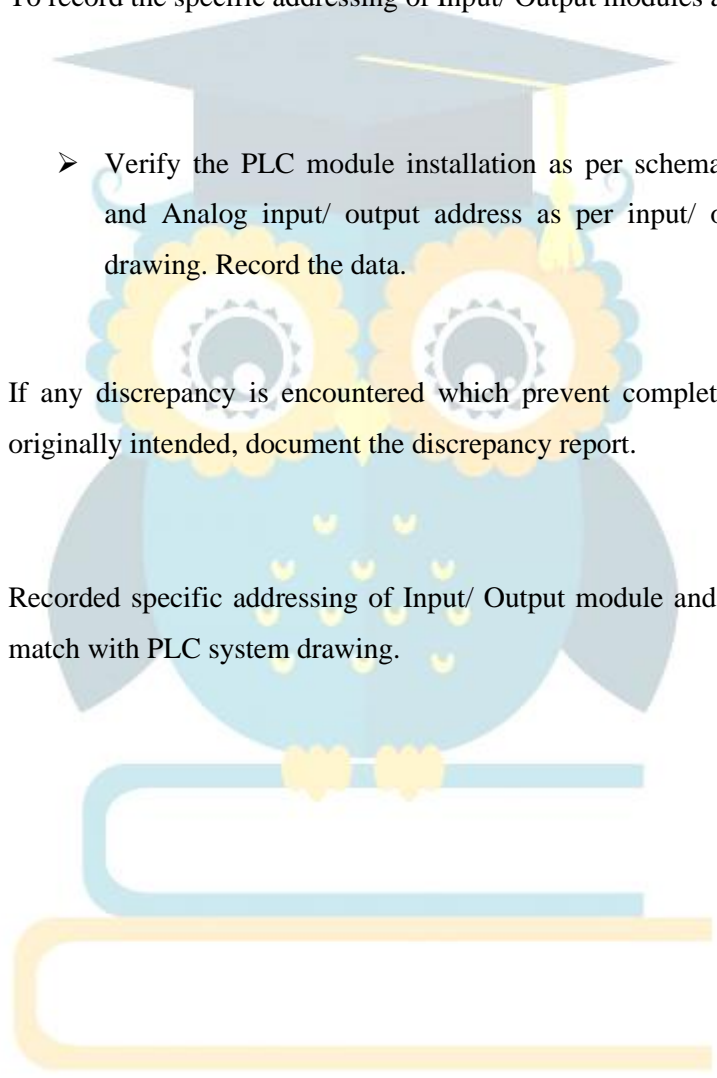
Purpose : Verify the Input/ Output address of PLC system.

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.





INSTALLATION QUALIFICATION DOCUMENT OF PLC SYSTEM FOR DOUBLE SIDE ROTARY TABLE COMPRESSION M/C 45 STN (ACCURA PRESS IV)

3.6.1 DATA TABLE OF PLC SYSTEM INPUT/ OUTPUT ADDRESS

Module	Model No.	Addressing	Actual Observation	Meets acceptance criteria:	Sign. & date
PLC	Allen Bradley Micro Logix 14000	<u>Digital Inputs</u> IN0-IN19,		Yes () No ()	
		<u>Digital Outputs</u> OUT0-OUT11,			
		<u>Analog Input</u> IN1-IN4			
		<u>Analog Output</u> OUT1-OUT2			
Digital Input card	1762 IQ16	<u>Digital Inputs</u> IN0-IN15		Yes () No ()	
Digital Output card	1762 OW8	<u>Digital Outputs</u> OUT0-OUT7		Yes () No ()	



PHARMA SCHOLARS

QUALITY ASSURANCE DEPARTMENT

PROTOCOL No.:

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Module	Model No.	Addressing	Actual Observation	Meets acceptance criteria:	Sign. & date
Analog Input & Output Card	IF2OF2	Analog input IN0 to IN1		Yes () No ()	
		Analog Output Out0 to Out1			

Comments/ Remarks:

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



**INSTALLATION QUALIFICATION DOCUMENT OF PLC SYSTEM FOR DOUBLE SIDE
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3.7.0 VERIFICATION OF PLC SYSTEM POWER SUPPLY

Purpose : Verify the power supply of PLC System.

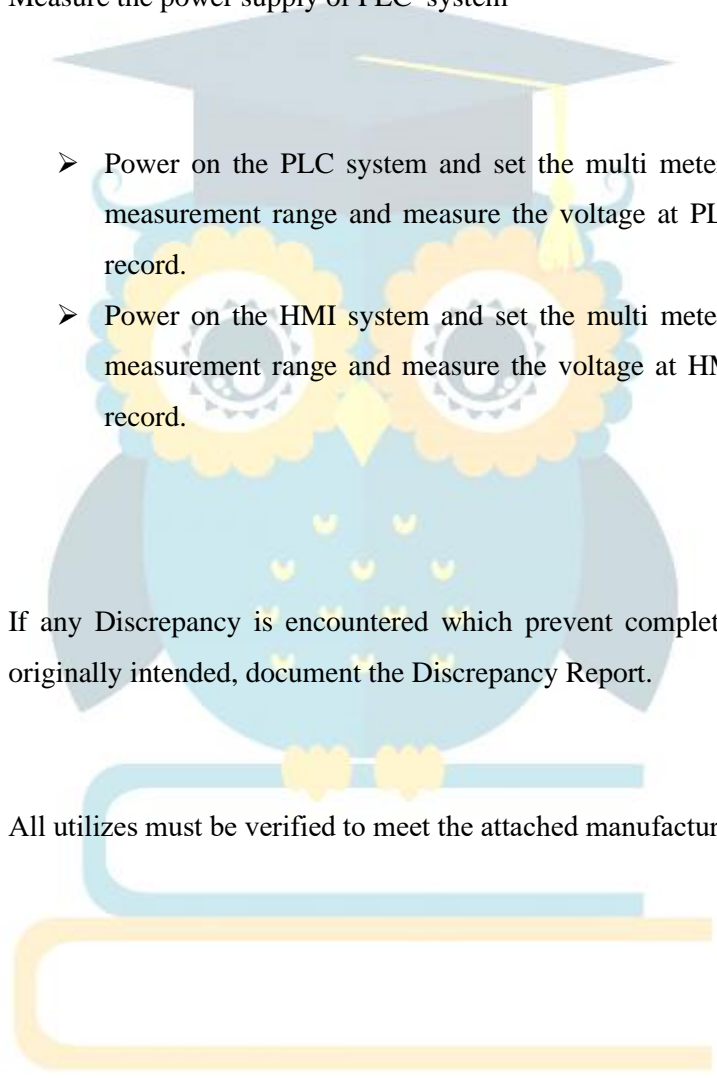
Scope : Measure the power supply of PLC system

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





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3.7.1 DATA SHEET OF PLC SYSTEM POWER SUPPLY

◆ PLC RATING:-

Specified Voltage range: 100 to 240 VAC Field Measurement Voltage:- _____ VAC

◆ HMI RATING:-

Specified Voltage range: +18 – 30 VDC Field Measurement Voltage:- _____ VDC

Meets acceptance criteria: Yes () No ()

Comments/ Remarks:

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



**INSTALLATION QUALIFICATION DOCUMENT OF PLC SYSTEM FOR DOUBLE SIDE
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3.8.0 VERIFICATION OF PHYSICAL AND LOGICAL SECURITY / ACCESS CONTROL OF PLC SYSTEM

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

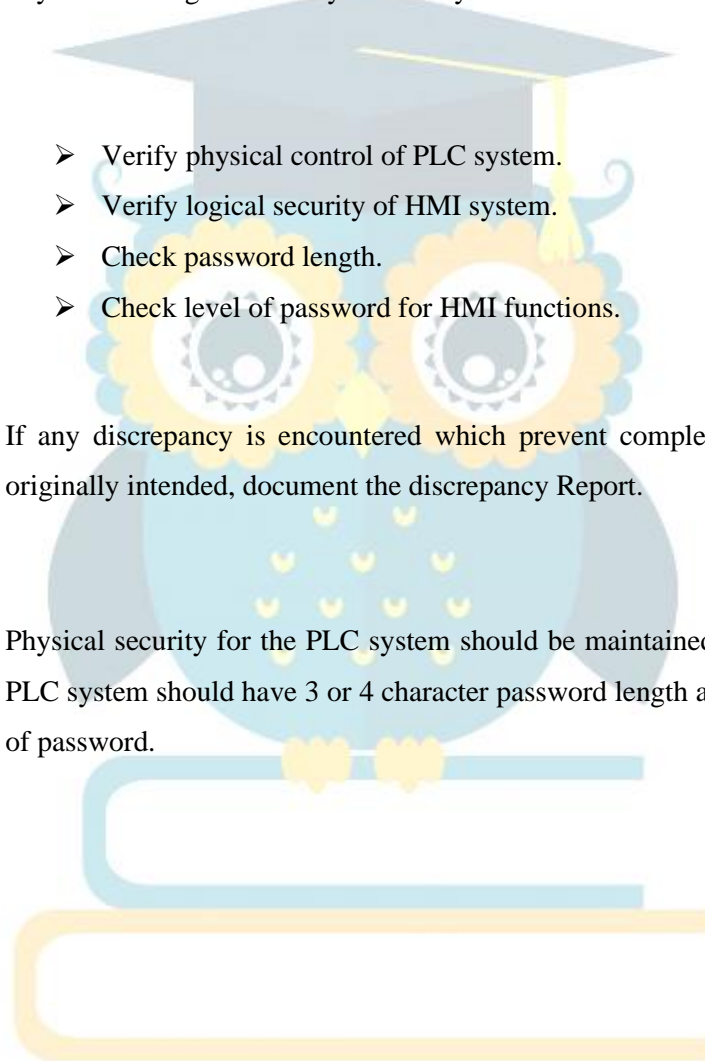
Scope : Physical and logical security of PLC system.

Procedure :

- Verify physical control of PLC system.
- Verify logical security of HMI system.
- Check password length.
- Check level of password for HMI functions.

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

Acceptance Criteria : Physical security for the PLC system should be maintained. Logical security of PLC system should have 3 or 4 character password length and minimum 2 levels of password.





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3.8.1 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 ()	

3.8.2 DATA TABLE OF LOGICAL SECURITY FOR HMI SYSTEM

Sr. No	Specified user	Security level	Logical security available Yes / No	Meets acceptance criteria:	Sign. & date
1	Operator	Level 1		Yes () No ()	
2	Supervisor	Level 2		Yes () No ()	
3	Manager	Level 3		Yes () No ()	



PHARMA SCHOLARS

QUALITY ASSURANCE DEPARTMENT

PROTOCOL No.:

.....

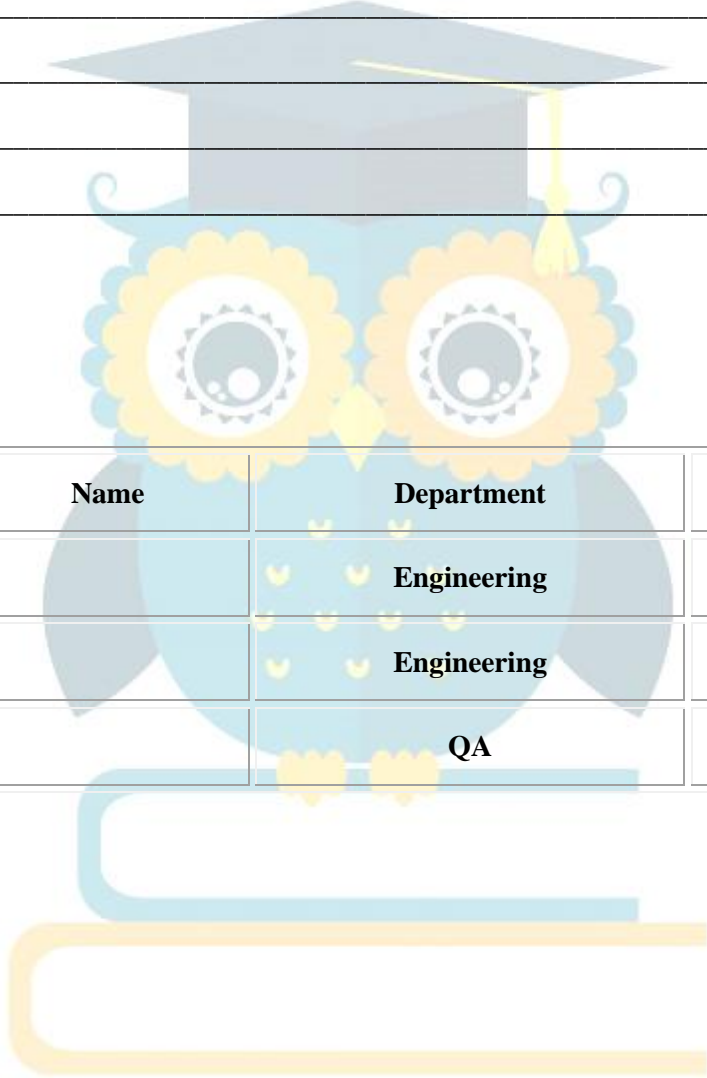
REVISION No: 00

EFFECTIVE DATE:

PAGE No.: 33 of 43

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Comments/ Remarks:



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



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3.9.0 VERIFICATION OF PLC AND HMI SOFTWARE

Purpose : Verify the software of PLC and HMI system.

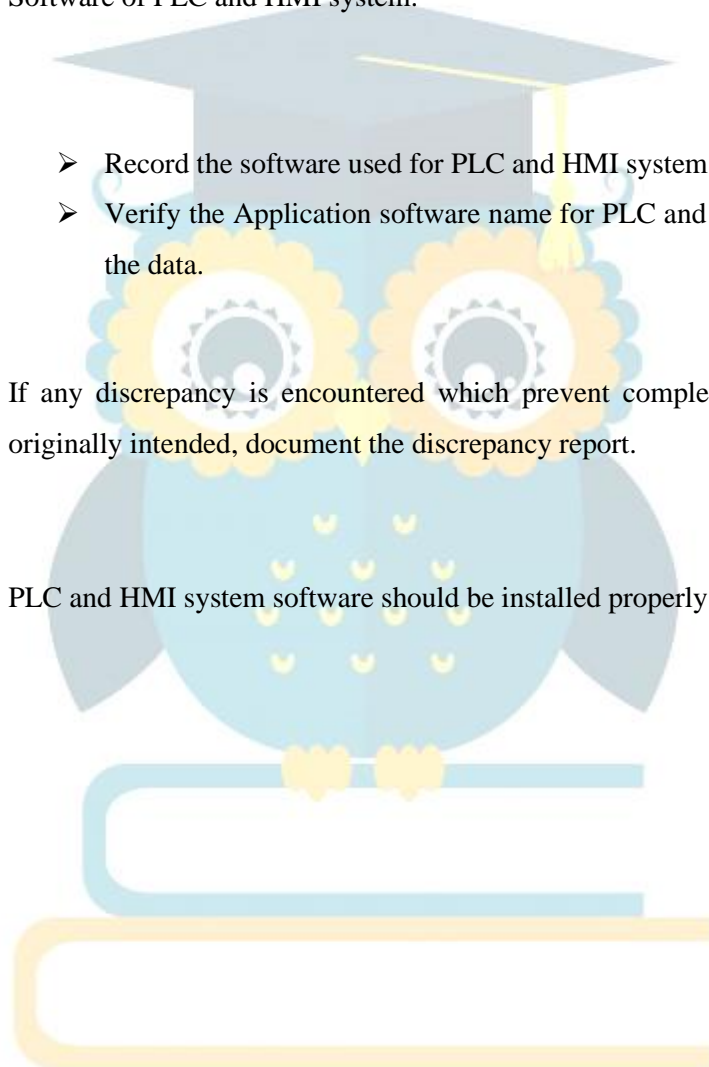
Scope : Software of PLC and HMI system.

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





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3.10.0 DATA TABLE OF PLC AND HMISOFTWARE

System	Specified	Actual Observation	Meets acceptance criteria:	Sign. & date
<u>PLC SYSTEM</u>				
Application Software Name	RS Logix 500		Yes () No ()	
Version	8.6		Yes () No ()	
<u>HMI SYSTEM</u>				
Application Software Name	Vejo Designer		Yes () No ()	
Version	6.1.0		Yes () No ()	

Comments/ Remarks:

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



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

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

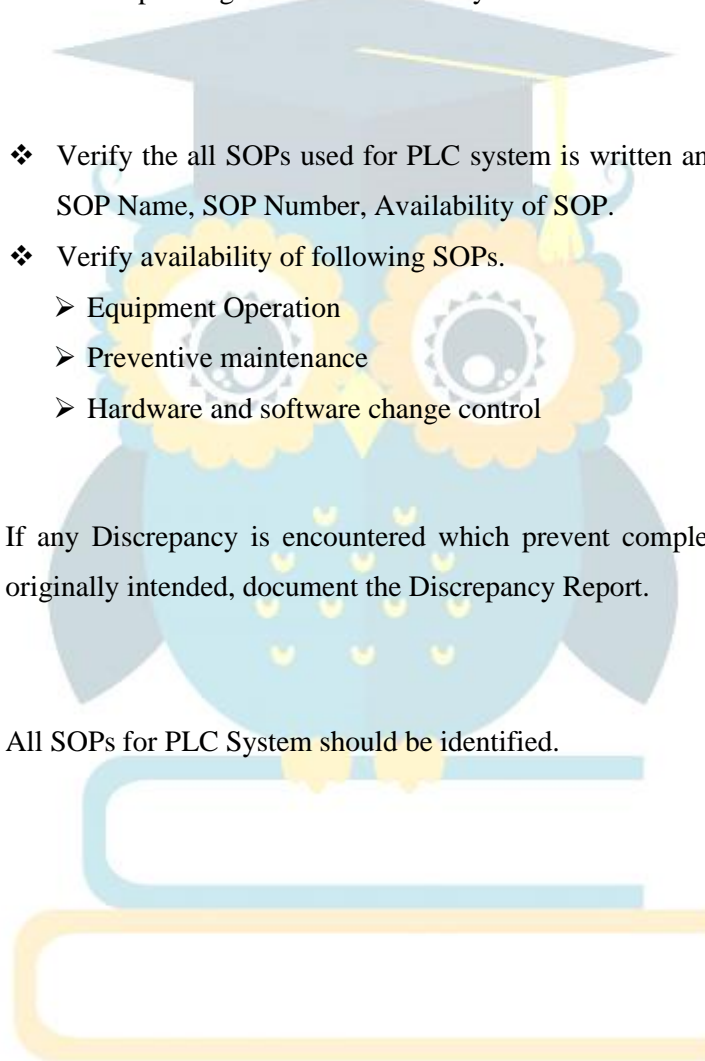
Scope : Standard Operating Procedure of PLC system.

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 DOUBLE SIDE ROTARY TABLET COMPRESSION M/C 45 STN (ACCURA PRESS IV)

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:

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



INSTALLATION QUALIFICATION DOCUMENT OF PLC SYSTEM FOR DOUBLE SIDE ROTARY TABLET COMPRESSION M/C 45 STN (ACCURA PRESS IV)

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):

<p>_____</p> <p>Engineering (Sign and date)</p>	<p>_____</p> <p>Quality Assurance (Sign and date)</p>
---	---

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



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5.0.0 SUMMARY REPORT

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



**INSTALLATION QUALIFICATION DOCUMENT OF PLC SYSTEM FOR DOUBLE SIDE
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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.

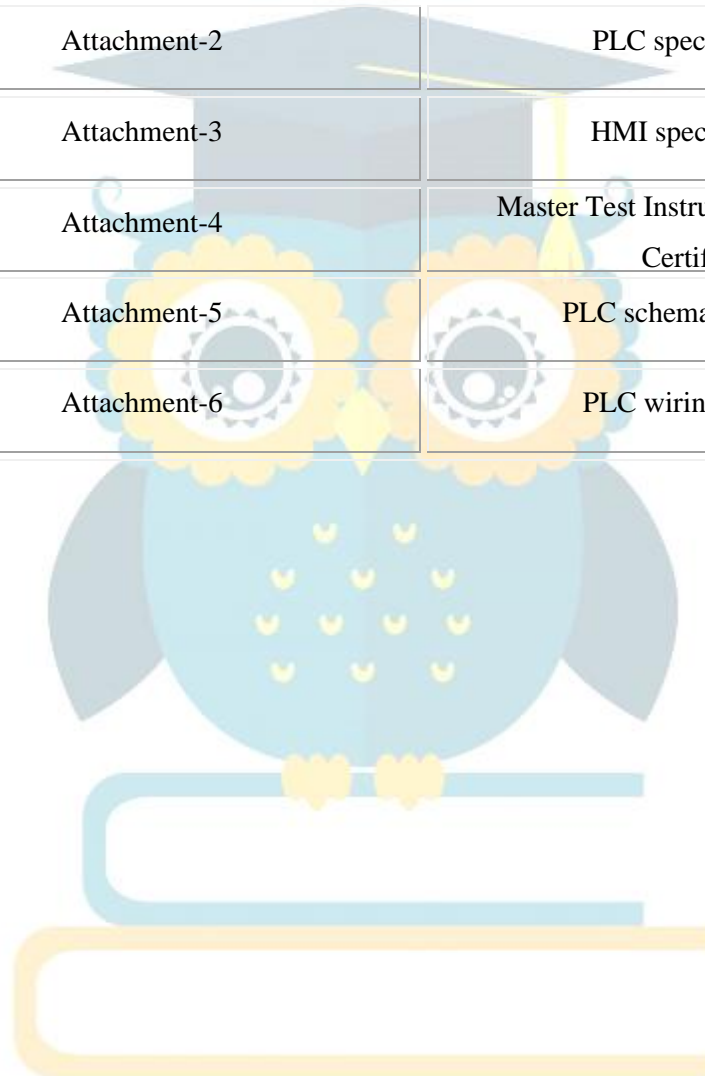
❖ **SOP :Standard Operating Procedure**



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7.0.0 LIST OF ATTACHMENTS

<u>Sr. No.</u>	<u>Reference</u>	<u>Description Of Attachment</u>
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 FOR DOUBLE SIDE
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8.0.0 LIST OF ABBREVIATIONS

<u>Acronym</u>	<u>Description</u>
CPU	→ Central Processing Unit
eGMP	→ Current Good Manufacturing Practices
GAMP	→ Good Automated Manufacturing Practices
GMP	→ Good Manufacturing Practices
ID	→ Identification Number
IO	→ Input Output
IQ	→ Installation Qualification
PLC	→ Programmable Logic Controller
SOP	→ Standard Operating Procedure
UPS	→ Uninterruptible Power Supply
VAC	→ Volts Alternating Current
VDC	→ Volts Direct Current
VMP	→ Validation Master Plan
HMI	→ Human Machine Interface





INSTALLATION QUALIFICATION DOCUMENT OF PLC SYSTEM FOR DOUBLE SIDE ROTARY TABLET COMPRESSION M/C 45 STN (ACCURA PRESS IV)

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	