INSTALLATION QUALIFICATION PROTOCOL OF PLC FOR 51 STATION DOUBLE ROTARY TABLET COMPRESSION MACHINE (EQ. ID NO. .....)

INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR 51 STATION DOUBLE ROTARY TABLET COMPRESSION MACHINE

The purpose of this document is to qualify the **PLC SYSTEM FOR COMPRESSION MACHINE** 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: M/s.		
PROJECT ENGINEER		
Reviewed by:		
ENGINEERING		
Approved by:		
Q.A		

INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR 51 STATION DOUBLE ROTARY TABLET COMPRESSION MACHINE

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INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR 51 STATION DOUBLE ROTARY TABLET COMPRESSION MACHINE

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 Compression Machine and define the qualification requirements and acceptance criteria for the same. Successful completion of these qualification requirements will provide assurance that the PLC of Compression Machine 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 Compression Machine.

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

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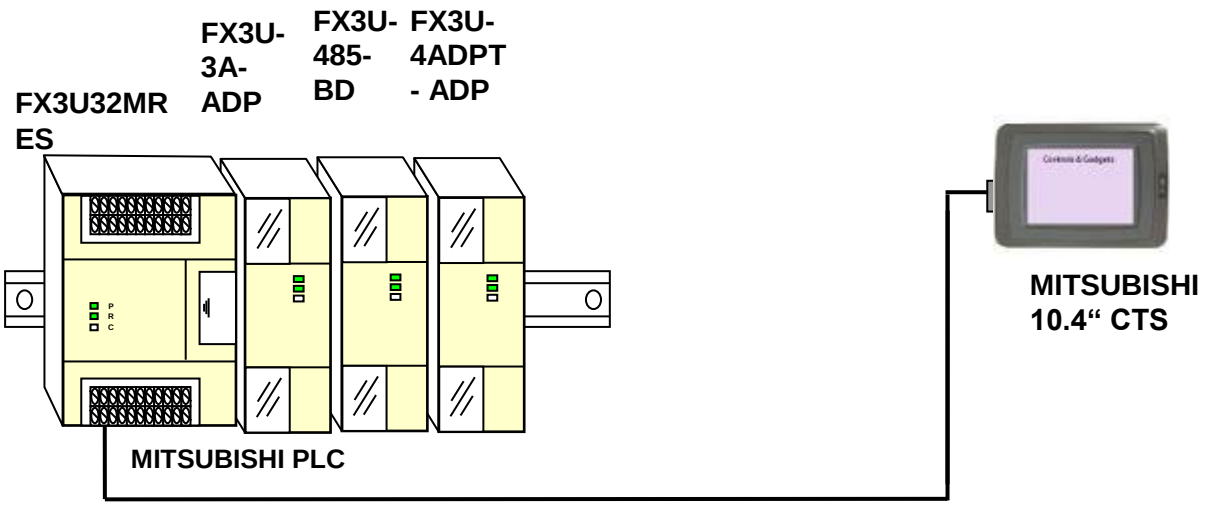
Test specification: Installation Qualification
References: General Principles of PLC Validation

3.0 EQUIPMENT / SYSTEM ARCHITECTURE

System Architecture:



MITSUBAC 19/3M Comm. Cable

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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 Compression machine shall be verified by executing the qualification studies described in this protocol. Successfully executed protocol documents that the PLC of Compression machine 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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Title:

Test specification: Installation Qualification
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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 Compression machine installation (applied components, settings, software and specifications) adhere to the specified design and that the PLC of Compression machine is produced and installed according to the customary regulations and recommendations. The Compression machine 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 Compression machine 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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Title:

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

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 CCOMPRESSION MACHINE BEFORE INSTALLATION QUALIFICATION TESTS

The following conditions have to be fulfilled before crrying 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.

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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)
IQ01	Installed System details	Identification of the system to be validated	
IQ02	Documents	Check for availability of master documents.	
IQ03	Hardware components	Check for system associated hardware components	
IQ04	Communication Cables	Check for Communication Cables Details	
IQ05	Power Utility	Check for Power Utility Details	
IQ06	User/access levels	Check for available User/access levels	
IQ07	Software Backup and Configuration	Check for the Software Backup and Configuration	
IQ08	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.

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Title:

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

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.

INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR 51 STATION DOUBLE ROTARY TABLET COMPRESSION MACHINE

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	Compression Machine				
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:

Appendix No : ___

INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR 51 STATION DOUBLE ROTARY TABLET COMPRESSION MACHINE

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.

INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR 51 STATION DOUBLE ROTARY TABLET COMPRESSION MACHINE

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 Compression Machine		
Operational Manual	Operational Manual		

INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR 51 STATION DOUBLE ROTARY TABLET COMPRESSION MACHINE

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:

Appendix No : ___

INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR 51 STATION DOUBLE ROTARY TABLET COMPRESSION MACHINE

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.

INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR 51 STATION DOUBLE ROTARY TABLET COMPRESSION MACHINE

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.	FX3U32MR/ES			
Quantity (No)	01			
Equipment ID/Model No.	FX3U3A ADP			
Quantity (No)	01			
Equipment ID/Model No.	FX3U485BD			
Quantity (No)	01			
Equipment ID/Model No.	FX3U4ADPT ADP			
Quantity (No)	01			
HMI				
Manufacturer / Supplier	Mitsubishi			
Model No.	10.4“ CTS			
Quantity (No)	01			
SMPS				
Manufacturer / Supplier	Siemens or Equivalent			
Quantity (No)	02			

INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR 51 STATION DOUBLE ROTARY TABLET COMPRESSION MACHINE

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

Comments/ deviations:

Appendix No : ___

INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR 51 STATION DOUBLE ROTARY TABLET COMPRESSION MACHINE

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.

INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR 51 STATION DOUBLE ROTARY TABLET COMPRESSION MACHINE

Title:

Test result sheet: Communication Cables

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

INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR 51 STATION DOUBLE ROTARY TABLET COMPRESSION MACHINE

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:

Appendix No : ___

INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR 51 STATION DOUBLE ROTARY TABLET COMPRESSION MACHINE

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.

INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR 51 STATION DOUBLE ROTARY TABLET COMPRESSION MACHINE

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:

Appendix No : ___

INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR 51 STATION DOUBLE ROTARY TABLET COMPRESSION MACHINE

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.

INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR 51 STATION DOUBLE ROTARY TABLET COMPRESSION MACHINE

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:

Appendix No : ___

INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR 51 STATION DOUBLE ROTARY TABLET COMPRESSION MACHINE

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 : ___

INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR 51 STATION DOUBLE ROTARY TABLET COMPRESSION MACHINE

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.

INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR 51 STATION DOUBLE ROTARY TABLET COMPRESSION MACHINE

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			

INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR 51 STATION DOUBLE ROTARY TABLET COMPRESSION MACHINE

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:

Appendix No : ___

INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR 51 STATION DOUBLE ROTARY TABLET COMPRESSION MACHINE

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				

INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR 51 STATION DOUBLE ROTARY TABLET COMPRESSION MACHINE

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		

INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR 51 STATION DOUBLE ROTARY TABLET COMPRESSION MACHINE

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.

INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR 51 STATION DOUBLE ROTARY TABLET COMPRESSION MACHINE

Title:

SUPPORTING DOCUMENTS / APPENDICES

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