



OPERATIONAL QUALIFICATION DOCUMENT OF PLC SYSTEM FOR AUTOMATIC ROTARY VACUUMATRIC DRY SYRUP FILLING WITH ROPP CAPPING MACHINE

**OPERATIONAL QUALIFICATION OF PLC SYSTEM
FOR AUTOMATIC ROTARY VACUUMATRIC DRY SYRUP
FILLING WITH ROPP CAPPING MACHINE**

System Name	Automatic Rotary Vacuumatric Dry Syrup Filling With ROPP Capping Machine
System ID
Location	Dry Syrup
Effective Date	



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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 Rotary Vacuumatric Dry Syrup Filling with ROPP Capping 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 Rotary Vacuumatric Dry Syrup Filling With ROPP Capping Machine” which is located in “Dry Syrup-1”.

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 Rotary Vacuumatric Dry Syrup Filling With ROPP Capping 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.

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

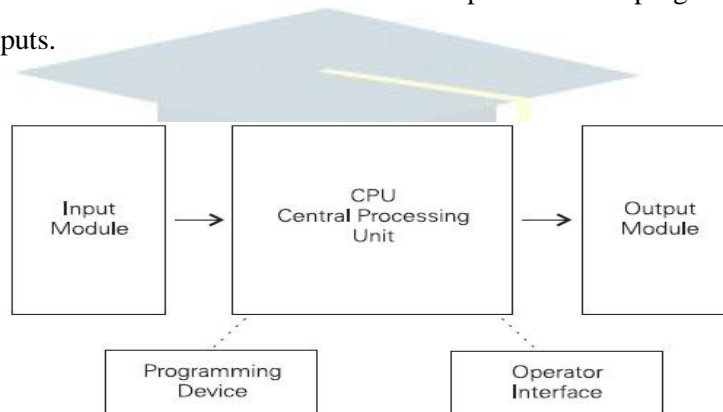


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2.9.0 PLC DESCRIPTION:

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.



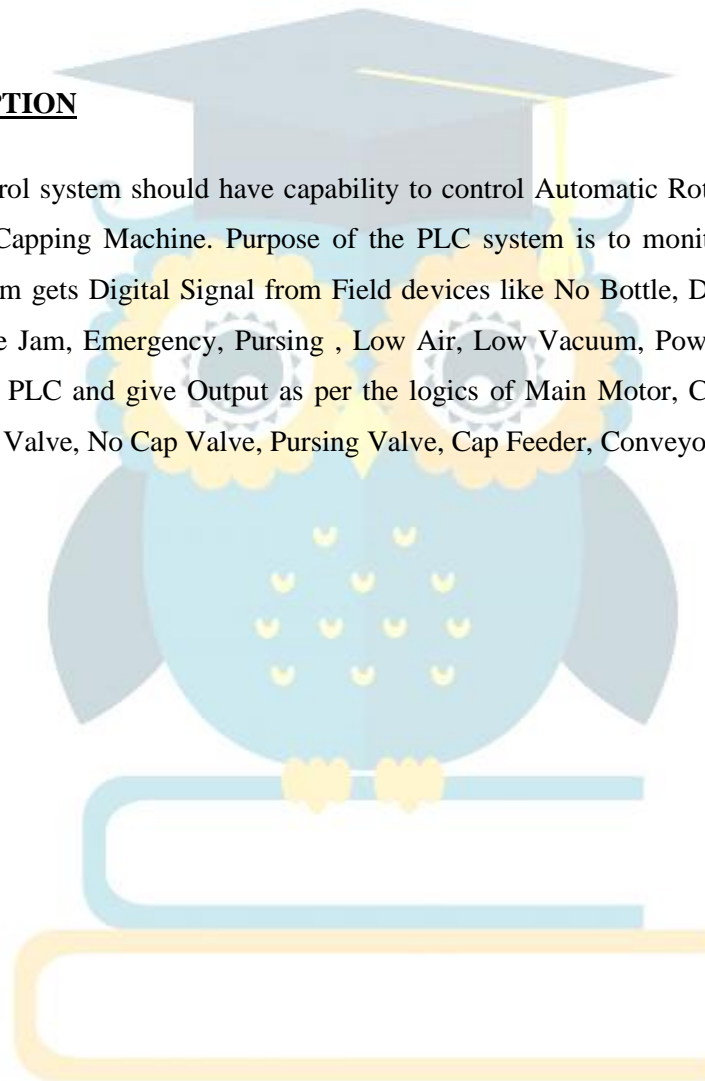
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Digital or discrete input/output has only two states, one is ON and another is OFF. Input and output have light emitting diode (LED) to indicate the state of each input/output. Analog input/output allow to monitor and controlling analog voltage and 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 Automatic Rotary Vacuumatric Dry syrup Filling With ROPP Capping Machine. Purpose of the PLC system is to monitor, operate and control the machine. PLC System gets Digital Signal from Field devices like No Bottle, Dose, No Cap, No Bottle No Cap, Inching, Spindle Jam, Emergency, Pursing , Low Air, Low Vacuum, Powder Level Low. The data is processed in CPU of PLC and give Output as per the logics of Main Motor, Conveyor 1, Vibrator Motor, Vacuum Pump, Dose Valve, No Cap Valve, Pursing Valve, Cap Feeder, Conveyor 2.

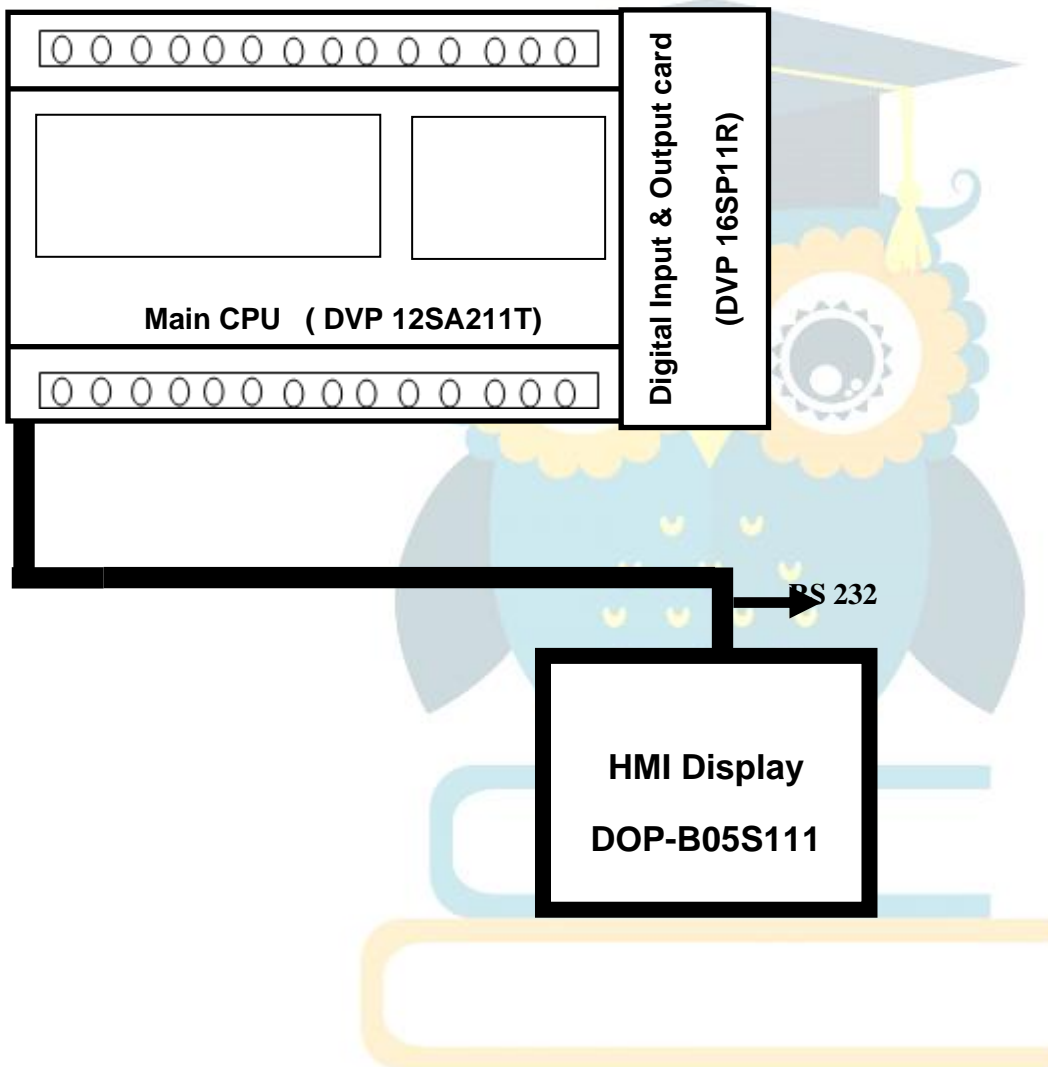




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2.11.0 PLC SYSTEM SCHEMATIC DIAGRAM

The PLC system schematic diagram for the “Automatic Rotary Vacuumatric Dry Syrup Filling With ROPP Capping Machine” automation is given below:





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3.0.0 OPERATIONAL QUALIFICATION TEST

<u>Sr. No.</u>	<u>Test Details</u>
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

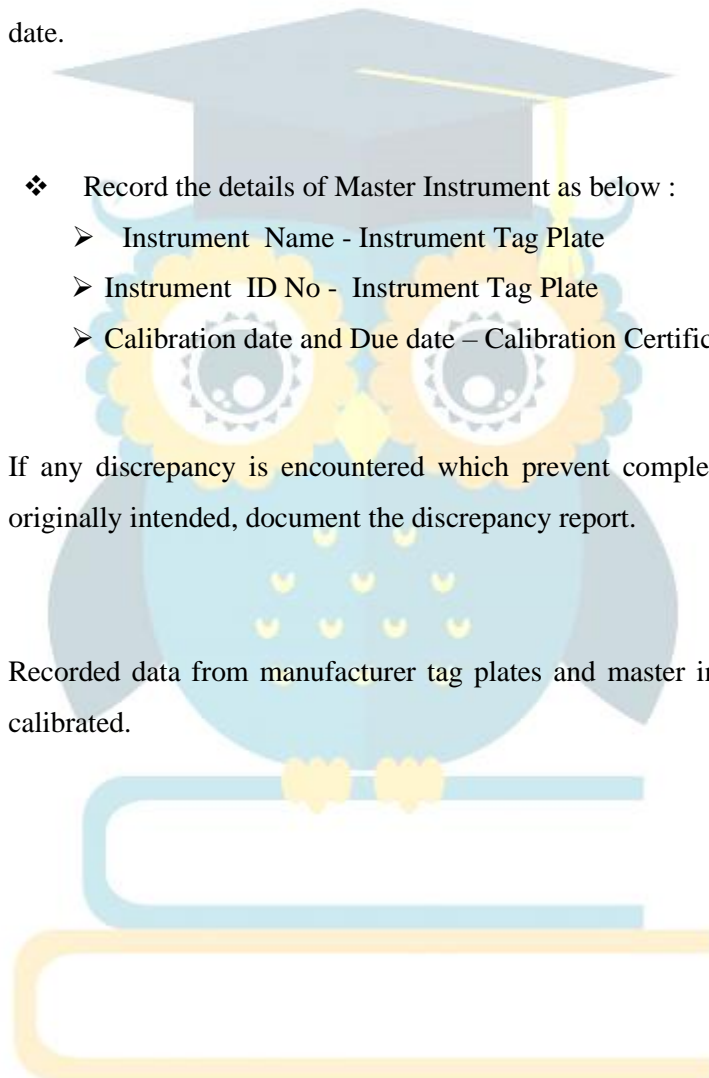
Purpose : This test is verified to master instrument which is used for testing.

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:

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



OPERATIONAL QUALIFICATION DOCUMENT OF PLC SYSTEM FOR AUTOMATIC ROTARY VACUUMATRIC DRY SYRUP FILLING WITH ROPP CAPPING MACHINE

3.2.0 VERIFICATION OF CALIBRATION CERTIFICATES OF SENSORS

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

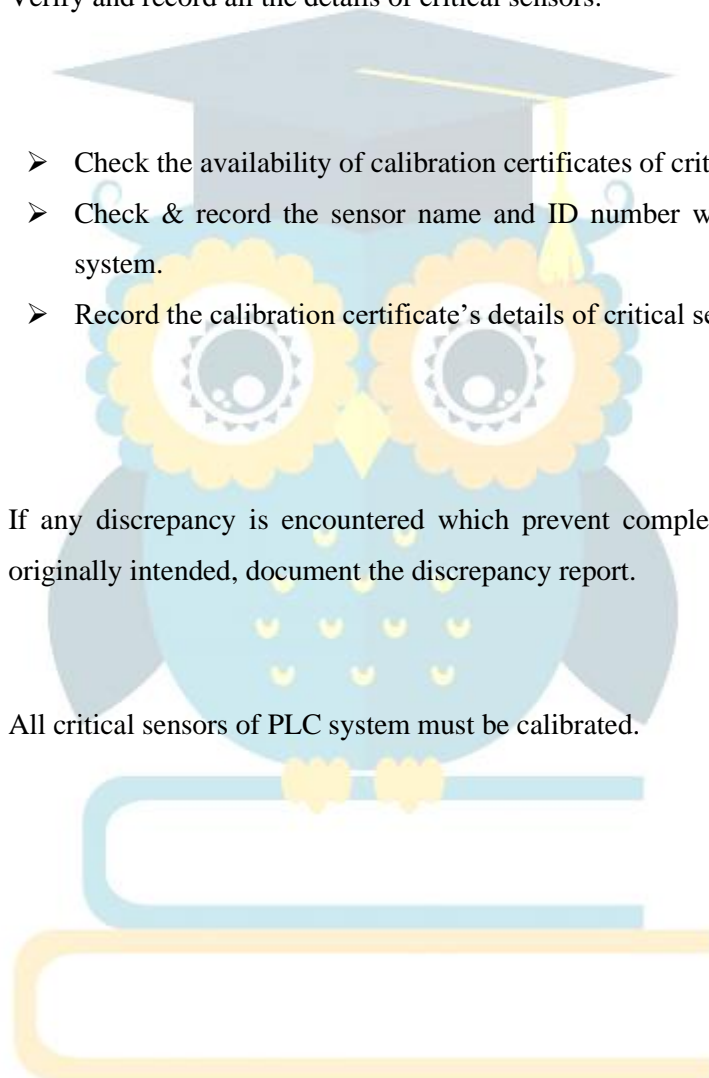
Scope : Verify and record all the details of critical sensors.

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

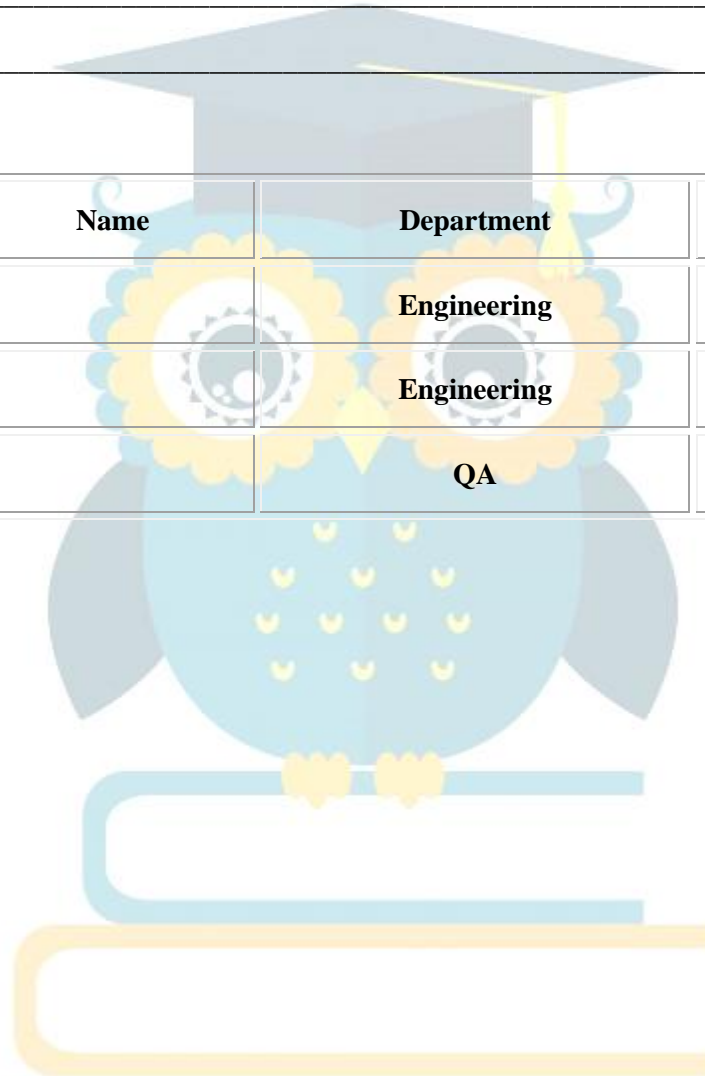




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Comments/ Remarks:

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

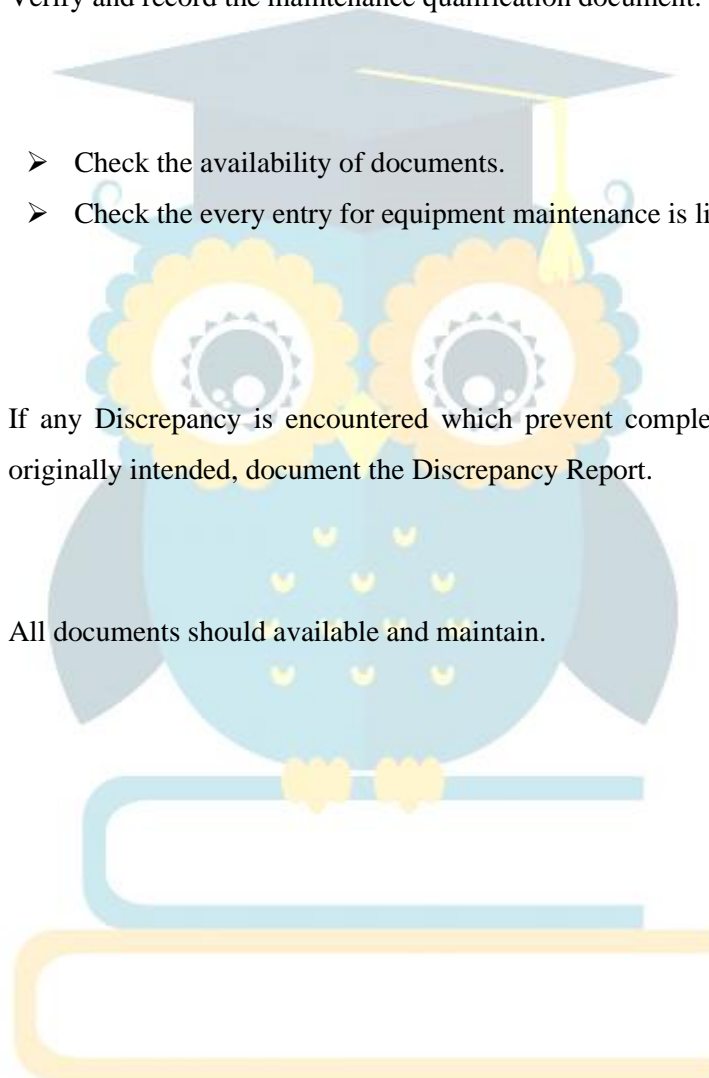
Purpose : Verify and review the documents of maintenance.

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:

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

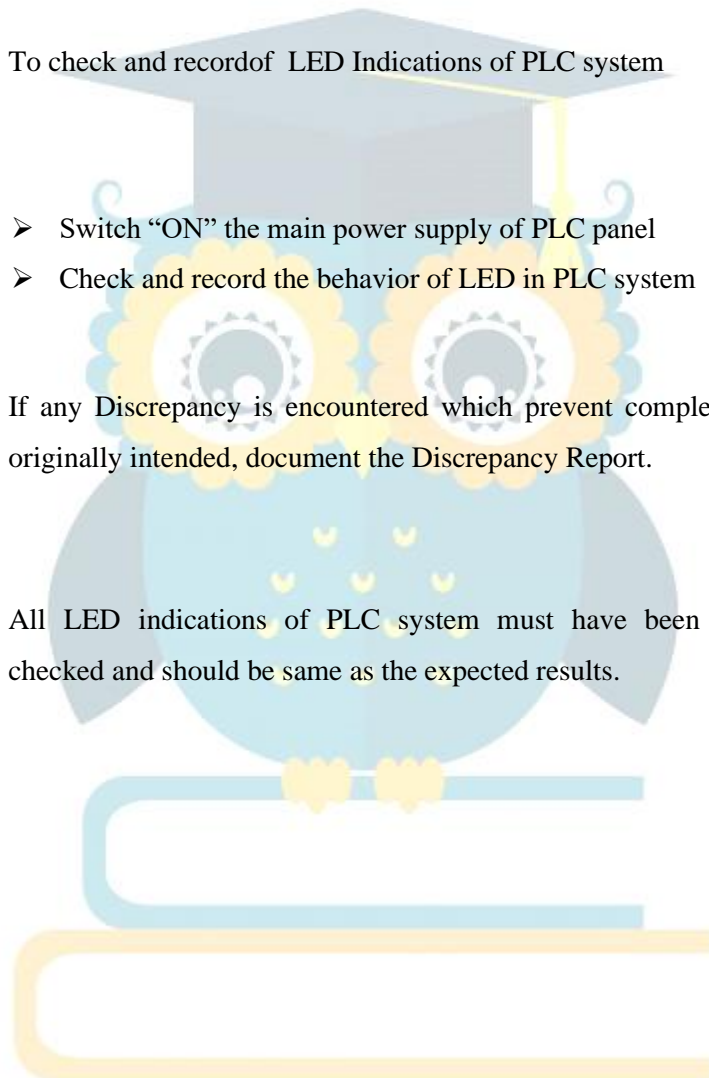
Purpose : To verify LED indications of PLC system.

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

LED	Expected state of LED	Actual state of LED	Meets acceptance criteria	Sign.& date
PLC PROCESSOR (DVP-12SA211T)				
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

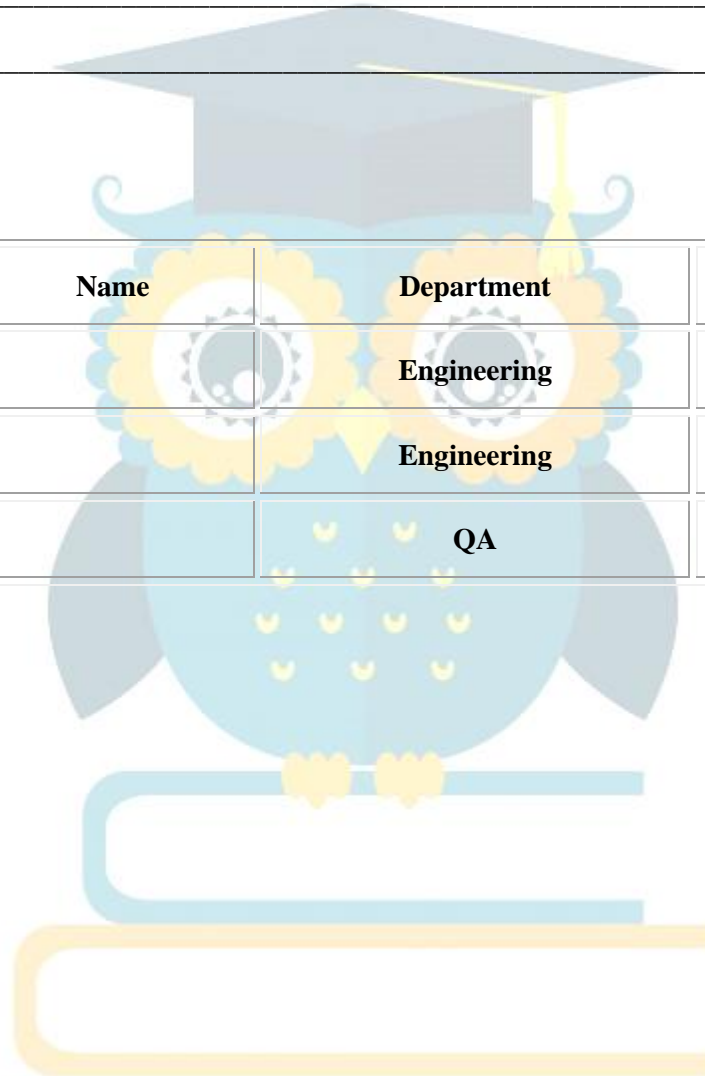
LED	Expected state of LED	Actual state of LED	Meets acceptance criteria	Sign.& date
PLC PROCESSOR (DVP-12SA211T)				
Power	ON		Yes () No ()	
Run	ON		Yes () No ()	
Error	OFF		Yes () No ()	
Comm 1	Blink		Yes () No ()	



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Comments/ Remarks:

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





OPERATIONAL QUALIFICATION DOCUMENT OF PLC SYSTEM FOR AUTOMATIC ROTARY VACUUMATRIC DRY SYRUP FILLING WITH ROPP CAPPING MACHINE

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 :

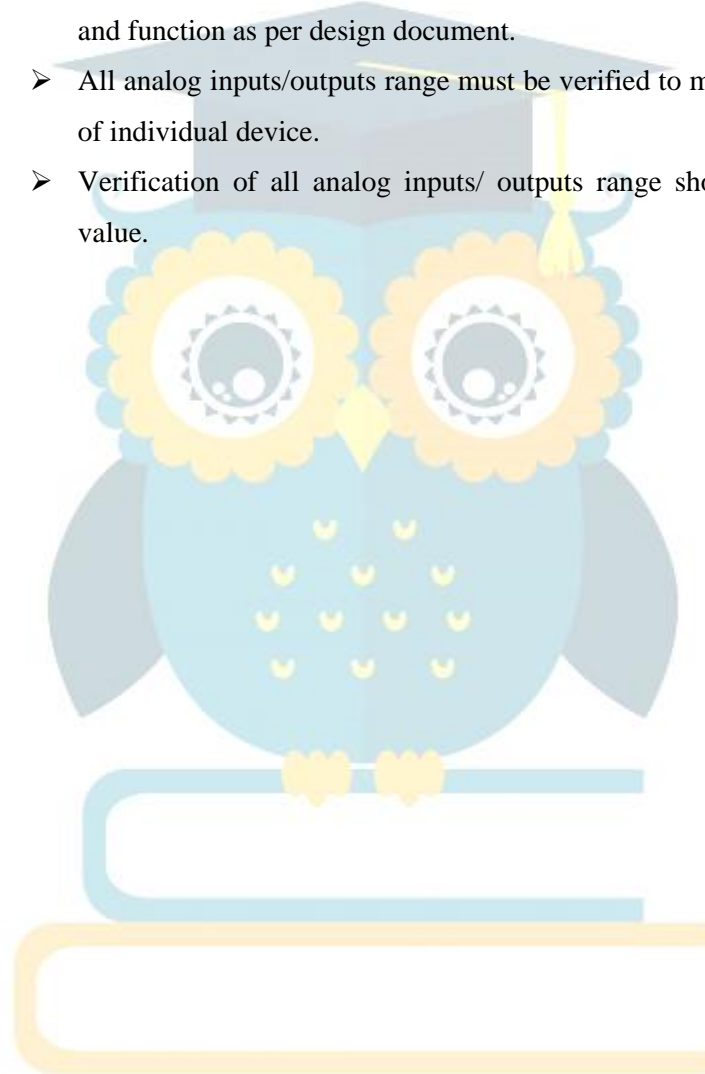
- Digital Inputs
 - Trigger/Force each given digital input from system.
 - Verify and record the status of digital inputs LED indication in PLC system and same time verify the PLC logics in PLC software.
- Digital Outputs
 - Force each digital output ON/OFF.
 - Verify and record the status of digital 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	Dose	ON		Yes () No ()	
		OFF		Yes () No ()	
X2	No Cap	ON		Yes () No ()	
		OFF		Yes () No ()	
X3	No Bottle No Cap	ON		Yes () No ()	
		OFF		Yes () No ()	
X4	No Bottle No Cap Gap	ON		Yes () No ()	
		OFF		Yes () No ()	
X5	Inching	ON		Yes () No ()	
		OFF		Yes () No ()	
X6	Spindle Jam	ON		Yes () No ()	
		OFF		Yes () No ()	
X7	Emergency	ON		Yes () No ()	
		OFF		Yes () No ()	
PLC Digital Input (DVP 16SP11R)					
X20	Pursing	ON		Yes () No ()	
		OFF		Yes () No ()	
X21	Low Air	ON		Yes () No ()	
		OFF		Yes () No ()	
X22	Low Vacuum	ON		Yes () No ()	
		OFF		Yes () No ()	
X23	Powder Level Low	ON		Yes () No ()	
		OFF		Yes () No ()	



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X24 to X27	Spare	NA	Yes () No ()
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3.5.2 DATA TABLE OF PLC DIGITAL OUTPUTS

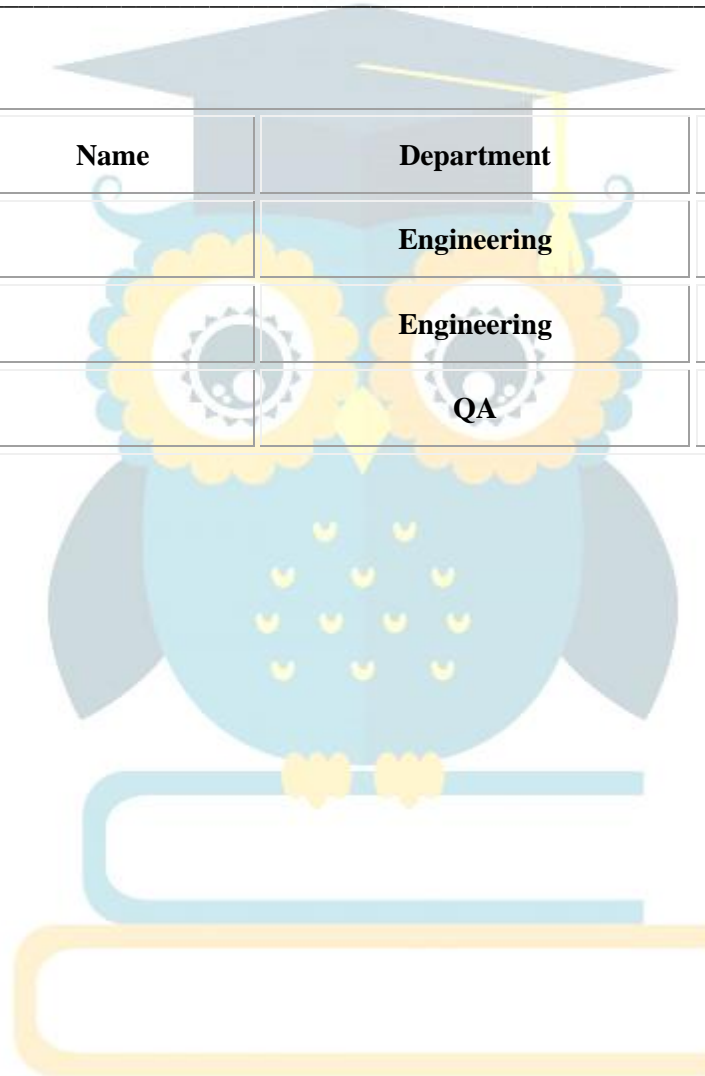
PLC Digital Outputs (DVP 12SA211T)						
PLC Address	Description	Expected state of LED	Actual state of LED	Meets acceptance criteria	Sign. & date	
Y0	Main Motor	ON		Yes () No ()		
		OFF		Yes () No ()		
Y1	Conveyor-1	ON		Yes () No ()		
		OFF		Yes () No ()		
Y2	Vibrator Motor	ON		Yes () No ()		
		OFF		Yes () No ()		
Y3	Vacuum Pump	ON		Yes () No ()		
		OFF		Yes () No ()		
PLC Digital Outputs (DVP 16SP11R)						
Y20	Dose Valve	ON		Yes () No ()		
		OFF		Yes () No ()		
Y21	No Cap Valve	ON		Yes () No ()		
		OFF		Yes () No ()		
Y22	Pursing Valve	ON		Yes () No ()		
		OFF		Yes () No ()		
Y23	Cap Feeder	ON		Yes () No ()		
		OFF		Yes () No ()		
Y24	Conveyor-2	ON		Yes () No ()		
		OFF		Yes () No ()		
Y25 to Y27	Spare	NA		Yes () No ()		



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VACUUMATRIC DRY SYRUP FILLING WITH ROPP CAPPING MACHINE**

Comments/ Remarks:

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





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3.6.0 VERIFICATION OF SECURITY LEVELS

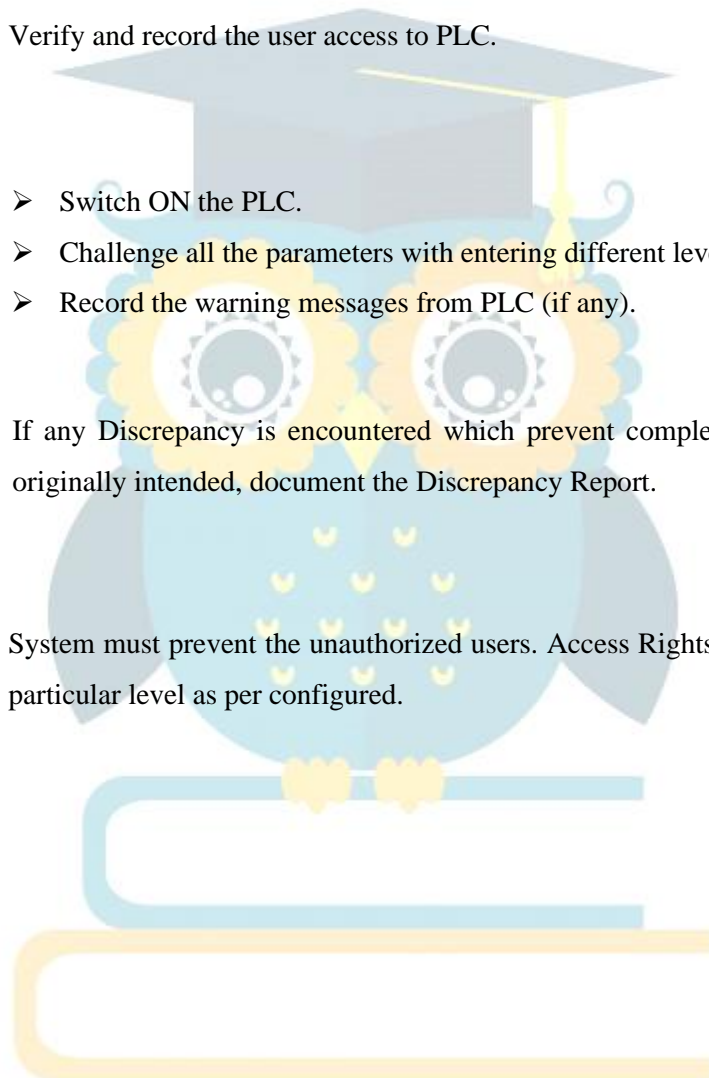
Purpose : Verify and testing of different security levels to prevent the unauthorized user access.

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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3.6.1 DATA TABLE OF PLC ACCESS

Procedure	Expected result	Actual result	Meets acceptance criteria	Sign. & date
LEVEL-0 (Operator)				
Attempt to gain access with an incorrect combination of user name and password for operator levels	User should not able to access the system		Yes () No ()	
Attempt to gain access with a correct combination of user name and password for operator levels	User should able to access the system		Yes () No ()	
LEVEL-5 (Supervisor)				
Attempt to gain access with an incorrect combination of user name and password for supervisor levels	User should not able to access the system		Yes () No ()	
Attempt to gain access with a correct combination of user name and password for supervisor levels	User should able to access the system		Yes () No ()	
LEVEL-6 (Manager)				
Attempt to gain access with an incorrect combination of user name and password for Admin levels	User should not able to access the system		Yes () No ()	
Attempt to gain access with a correct combination of user name and password for Admin levels	User should able to access the system		Yes () No ()	



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Procedure	Expected result	Actual result	Meets acceptance criteria	Sign. & date
LEVEL-7 (Admin)				
Attempt to gain access with an incorrect combination of user name and password for Manager levels	User should not able to access the system		Yes () No ()	
Attempt to gain access with a correct combination of user name and password for Manager levels	User should able to access the system		Yes () No ()	





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3.6.2 DATA TABLE OF FUNCTION CONFIGURATION

Functions	Level				Meets acceptance criteria	Sign. & date
	0	5	6	7		
Auto Mode	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Yes () No ()	





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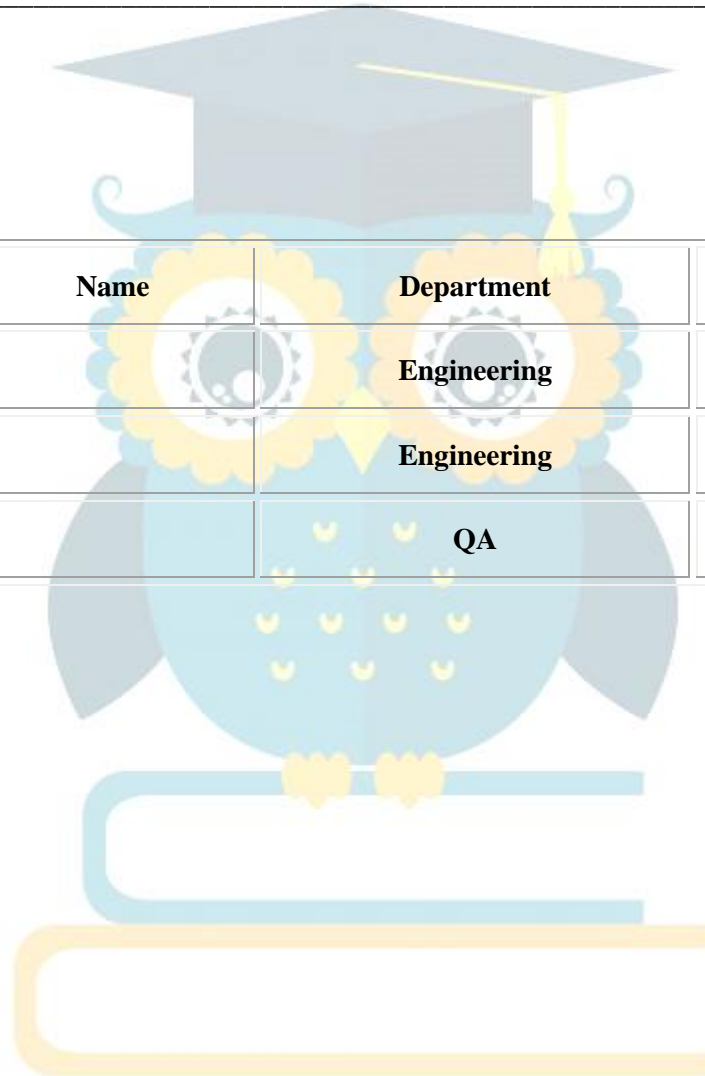
Manual Mode	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Yes () No ()
Recipe Setting	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Yes () No ()
Product Counter	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Yes () No ()
Fault Display	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Yes () No ()
Timer Setting Screen	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Yes () No ()
Input Status Screen	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Yes () No ()
Output Status Screen	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Yes () No ()
Machine Parameter Screen	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Yes () No ()
Machine Parameter Setting Screen	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Yes () No ()



OPERATIONAL QUALIFICATION DOCUMENT OF PLC SYSTEM FOR AUTOMATIC ROTARY VACUUMATRIC DRY SYRUP FILLING WITH ROPP CAPPING MACHINE

Comments/ Remarks:

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





OPERATIONAL QUALIFICATION DOCUMENT OF PLC SYSTEM FOR AUTOMATIC ROTARY VACUUMATRIC DRY SYRUP FILLING WITH ROPP CAPPING MACHINE

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



OPERATIONAL QUALIFICATION DOCUMENT OF PLC SYSTEM FOR AUTOMATIC ROTARY VACUUMATRIC DRY SYRUP FILLING WITH ROPP CAPPING MACHINE

3.7.1 DATATABLE OF HMI SCREENS

Sr. No.	Screen Name	Available Yes/No	Meets acceptance criteria	Sign. & date
01	Welcome Screen		Yes () No ()	
02	Run Mode Screen		Yes () No ()	
03	Manual Mode Screen		Yes () No ()	
04	Speed Setting Screen		Yes () No ()	
05	Product Counter Screen		Yes () No ()	
06	Login Screen		Yes () No ()	
07	Fault Display Screen		Yes () No ()	
08	Timer Setting Screen		Yes () No ()	
09	Input Status Screen		Yes () No ()	
10	Output Status Screen		Yes () No ()	
11	Machine Parameter Screen		Yes () No ()	
12	Machine Parameter Setting Screen		Yes () No ()	



OPERATIONAL QUALIFICATION DOCUMENT OF PLC SYSTEM FOR AUTOMATIC ROTARY VACUUMATRIC DRY SYRUP FILLING WITH ROPP CAPPING MACHINE

3.7.2 DATATABLE OF HMI DISPLAY

Parameter	Span	Actual Result	Meet Acceptance Criteria	Sign. & Date
Run Mode Screen				
VIB. Motor	0.0 to 50.0		Yes () No ()	
Counter	Numeric		Yes () No ()	
Manual Mode Screen				
Main Motor Stop	0.0 to 120.0		Yes () No ()	
Conveyor 1 Stop	0.0 to 50.0		Yes () No ()	
VIB. Motor Stop	0.0 to 50.0		Yes () No ()	
Conveyor 2 Stop	0.0 to 60.0		Yes () No ()	
Speed Setting Screen				
Main Motor (BPM)	0.0 to 120.0		Yes () No ()	
Conveyor 1 H.Z	0.0 to 120.0		Yes () No ()	
Conveyor 2 H.Z	0.0 to 120.0		Yes () No ()	
Main Motor (BPM)	0.0 to 120.0		Yes () No ()	
Conveyor 1 H.Z	0 to 50		Yes () No ()	
Conveyor 2 H.Z	0 to 50		Yes () No ()	
Recipe	0 to 50		Yes () No ()	
Product Counter Screen				
Counter	Numeric		Yes () No ()	



OPERATIONAL QUALIFICATION DOCUMENT OF PLC SYSTEM FOR AUTOMATIC ROTARY VACUUMATRIC DRY SYRUP FILLING WITH ROPP CAPPING MACHINE

Parameter	Span	Actual Result	Meet Acceptance Criteria	Sign. & Date
Timer Setting Screen				
No Bottle ON TMR	0.0 to 99.9		Yes () No ()	
No Bottle OFF TMR	0.0 to 99.9		Yes () No ()	
NO Cap ON TMR	0.0 to 99.9		Yes () No ()	
NO Cap OFF TMR	0.0 to 99.9		Yes () No ()	
Dossing TMR	0.000 to 9.999		Yes () No ()	
Purzing ON Delay Time	0.00 to 99.99		Yes () No ()	
Purzing OFF Delay Time	0.00 to 99.99		Yes () No ()	
Powder Level ON TMR	0.00 to 99.99		Yes () No ()	

Comments/ Remarks:

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



OPERATIONAL QUALIFICATION DOCUMENT OF PLC SYSTEM FOR AUTOMATIC ROTARY VACUUMATRIC DRY SYRUP FILLING WITH ROPP CAPPING 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 ROTARY VACUUMATRIC DRY SYRUP FILLING WITH ROPP CAPPING 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
Run Mode Screen											
VIB. Motor	0.0 to 50.0		Yes () No ()		Yes () No ()		Yes () No ()		Yes () No ()	Yes () No ()	
Manual Mode Screen											
Main Motor Stop	0.0 to 120.0		Yes () No ()		Yes () No ()		Yes () No ()		Yes () No ()	Yes () No ()	
Conveyor 1 Stop	0.0 to 50.0		Yes () No ()		Yes () No ()		Yes () No ()		Yes () No ()	Yes () No ()	
VIB. Motor Stop	0.0 to 50.0		Yes () No ()		Yes () No ()		Yes () No ()		Yes () No ()	Yes () No ()	
Conveyor 2 Stop	0.0 to 60.0		Yes () No ()		Yes () No ()		Yes () No ()		Yes () No ()	Yes () No ()	



OPERATIONAL QUALIFICATION DOCUMENT OF PLC SYSTEM FOR AUTOMATIC ROTARY VACUUMATRIC DRY SYRUP FILLING WITH ROPP CAPPING 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
Speed Setting Screen											
Main Motor (BPM)	0.0 to 120.0		Yes () No ()		Yes () No ()		Yes () No ()		Yes () No ()	Yes () No ()	
Conveyor 1 H.Z	0.0 to 120.0		Yes () No ()		Yes () No ()		Yes () No ()		Yes () No ()	Yes () No ()	
Conveyor 2 H.Z	0.0 to 120.0		Yes () No ()		Yes () No ()		Yes () No ()		Yes () No ()	Yes () No ()	
Main Motor (BPM)	0.0 to 120.0		Yes () No ()		Yes () No ()		Yes () No ()		Yes () No ()	Yes () No ()	
Conveyor 1 H.Z	0 to 50		Yes () No ()		Yes () No ()		Yes () No ()		Yes () No ()	Yes () No ()	
Conveyor 2 H.Z	0 to 50		Yes () No ()		Yes () No ()		Yes () No ()		Yes () No ()	Yes () No ()	
Recipe	0 to 50		Yes () No ()		Yes () No ()		Yes () No ()		Yes () No ()	Yes () No ()	



OPERATIONAL QUALIFICATION DOCUMENT OF PLC SYSTEM FOR AUTOMATIC ROTARY VACUUMATRIC DRY SYRUP FILLING WITH ROPP CAPPING 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
Timer Setting Screen											
No Bottle ON TMR	0.0 to 99.9		Yes () No ()		Yes () No ()		Yes () No ()		Yes () No ()	Yes () No ()	
No Bottle OFF TMR	0.0 to 99.9		Yes () No ()		Yes () No ()		Yes () No ()		Yes () No ()	Yes () No ()	
NO Cap ON TMR	0.0 to 99.9		Yes () No ()		Yes () No ()		Yes () No ()		Yes () No ()	Yes () No ()	
NO Cap OFF TMR	0.0 to 99.9		Yes () No ()		Yes () No ()		Yes () No ()		Yes () No ()	Yes () No ()	
Dossing TMR	0.000 to 9.999		Yes () No ()		Yes () No ()		Yes () No ()		Yes () No ()	Yes () No ()	
Purzing ON Delay Time	0.00 to 99.99		Yes () No ()		Yes () No ()		Yes () No ()		Yes () No ()	Yes () No ()	
Purzing OFF Delay Time	0.00 to 99.99		Yes () No ()		Yes () No ()		Yes () No ()		Yes () No ()	Yes () No ()	
Powder Level ON TMR	0.00 to 99.99		Yes () No ()		Yes () No ()		Yes () No ()		Yes () No ()	Yes () No ()	



PHARMA SCHOLARS

QUALITY ASSURANCE DEPARTMENT

PROTOCOL No.:

.....

REVISION No: 00

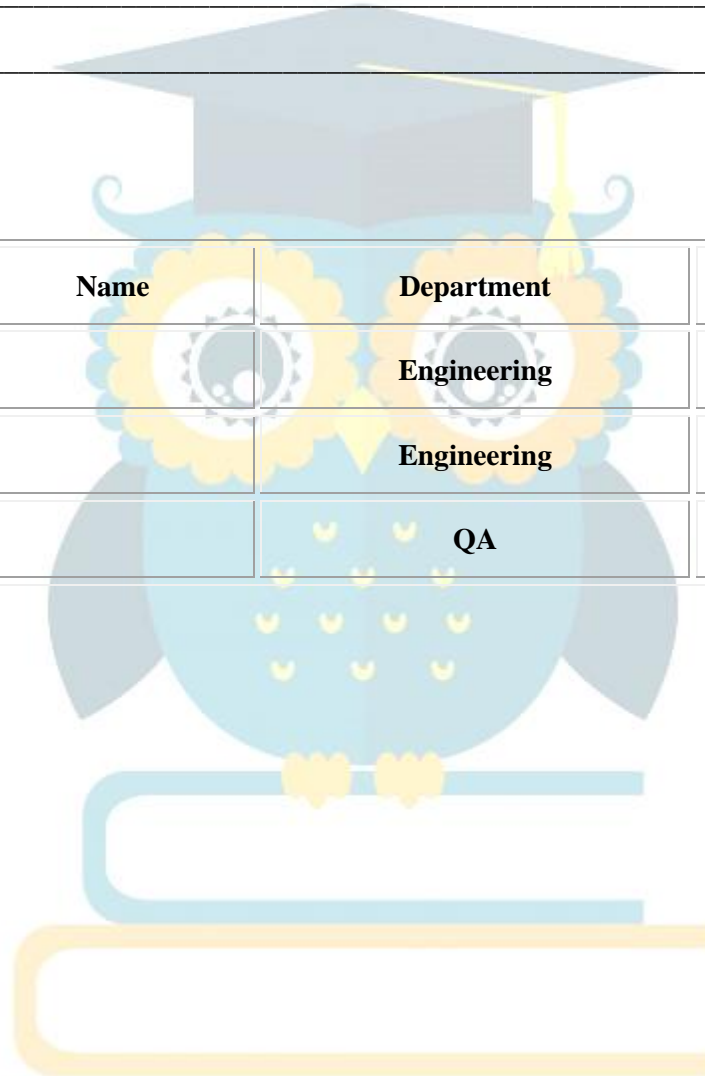
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OPERATIONAL QUALIFICATION DOCUMENT OF PLC SYSTEM FOR AUTOMATIC ROTARY VACUUMATRIC DRY SYRUP FILLING WITH ROPP CAPPING MACHINE

Comments/ Remarks:

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





OPERATIONAL QUALIFICATION DOCUMENT OF PLC SYSTEM FOR AUTOMATIC ROTARY VACUUMATRIC DRY SYRUP FILLING WITH ROPP CAPPING 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 ROTARYs
VACUUMATRIC DRY SYRUP FILLING WITH ROPP CAPPING MACHINE**

3.9.1 DATA TABLE OF POWER LOSS RECOVERY CONDITION

Parameter Description	Value Before power loss	Value after power recovery	Expected Result	Meets acceptance criteria	Sign. & date
Run Mode Screen					
VIB. Motor			Value remains same	Yes () No ()	
Manual Mode Screen					
Main Motor Stop			Value remains same	Yes () No ()	
Conveyor 1 Stop			Value remains same	Yes () No ()	
VIB. Motor Stop			Value remains same	Yes () No ()	
Conveyor 2 Stop			Value remains same	Yes () No ()	
Speed Setting Screen					
Main Motor (BPM)			Value remains same	Yes () No ()	
Conveyor 1 H.Z			Value remains same	Yes () No ()	
Conveyor 2 H.Z			Value remains same	Yes () No ()	
Main Motor (BPM)			Value remains same	Yes () No ()	
Conveyor 1 H.Z			Value remains same	Yes () No ()	
Conveyor 2 H.Z			Value remains same	Yes () No ()	
Recipe			Value remains same	Yes () No ()	



**OPERATIONAL QUALIFICATION DOCUMENT OF PLC SYSTEM FOR AUTOMATIC ROTARYs
VACUUMATRIC DRY SYRUP FILLING WITH ROPP CAPPING MACHINE**

Parameter Description	Value Before power loss	Value after power recovery	Expected Result	Meets acceptance criteria	Sign. & date
Timer Setting Screen					
No Bottle ON TMR			Value remains same	Yes () No ()	
No Bottle OFF TMR			Value remains same	Yes () No ()	
NO Cap ON TMR			Value remains same	Yes () No ()	
NO Cap OFF TMR			Value remains same	Yes () No ()	
Dossing TMR			Value remains same	Yes () No ()	
Purzing ON Delay Time			Value remains same	Yes () No ()	
Purzing OFF Delay Time			Value remains same	Yes () No ()	
Powder Level ON TMR			Value remains same	Yes () No ()	

Comments/ Remarks:

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



PHARMA SCHOLARS

QUALITY ASSURANCE DEPARTMENT

PROTOCOL No.:

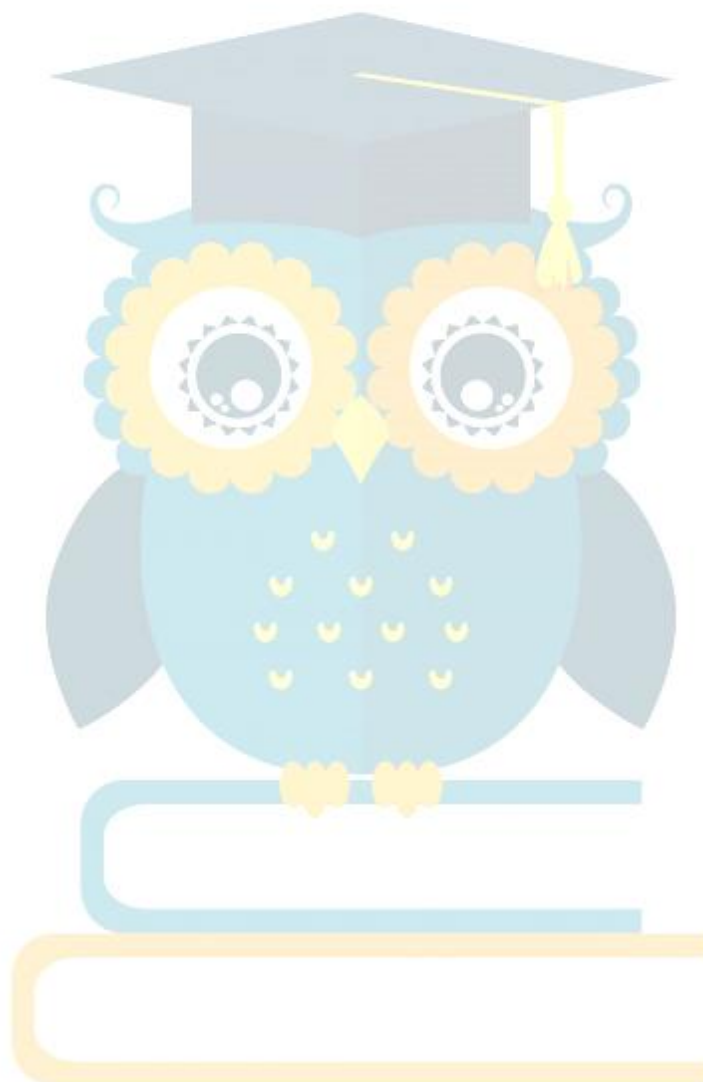
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**OPERATIONAL QUALIFICATION DOCUMENT OF PLC SYSTEM FOR AUTOMATIC ROTARYs
VACUUMATRIC DRY SYRUP FILLING WITH ROPP CAPPING MACHINE**





**OPERATIONAL QUALIFICATION DOCUMENT OF PLC SYSTEM FOR AUTOMATIC ROTARYs
VACUUMATRIC DRY SYRUP FILLING WITH ROPP CAPPING 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 : ➤ In communication link failure condition, message must appear in HMI screen.

Criteria

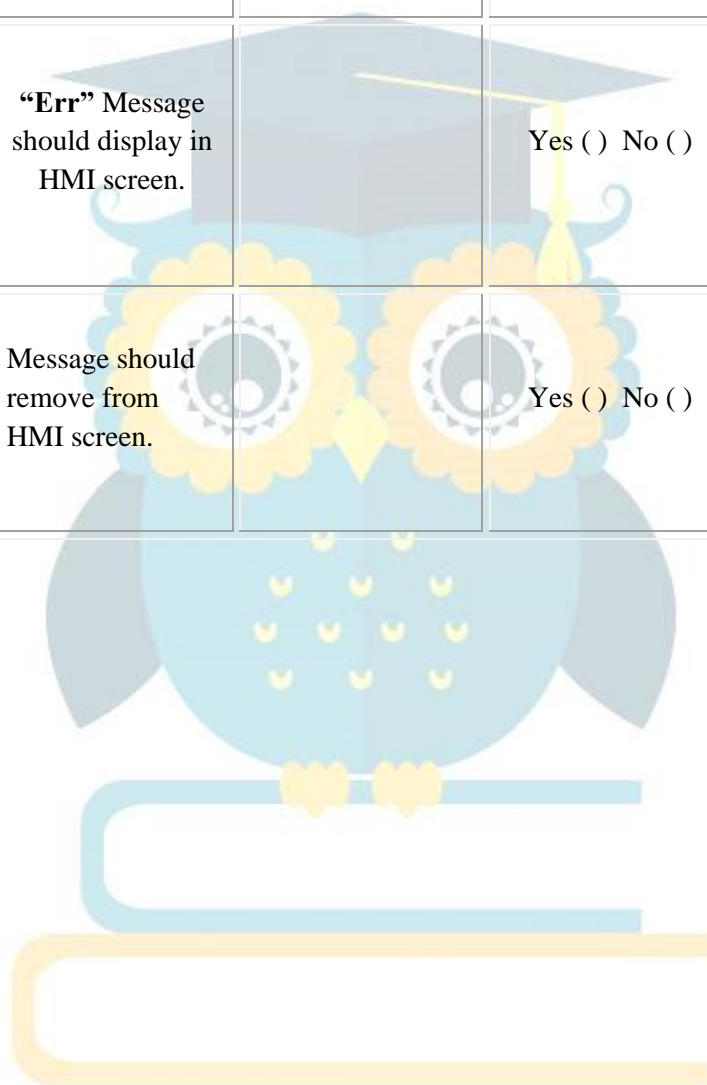
- When communication link fails the recipe should not be changed or saved.
- After communication link reconnect, the set-parameters should not be changed.
- Machine works normally after communication failure condition.



**OPERATIONAL QUALIFICATION DOCUMENT OF PLC SYSTEM FOR AUTOMATIC ROTARYs
VACUUMATRIC DRY SYRUP FILLING WITH ROPP CAPPING MACHINE**

3.10.1 DATA TABLE OF COMMUNICATION FAILURE CONDITION

Procedure	Expected result	Actual Result	Meets acceptance criteria	Sign. & date
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 ROTARYs
VACUUMATRIC DRY SYRUP FILLING WITH ROPP CAPPING MACHINE**

Parameter Description	Value Before Communicati on unplug	Value after Communicat ion link reconnect	Expected Result	Meets acceptance criteria	Sign. & date
Run Mode Screen					
VIB. Motor			Value remains same	Yes () No ()	
Manual Mode Screen					
Main Motor Stop			Value remains same	Yes () No ()	
Conveyor 1 Stop			Value remains same	Yes () No ()	
VIB. Motor Stop			Value remains same	Yes () No ()	
Conveyor 2 Stop			Value remains same	Yes () No ()	
Speed Setting Screen					
Main Motor (BPM)			Value remains same	Yes () No ()	
Conveyor 1 H.Z			Value remains same	Yes () No ()	
Conveyor 2 H.Z			Value remains same	Yes () No ()	
Main Motor (BPM)			Value remains same	Yes () No ()	
Conveyor 1 H.Z			Value remains same	Yes () No ()	
Conveyor 2 H.Z			Value remains same	Yes () No ()	
Recipe			Value remains same	Yes () No ()	



OPERATIONAL QUALIFICATION DOCUMENT OF PLC SYSTEM FOR AUTOMATIC ROTARYs VACUUMATRIC DRY SYRUP FILLING WITH ROPP CAPPING MACHINE

Parameter Description	Value Before Communicati on unplug	Value after Communicat ion link reconnect	Expected Result	Meets acceptance criteria	Sign. & date
Timer Setting Screen					
No Bottle ON TMR			Value remains same	Yes () No ()	
No Bottle OFF TMR			Value remains same	Yes () No ()	
NO Cap ON TMR			Value remains same	Yes () No ()	
NO Cap OFF TMR			Value remains same	Yes () No ()	
Dossing TMR			Value remains same	Yes () No ()	
Purzing ON Delay Time			Value remains same	Yes () No ()	
Purzing OFF Delay Time			Value remains same	Yes () No ()	
Powder Level ON TMR			Value remains same	Yes () No ()	

Comments/ Remarks:

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



**OPERATIONAL QUALIFICATION DOCUMENT OF PLC SYSTEM FOR AUTOMATIC ROTARYs
VACUUMATRIC DRY SYRUP FILLING WITH ROPP CAPPING MACHINE**

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.

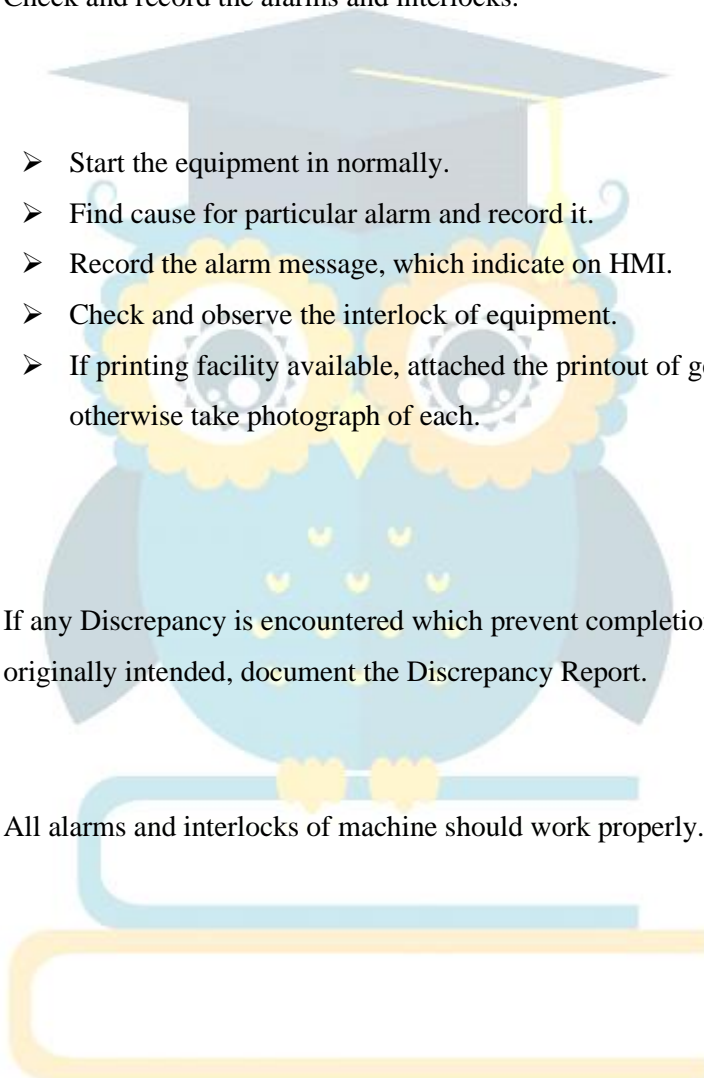
Procedure :

- 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 AUTOMATIC ROTARY VACUUMATRIC DRY SYRUP FILLING WITH ROPP CAPPING MACHINE

3.11.1 DATA TABLE OF ALARMS AND INTERLOCKS

Cause	Expected Result	Actual Result	Correction	Meets acceptance criteria	Sign. & date
Emergency					
If emergency push button is pressed	“Emergency”Input (X7)should Active in HMI input Status screen and Auto Cycle Deactivated And The Total System Should Go In Hold Mode.		Release the emergency push button	Yes () No ()	
No Bottle Sensor					
If there is no bottle on conveyor or any one bottle is not pass through the bottle sensing sensor.	“No Bottle Sensor”input (X0) should active in HMI input status screen and Auto Cycle Deactivated And The Total System Should Go In Hold Mode.		Check the bottle sensor and maintain the bottle quantity through running filling process.	Yes () No ()	



OPERATIONAL QUALIFICATION DOCUMENT OF PLC SYSTEM FOR AUTOMATIC ROTARY VACUUMATRIC DRY SYRUP FILLING WITH ROPP CAPPING MACHINE

Cause	Expected Result	Actual Result	Correction	Meets acceptance criteria	Sign. & date
No Cap Sensor					
If cap level is below than cap sensing sensor Which is placed in cap feeder bowl.	“No Cap Sensor” Input (X2) should Active in HMI input Status screen and Auto Cycle Deactivated And The Total System Should Go In Hold Mode.		Release the emergency push button.	Yes () No ()	
Air Low Level					
If air level is less than certain limit	“Air Low Level” input (X21) should active in HMI input status screen and Auto Cycle Deactivated And The Total System Should Go In Hold Mode.		Maintain the air level.	Yes () No ()	



OPERATIONAL QUALIFICATION DOCUMENT OF PLC SYSTEM FOR AUTOMATIC ROTARY VACUUMATRIC DRY SYRUP FILLING WITH ROPP CAPPING MACHINE

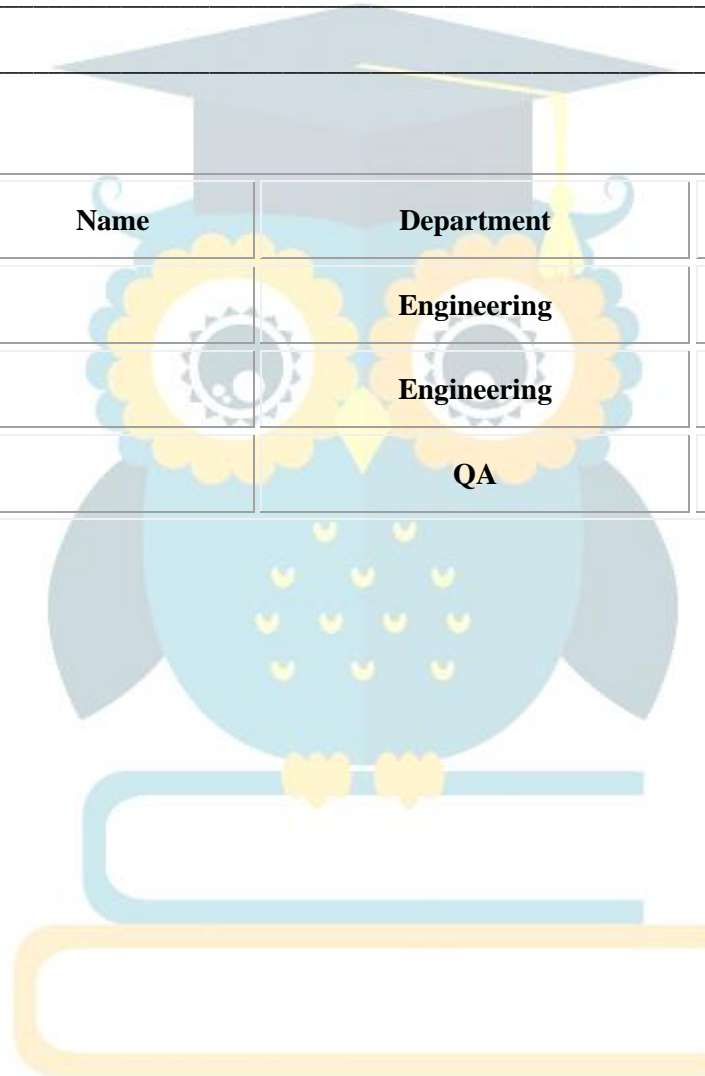
Cause	Expected Result	Actual Result	Correction	Meets acceptance criteria	Sign. & date
Vacuum Low					
If Vacuum is less than decided level	“ Vacuum Low ”Input (X22) should Active in HMI input Status screen and Auto Cycle Deactivated And The Total System Should Go In Hold Mode.		Release the emergency push button.	Yes () No ()	
Powder Level Low					
If powder level goes below than Powder level checking sensor which placed in powder feeder hooper.	“ Powder Level Low ”Input (X23) should Active in HMI input Status screen and Auto Cycle Deactivated And The Total System Should Go In Hold Mode.		Maintain the powder quantity in powder feeder hooper. And check the powder level sensor.	Yes () No ()	



OPERATIONAL QUALIFICATION DOCUMENT OF PLC SYSTEM FOR AUTOMATIC ROTARY VACUUMATRIC DRY SYRUP FILLING WITH ROPP CAPPING MACHINE

Comments/ Remarks:

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





OPERATIONAL QUALIFICATION DOCUMENT OF PLC SYSTEM FOR AUTOMATIC ROTARY VACUUMATRIC DRY SYRUP FILLING WITH ROPP CAPPING 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



OPERATIONAL QUALIFICATION DOCUMENT OF PLC SYSTEM FOR AUTOMATIC ROTARY VACUUMATRIC DRY SYRUP FILLING WITH ROPP CAPPING MACHINE

3.12.1 DATA TABLE OF CONTROL LOOP TEST

<u>Set Parameters</u>	<u>Set Value</u>
Main Motor Speed (BPM)	
VIB. Motor (RPM)	

Time (min)	Main Motor Speed (BPM)	VIB. Motor (RPM)	Meets acceptance criteria	Sign. & date
			Yes () No ()	
			Yes () No ()	
			Yes () No ()	
			Yes () No ()	
			Yes () No ()	



OPERATIONAL QUALIFICATION DOCUMENT OF PLC SYSTEM FOR AUTOMATIC ROTARY VACUUMATRIC DRY SYRUP FILLING WITH ROPP CAPPING MACHINE

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

Comments/ Remarks:

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



OPERATIONAL QUALIFICATION DOCUMENT OF PLC SYSTEM FOR AUTOMATIC ROTARY VACUUMATRIC DRY SYRUP FILLING WITH ROPP CAPPING 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

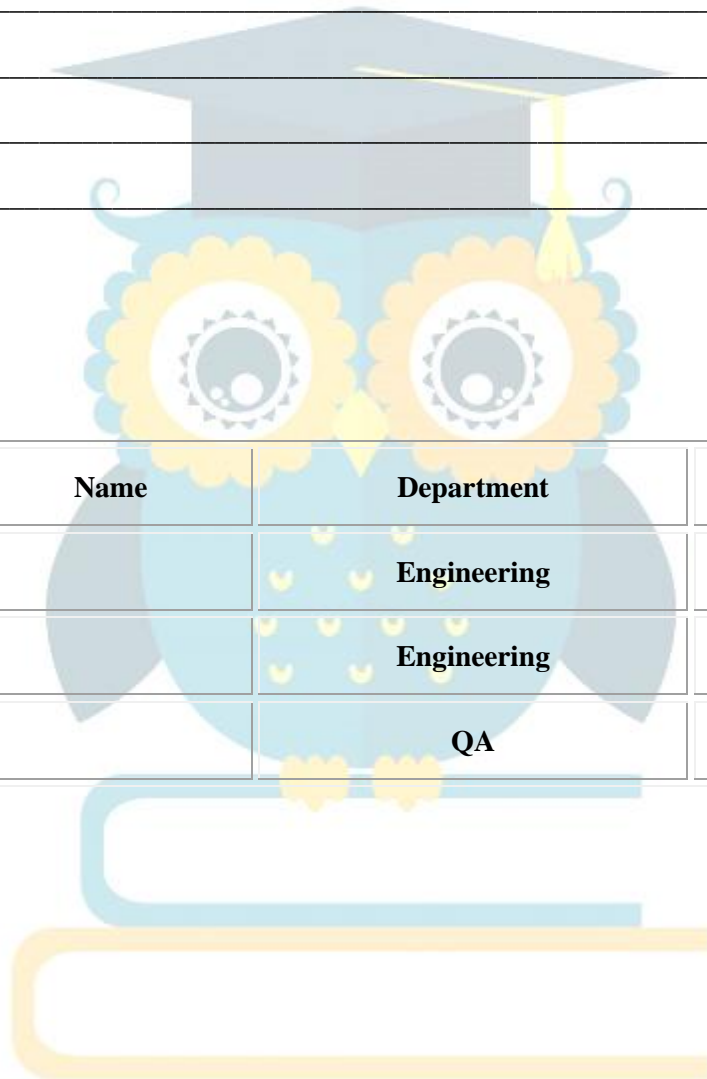
Category C: Deficiency to be rectified before proceeding further



OPERATIONAL QUALIFICATION DOCUMENT OF PLC SYSTEM FOR AUTOMATIC ROTARY VACUUMATRIC DRY SYRUP FILLING WITH ROPP CAPPING MACHINE

5.0.0 SUMMARY REPORT

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





OPERATIONAL QUALIFICATION DOCUMENT OF PLC SYSTEM FOR AUTOMATIC ROTARY VACUUMATRIC DRY SYRUP FILLING WITH ROPP CAPPING 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.

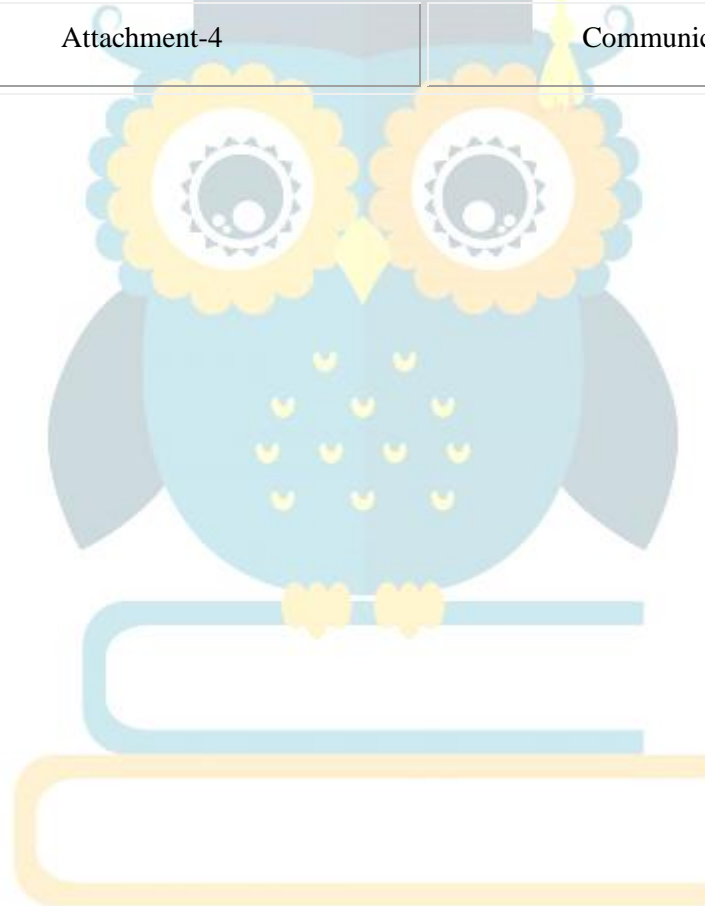
❖ **SOP :Standard Operating Procedure**



OPERATIONAL QUALIFICATION DOCUMENT OF PLC SYSTEM FOR AUTOMATIC ROTARY VACUUMATRIC DRY SYRUP FILLING WITH ROPP CAPPING MACHINE

7.0.0 LIST OF ATTACHMENTS

<u>Sr. No.</u>	<u>Reference</u>	<u>Description Of Attachment</u>
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





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8.0.0 LIST OF ABBREVIATIONS

<u>Acronym</u>	<u>Description</u>
CPU	→ Central Processing Unit
CGMP	→ Current Good Manufacturing Practices
GAMP	→ Good Automated Manufacturing Practices
GMP	→ Good Manufacturing Practices
ID	→ Identification Number
IO	→ Input Output
RQ	→ Re-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





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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	