INSTALLATION QUALIFICATION PROTOCOL OF PLC FOR AUTOCOATER 66“

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

INSTALLATION QUALIFICATION PROTOCOL OF PLC FOR AUTOCOATER 66“

EQUIPMENT ID NO. **: .....**
AREA **: .....**
MAKE **: SOLACE ENGINEER(MKTG.) PVT. LTD.**
EQUIPMENT NAME **: AUTOCOATER 66“**
PROTOCOL NO. **: .....**

The purpose of this document is to qualify the **PLC SYSTEM FOR AUTO COATER 66** and its control systems.

This document provides evidence that the PLC system is installed according to design specification, and operates as per design specification and complies with that standard operating practice and thus meets the cGMP obligation.

PROTOCOL PRE-APPROVAL PAGE

Signing of this approval page of protocol No. **.....** indicates agreement with the qualification approach described in this document. Modifications to the qualification approach become necessary, an addendum shall be prepared and approved. The protocol cannot be used for execution unless approved by the following authorities.

Name and Designation of Authorized Person	Signature	Date
Performed by:		
PROJECT ENGINEER		
Reviewed by:		
ENGINEERING		
Approved by:		
Q.A		

INSTALLATION QUALIFICATION PROTOCOL OF PLC FOR AUTOCOATER 66“

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INSTALLATION QUALIFICATION PROTOCOL OF PLC FOR AUTOCOATER 66“

Title:

Test specification: Installation Qualification
References: General Principles of PLC Validation

1.0 DOCUMENT REVISION HISTORY

Version No.	Reason for Revision	Status	Approval Date
1.0	First Version	Approved	

1.1 GLOSSARY/ DEFINITIONS

PLC		Programmable Logic Controller
HMI		Human Machine Interface
OIT		Operator Interface Terminal
NA		Not Applicable
GUI		Graphical User Interface
PC		Personal Computer
IQ		Installation Qualification
OQ		Operational Qualification
LED		Light Emitting Diode
CPU		Central Processing Unit
SOP		Standard Operating Procedure
ID		Identification

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2.0 GENERAL

2.1 OBJECTIVE

The objective of developing and executing this protocol is to collect sufficient data pertaining to the Autocoater 66“ and define the qualification requirements and acceptance criteria for the same. Successful completion of these qualification requirements will provide assurance that the PLC of Autocoater 66“ is installed and adheres to the specified design and that the system is installed according to the customary regulations and recommendations and meets Installation requirements.

2.2 SCOPE

The qualification study shall be performed to the Autocoater 66“.

This Protocol shall define the test procedures, documentation, references and acceptance criteria to establish that the Autocoater 66“ is installed as intended and is in accordance to the directives from the manufacturer/supplier of the Autocoater 66“.

Subsequently on the fulfillment of the Installation Qualification validation shall include the associated interfacing hardware and software.

2.3 REFERENCES

The Publications listed below form part of this protocol. Each publication shall be the latest revision and addendum in effect on the date this protocol is approved for execution unless noted otherwise. Expect as modified by the requirements specified herein or the details of the drawings, work included in this protocol shall conform to the applicable provision of these publications.

1. 21 CFR 210 Code of Federal Regulations; Current Good Manufacturing Practice in Manufacturing, Processing, Packing or Holding of Drugs
2. 21 CFR 210 Code of Federal Regulations; Current Good Manufacturing Practice for Finished Pharmaceuticals
3. GAMP 5 Good Automated Manufacturing Practice; Version 5.0

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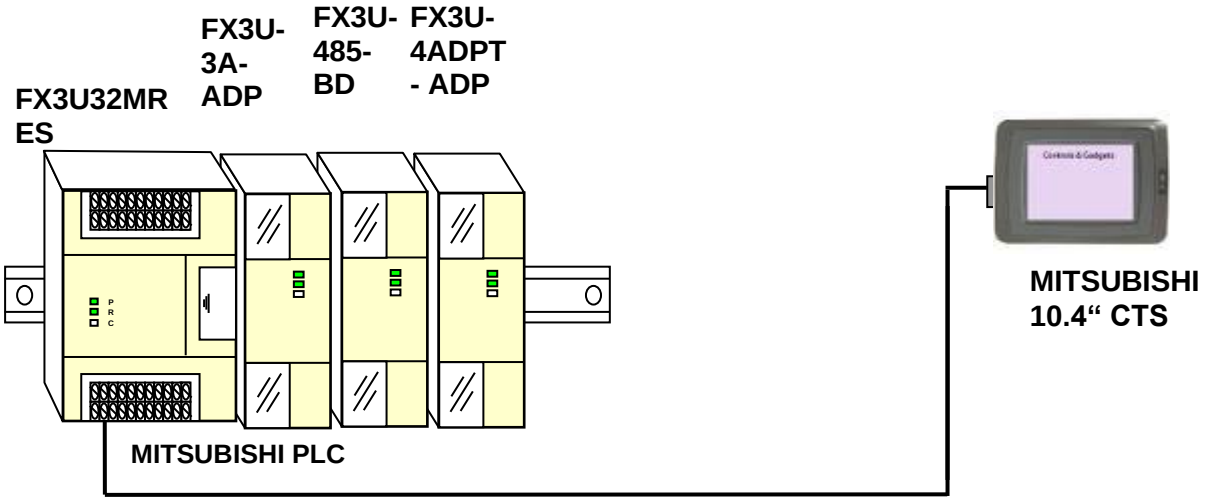
References: General Principles of PLC Validation

3.0 EQUIPMENT / SYSTEM ARCHITECTURE

System Architecture:



Title:

Test specification: Installation Qualification
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3.1 DESIGN DOCUMENTS

Design requirements and sequence of operation are based on the following documentation:

- System architecture diagram, along with a complete hardware listing of the components supplied with the PLC wiring Diagram (if not listed on the architecture diagrams).
- System Operation Manuals & Guides.
- Communication cables directly interfacing with the system.

3.2 TEST QUALIFICATION INSTRUMENTS

To execute this protocol, the following will be needed by the executor:
Standard devices (used for reference readings) calibration certificates shall be provided.

Multimeter - 600 volts maximum, 10 amperes maximum.

The above test instruments should have valid calibration on the date of report execution and validity certificate to that effect should be available and traceable to National standard.

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4.0 EXECUTION

4.1 GENERAL

The satisfactory installation and integration of the Autocoater 66“ shall be verified by executing the qualification studies described in this protocol. Successfully executed protocol documents that the PLC of Autocoater 66“ is installed and satisfactorily integrated.

4.2 IDENTIFICATION OF PERFORMERS AND EXECUTOR

All Performers involved in this protocol execution are to sign within the prescribed format given below:

Name	Designation	Signature	Initial	Date

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5.0 PURPOSE OF THE INSTALLATION QUALIFICATION

The Installation Qualification documents prepared by the **M/s. .....** provide the documented verification that all key aspects of the PLC of Autocoater 66“ installation (applied components, settings, software and specifications) adhere to the specified design and that the PLC of Autocoater 66“ is produced and installed according to the customary regulations and recommendations. The Autocoater 66“ tests described in these documents will be carried out by qualified personnel.

6.0 CONTENTS OF THE INSTALLATION QUALIFICATION

In order to guarantee that the Autocoater 66“corresponds to the specified design, the following items shall be checked:

- Check for the PLC installed system details
- Check if the Documents to be delivered are available, readable and complete.
- Check for the installed system Hardware components
- Check for the Communication Cables
- Check for the Power Utility of System
- Check for the User/access levels
- Check for the Software Backup and Configuration
- Check for the General System Inspection for the Control Panel

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7.0 STRUCTURE AND PROCEDURE OF THE INSTALLATION QUALIFICATION TESTS

The individual tests consist of the following two elements:

a) Test procedure sheet.
b) Test result sheets and Annexure for each individual test (dependent on the respective test).

The Test Specification of the individual IQ tests is structured as follows:

- Designation of each test by a **Title**.
- The section **Purpose** describes background or aim of the test.
- The sections **Tools/reference documents** specify tools or documents required for the test.
- **Prerequisites** define the necessary test conditions or preparations.
- The section **Test procedure** describes step by step the actions to be performed by the executor/performer.
- The section **Acceptance criteria** defines the set of expected results that shall be met for the test to be passed.
- The section **Actual result meets acceptance criteria** must be filled out and signed by the executor/performer and a **witness** or **approval** person from the customer.

Comments/Deviations are noted by the executor/performer if the test can't be carried out in the prescribed way or the expected result was not met.

- The section **Appendices** is used to support the test sheets.

8.0 CONDITION OF AUTOCOATER 66“ BEFORE INSTALLATION QUALIFICATION TESTS

The following conditions have to be fulfilled before carrying out the IQ tests:

- The installation of the System must be completed.
- The system marking (Tag No., cable No.) must be correctly executed.
- The manufacturer Manuals must be completely filled and available.

Title:

Test specification: Installation Qualification
References: General Principles of PLC Validation

9.0 OVERVIEW OF THE INSTALLATION QUALIFICATION TESTS

The above-described content of the IQ is divided into the following tests:

Test No.	Title	Test purpose	Test Performed by (Date/ Sign)
	Installed System details	Identification of the system to be validated	
	Documents	Check for availability of master documents.	
	Hardware components	Check for system associated hardware components	
	Communication Cables	Check for Communication Cables Details	
	Power Utility	Check for Power Utility Details	
	User/access levels	Check for available User/access levels	
	Software Backup and Configuration	Check for the Software Backup and Configuration	
	General System Inspection for Control Panel	Check for General System Inspection for Control Panel	

The overview of the IQ can also be taken as a check list for the state of test execution.

The Installation Qualification is successfully completed, if the results of all above mentioned IQ test items meet the acceptance criteria.

Title:

Test specification: Installation Qualification
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10.0 REVIEW SUMMARY

The review summary has to be filled out after carrying all installation qualification tests. Possible corrective actions or differences from the test protocols have to be recorded.

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Title:

Test IQ 1: Installed System Details

Purpose:
This test sheet of the IQ is intended to describe which and what system is being validated.

Tools/ reference documents:
Nil

Prerequisites:
Nil

Test procedure:
- Confirm the identification tag No., supplier, model No., location of the system
- Record the parameters in the test sheet with verification source.

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Title:

Test result sheet: Installed System Details

Description	Specified As	As Observed	Verification Source	Discrepancy? (Yes/No)	Acceptable? (Yes/No)
System Name	Autocoater 66“				
ID No.					
Area					
Manufacturer / Supplier	SOLACE Engineers (MKTG.) Pvt. Ltd.				

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Acceptance criteria:
- Data recorded from the name tag plates/room plates shall match with the data specified in test data table.

Actual result meets acceptance criteria:

(Yes/No) _____

Tests performed at:	Verified By	Company/ Dept.	Date	Sign
Tests performed at:	Checked By	Company/ Dept.	Date	Sign

Comments/ deviations:

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Title:

Test IQ 2 : Documents

Purpose:
Check that the documents listed in the following table are available, readable and complete.

Tools/ reference documents:
Nil

Prerequisites:
Nil

Test procedure:
- Check that the documents to deliver, listed in the test result sheet: **"Documents"** are available.
- Check that the documents are readable and complete.

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Title:

Test result sheet: Documents

Document /Software name	Title/Make	Document/Software version or ID-No.	Document/Software present, readable and complete (Yes/No)
Wiring Drawing	Electrical Drawing of Autocoater-66		
Operational Manual	Operational Manual		

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Acceptance criteria:
- The Documents listed in the test result sheet: **"Documents"** (next page) are available, readable and complete.

Actual result meets acceptance criteria:

(Yes/No) _____

Tests performed at:	Verified By	Company/ Dept.	Date	Sign
Tests performed at:	Checked By	Company/ Dept.	Date	Sign

Comments/ deviations:

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Title:

Test IQ 3 : System Hardware Components

Purpose:
To verify Physical system installation with system documents.

Tools/ reference documents:
Nil

Prerequisites:
Nil

Test procedure:
- Verify the installed system by visual inspection and record the relevant details of the individual hardware components.
- Identify all components model number, quantities and document the same.

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Title:

Test IQ 3 : System Hardware Components

Component Description	Manufacturer Specification	Actual Observation	Discrepancy?(Yes/No)	Acceptable?(Yes/No)
PLC				
Manufacturer / Supplier	Mitsubishi			
Equipment ID/Model No.				
Quantity (No)	01			
Equipment ID/Model No.				
Quantity (No)	01			
Equipment ID/Model No.				
Quantity (No)	01			
Equipment ID/Model No.				
Quantity (No)	01			
HMI				
Manufacturer / Supplier	Mitsubishi			
Model No.	10.4“ CTS			
Quantity (No)	01			
SMPS				
Manufacturer / Supplier	Siemens or Equivalent			
Quantity (No)	02			

Acceptance criteria:

- Physical installation of the system shall be verified and details shall be recorded. Model number and quantity of the system component shall match with the physical system installation.

Actual result meets acceptance criteria:

(Yes/No) _____

Tests performed at:	Verified By	Company/ Dept.	Date	Sign
Tests performed at:	Checked By	Company/ Dept.	Date	Sign

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Component Description	Manufacturer Specification	Actual Observation	Discrepancy?(Yes/No)	Acceptable?(Yes/No)

Comments/ deviations:

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Title:

Test IQ 4 : Communication Cables

Purpose:
To Verify the communication cables used for interfacing between system components.

Tools/ reference documents:
Nil

Prerequisites:
Nil

Test procedure:
- Verify model/catalogue numbers and connectivity of the cables.

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Title:

Test result sheet: Communication Cables

Source	Destination	Make/Type	Actual Observation	Discrepancy?(Yes/No)	Acceptable?(Yes/No)
PLC	HMI				
HMI	Printer				

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Acceptance criteria:

- Details of the communication cables used for the system shall be identified.

Actual result meets acceptance criteria:

(Yes/No) _____

Tests performed at:	Verified By	Company/ Dept.	Date	Sign
Tests performed at:	Checked By	Company/ Dept.	Date	Sign

Comments/ deviations:

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Title:

Test IQ 5 : Power Utility

Purpose:
To verify that the electrical utilities are installed and are available as specified.

Tools/ reference documents:
Digital Multimeter

Prerequisites:
Nil

Test procedure:
- Power on the system and put the multimeter in AC/DC voltage measurement range and measure the voltage at terminal end. Note down the voltage reading in the test data sheet. Repeat above step for all system modules those are separately powered.

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Title: **Test result sheet:** Power Utility

Description	**Specified Range**	**Measurement Results**	**Within Range? (Yes/No)**	**Discrepancy? Yes/No)**
PLC System				
Voltage	24 V DC (± 2V)			
HMI				
Voltage	24 V DC (± 2V)			

Title: **Test Instrument Used**

Test Instrument	**Manufacturer**	**Tag number**	**Calibrated Date**	**Calibration Due Date**
Digital Multimeter				

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Acceptance criteria:
- Recorded measurements for voltage shall fall within their specified range.

Actual result meets acceptance criteria:

(Yes/No) _____

Tests performed at:	Verified By	Company/ Dept.	Date	Sign
		.		
Tests performed at:	Checked By	Company/ Dept.	Date	Sign

Comments/ deviations:

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Title:

Test IQ 6 : Users/ Access Availability

Purpose:
To verify availability of users those can access to system for logged data files.

Tools/ reference documents:
Nil

Prerequisites:
Nil

Test procedure:
- Run the System.
- Check & list out the available users in system.

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Title:

Test result sheet : Users/ Access Availability

Users List	User Level	Available? (Y/N)	Discrepancy? (Yes/No)	Acceptable? (Yes/No)
Operator	Level 1			
Supervisor	Level 2			
Master	Level 3			

Acceptance criteria:

- All listed users shall be available to access the System and Software Operations should have user levels for protection the logged data files.

Actual result meets acceptance criteria:

(Yes/No) _____

Tests performed at:	Verified By	Company/ Dept.	Date	Sign
Tests performed at:	Checked By	Company/ Dept.	Date	Sign

Comments/ deviations:

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Title:

Test IQ 7 : Software Backup and Configuration

Purpose:
To verify availability of Customized application Backup and Configuration.

Tools/ reference documents:
Nil

Prerequisites:
Nil

Test procedure:

- Take the PLC backup.
- Scan the backup copy for viruses using the most current vendor or client-supplied virus detection utility.
  Or
- Ensure availability of willingness letter given by system supplier.
  Or
- Ensure availability of hard copy of Program Backup.

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Title:

Test result sheet : Software Backup and Configuration

Application Software Name	Application software version	Backup Available? (Yes/No)	Discrepancy? (Yes/No)	Acceptable? (Yes/No)
Gx Developer				

OR

Description	Specified As	As Observed (Yes/No)	Discrepancy? (Yes/No)
Willingness letter availability	Willingness letter should available.		

OR

Description	Specified As	As Observed (Yes/No)	Discrepancy? (Yes/No)
Hardcopy of Program Backup	Hardcopy of Program Backup should available.		

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Acceptance criteria:

- PLC Program backup shall be readable in well defined application software version.
  OR
- Willingness Letter Shall be available.
  OR
- Hardcopy of Program Backup Shall be available.

Actual result meets acceptance criteria:

(Yes/No) _____

Tests performed at:	Verified By	Company/ Dept.	Date	Sign
.		.		
Tests performed at:	Checked By	Company/ Dept.	Date	Sign

Comments/ deviations:

Appendix No : ___

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Title:

Test IQ 8: General System Inspection For Control Panel

Purpose:
To Inspect the system for General Cleanliness and break-free wirings.

Tools/ reference documents:
Multimeter

Prerequisites:
Nil

Test procedure:
- Visually Inspect the Control Panel Cabinet for General Cleanliness.
- Search for any un-terminated or broken Wiring/Modules in Controller panel.
- Visually Inspect the Separation of Power and Signal cables.
  Verification of components such as Exhaust fans, Service lights, glands position, cables ferruling, tags for components.

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Title:

Test result sheet: General System Inspection For Control Panel

Procedures	Expected Result	Actual Observations	Discrepancy?(Yes/No)	Acceptable? (Yes/No)
Control Panel cabinet	It should be cleanliness and dust free			
Proper Wiring	It should not be un-terminated or broken wiring/modules			
Communication cables	It should be separate for Power and Signal Cables			
Exhaust Fan, Service Light, Glands Position	It should be available depending upon the Panel Design			
Earthing	Panel Earthing Should be made with proper Conductor and Voltage between Neutral And Earth should be less than 1volt			

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Acceptance criteria:
Cabinet must be Clean; there shall not be any broken Wires/Modules.
High voltage (i.e. > 440 V) and Signal Cables must be separate

Actual result meets acceptance criteria:

(Yes/No) _____

Tests performed at:	Verified By	Company/ Dept.	Date	Sign
Tests performed at:	Checked By	Company/ Dept.	Date	Sign

Comments/ deviations:

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Title:

INSTALLATION QUALIFICATION TEST STATUS

Test Number	Test Name	Pass/Fail		Discrepancy Found	
		Pass	Fail	Yes	No
1	Installed System details				
2	Documents				
3	Hardware components				
4	Communication Cables				
5	Power Utility				
6	Users/ Access Availability				
7	Software Backup and Configuration				
8	General System Inspection for Control Panel				

Title:

QUALIFICATION COMPLETION AND APPROVAL

Verified that all test cases required by this reports are completed, reconciled and attached to this report and are included in the Qualification summary report.

Signatures in the block below indicate that all items in this Installation Qualification have been reviewed and approved.

POST APPROVAL PAGE		
Name and Designation of Authorized Person	**Signature**	**Date**
Performed by: M/s.		
PROJECT ENGINEER		
Reviewed by: M/s.		
ENGINEERING		
Reviewed by: M/s.		
PRODUCTION		
Approved by: M/s.		
Q.A		

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Title:

TERMINOLOGIES

A. Alarm
A device or function that signals the existence of an abnormal condition by means of an audible or visible discrete change, or both, intended to attract attention.

B. Control System
A system in which deliberate guidance or manipulation is used to achieve a prescribed value of a variable.

C. Interlock
An arrangement of signals, which perform a logical function in a control system.

D. LED
Light Emitting Diode. Status indicators available on the PLC modules to reflect the Input/output and processor status.

E. HMI
Human Machine Interface, which is used to interface the application program with Programmable Logic Controller.

F. CIQ
Control System Installation Qualification, which includes the static behaviour of the system.

G. NABL
National Accreditation Board for Testing and Calibration laboratories according to ISO 17025.

H. PLC
Programmable logic Controller, which is programmed, based on the system requirement by the software. After that whole system controls based on the PLC Commands.

I. I/O
Input and Output signals of PLC system.

J. M/C
Machine.

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Title:

SUPPORTING DOCUMENTS / APPENDICES

S.No.	Description Of Attachment	Reference	Checked By / Date