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

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

CONTENTS

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**	

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 "Double Side Rotary Tablet Compression M/C 45 STN (Accura Press IV)" 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 "Double Side Rotary Tablet Compression M/C 45 STN (Accura Press IV)" which is located in "Compression-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 "Double Side Rotary Tablet Compression M/C 45 STN (Accura Press IV)" has been operated in accordance with the master documentations.

2.3.0 BACKGROUND:

The **"Double Side Rotary Tablet Compression M/C 45 STN (Accura Press IV)"** is a new system purchase specifically for use at …….

2.4.0 REVISION HISTORY:

Version No.	Effective Date	Reason for Change
00		New Document

2.5.0 REFERENCES:

The test and execution procedure within the scope of the qualification document are consistence with the following reference.

Guideline	Details
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		

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
➢ Co-ordinate during execution of Qualification activities.	➢ Co-ordinate during execution of Qualification activities.	➢ Co-ordinate during execution of Qualification activities.
➢ To provide utilities for Qualification activity.	➢ Provide personnel for facilitating the execution of Qualification activity.	➢ To review and approve the Qualification document.
➢ To review the operational qualification document.	➢ Check that test requirements ➢ To Review the operational qualification document.	

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: _____

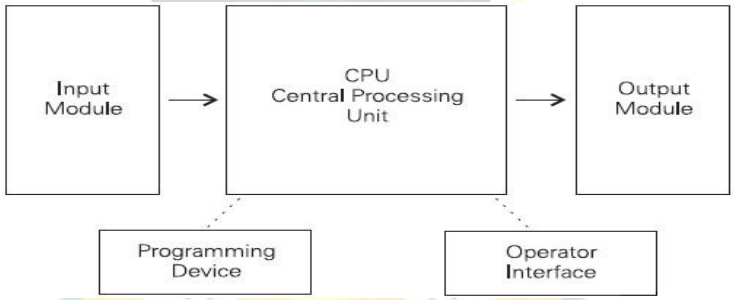
Designation: _____ Designation: _____

Signature: _____ Signature: _____

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.

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

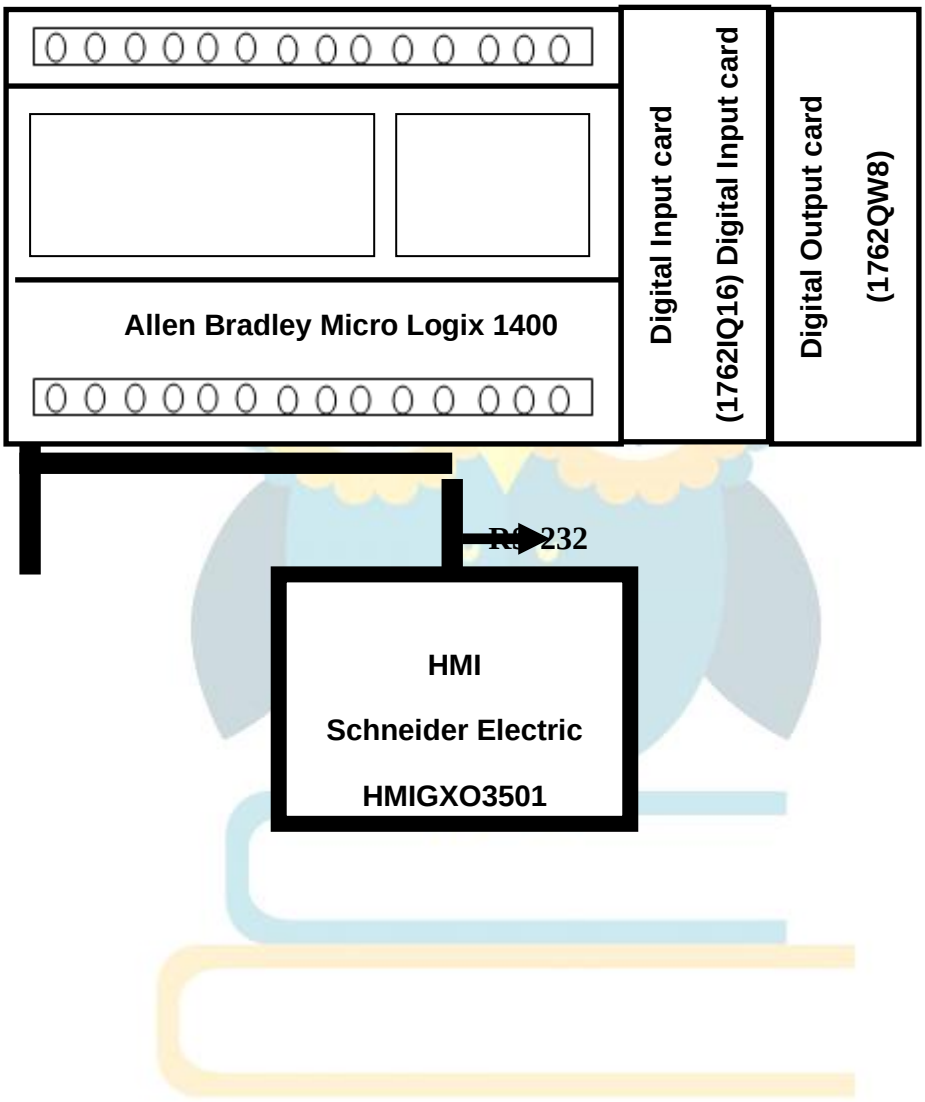
"Human Machine Interface" (HMI) is platform which is assist the operator to supervise and control the equipment. Operator has displayed information from the HMI and gives the command to PLC then PLC will execute the command.

2.10.0 SYSTEM DESCRIPTION

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

2.11.0 PLC SYSTEM SCHEMATIC DIAGRAM

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



3.0.0 OPERATIONAL QUALIFICATION TEST

Sr. No.	Test Details
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

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.

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	

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 Criteria : All critical sensors of PLC system must be calibrated.

3.2.1 DATA TABLE OF CALIBRATION CERTIFICATES OF SENSORS

Sr. No.	Sensor Name	Sensor ID No	Calibration Date	Calibration Due Date	Sign. & date

Comments/ Remarks:

_____

_____

_____

_____

_____

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

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.

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	

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.

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 (Micro Logix 1400)				
POWER	OFF		Yes ( ) No ( )	
RUN	OFF		Yes ( ) No ( )	
FAULT	OFF		Yes ( ) No ( )	
FORCE	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 (Micro Logix 1400)				
POWER	ON		Yes ( ) No ( )	
RUN	ON		Yes ( ) No ( )	
FAULT	OFF		Yes ( ) No ( )	
FORCE	OFF		Yes ( ) No ( )	

Comments/ Remarks:

_____

_____

_____

_____

_____

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

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 (If Applicable)
- Feed 4-20mA current or appropriate Ohms signal to PLC system using calibrated Universal Calibrator.
- Simultaneously check the reading in PLC.
- Verify and record the reading of it.

Analog Output (If Applicable)
- Measure appropriate current signal from output terminal of PLC system using calibrated universal calibrator.
- Verify and record the reading of it.

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.

3.5.1 DATA TABLE OF PLC DIGITAL INPUTS

PLC Processor (Micro Logix 1400)					
PLC Address	**Description**	**Expected state of LED**	**Actual state of LED**	**Meets acceptance criteria**	**Sign. & date**
IN00	Servo O/P signal	ON		Yes ( ) No ( )	
		OFF		Yes ( ) No ( )	
IN01	Servo O/P signal	ON		Yes ( ) No ( )	
		OFF		Yes ( ) No ( )	
IN02	Servo O/P signal	ON		Yes ( ) No ( )	
		OFF		Yes ( ) No ( )	
IN03	Servo O/P signal	ON		Yes ( ) No ( )	
		OFF		Yes ( ) No ( )	
IN04	Servo O/P signal	ON		Yes ( ) No ( )	
		OFF		Yes ( ) No ( )	
IN05	Servo O/P signal	ON		Yes ( ) No ( )	
		OFF		Yes ( ) No ( )	
IN06	Proxy	ON		Yes ( ) No ( )	
		OFF		Yes ( ) No ( )	
IN07	HYD. Trip	ON		Yes ( ) No ( )	
		OFF		Yes ( ) No ( )	
IN08	VFD1 trip	ON		Yes ( ) No ( )	
		OFF		Yes ( ) No ( )	
IN09	VFD2 trip	ON		Yes ( ) No ( )	

		OFF		Yes ( ) No ( )	

PLC Processor (Micro Logix 1400)					
PLC Address	**Description**	**Expected state of LED**	**Actual state of LED**	**Meets acceptance criteria**	**Sign. & date**
IN10	F1 O/L	ON		Yes ( ) No ( )	
		OFF		Yes ( ) No ( )	
IN11	F2 O/L	ON		Yes ( ) No ( )	
		OFF		Yes ( ) No ( )	
IN12	E. Stop	ON		Yes ( ) No ( )	
		OFF		Yes ( ) No ( )	
IN13	LHS main Press OK	ON		Yes ( ) No ( )	
		OFF		Yes ( ) No ( )	
IN14	RHS Main Press OK	ON		Yes ( ) No ( )	
		OFF		Yes ( ) No ( )	
IN15	LHS Guard	ON		Yes ( ) No ( )	
		OFF		Yes ( ) No ( )	
IN16	RHS Guard	ON		Yes ( ) No ( )	
		OFF		Yes ( ) No ( )	
IN17	Lub. Oil level ok	ON		Yes ( ) No ( )	
		OFF		Yes ( ) No ( )	
IN18	Hyd. Press switch	ON		Yes ( ) No ( )	
		OFF		Yes ( ) No ( )	
IN19	LH PWD level	ON		Yes ( ) No ( )	

		OFF		Yes ( ) No ( )	

Input card (1762 IQ16)					
PLC Address	**Description**	**Expected state of LED**	**Actual state of LED**	**Meets acceptance criteria**	**Sign. & date**
IN00	RH PWD level	ON		Yes ( ) No ( )	
		OFF		Yes ( ) No ( )	
IN01	Dust EXT.	ON		Yes ( ) No ( )	
		OFF		Yes ( ) No ( )	
IN02	Spare	NA		Yes ( ) No ( )	
IN03	LHS Dozzer Present	ON		Yes ( ) No ( )	
		OFF		Yes ( ) No ( )	
IN04	RHS Dozzer Present	ON		Yes ( ) No ( )	
		OFF		Yes ( ) No ( )	
IN05	LHS Pre Press OK	ON		Yes ( ) No ( )	
		OFF		Yes ( ) No ( )	
IN06	RHS Pre Press OK	ON		Yes ( ) No ( )	
		OFF		Yes ( ) No ( )	
IN07	Front Guard	ON		Yes ( ) No ( )	
		OFF		Yes ( ) No ( )	
IN08	Rear Guard	ON		Yes ( ) No ( )	
		OFF		Yes ( ) No ( )	
IN09	LH MIN	ON		Yes ( ) No ( )	
		OFF		Yes ( ) No ( )	

Input card (1762 IQ16)					
PLC Address	**Description**	**Expected state of LED**	**Actual state of LED**	**Meets acceptance criteria**	**Sign. & date**
IN10	LH MAX	ON		Yes ( ) No ( )	
		OFF		Yes ( ) No ( )	
IN11	RH MIN	ON		Yes ( ) No ( )	
		OFF		Yes ( ) No ( )	
IN12	RH MAX	ON		Yes ( ) No ( )	
		OFF		Yes ( ) No ( )	
IN13	Spare	NA		Yes ( ) No ( )	
IN14	Spare	NA		Yes ( ) No ( )	
IN15	Spare	NA		Yes ( ) No ( )	
IN16	Spare	NA		Yes ( ) No ( )	

3.5.2 DATA TABLE OF PLC DIGITAL OUTPUTS

PLC Processor (Micro Logix 1400)					
PLC Address	**Description**	**Expected state of LED**	**Actual state of LED**	**Meets acceptance criteria**	**Sign. & date**
OUT00	SER 1 80	ON		Yes ( ) No ( )	
		OFF		Yes ( ) No ( )	
OUT02	SER 2 81	ON		Yes ( ) No ( )	
		OFF		Yes ( ) No ( )	
OUT03	SER 3 82	ON		Yes ( ) No ( )	
		OFF		Yes ( ) No ( )	
OUT03	SER 4 83	ON		Yes ( ) No ( )	
		OFF		Yes ( ) No ( )	
OUT04	VFD1	ON		Yes ( ) No ( )	
		OFF		Yes ( ) No ( )	
OUT05	Clutch	ON		Yes ( ) No ( )	
		OFF		Yes ( ) No ( )	
OUT06	F1	ON		Yes ( ) No ( )	
		OFF		Yes ( ) No ( )	
OUT07	F2	ON		Yes ( ) No ( )	
		OFF		Yes ( ) No ( )	
OUT08	HYD.	ON		Yes ( ) No ( )	
		OFF		Yes ( ) No ( )	
OUT09	DEC Valve	ON		Yes ( ) No ( )	

		OFF		Yes ( ) No ( )	

PLC Processor Micro Logix 1400					
PLC Address	**Description**	**Expected state of LED**	**Actual state of LED**	**Meets acceptance criteria**	**Sign. & date**
OUT10	LUB. Valve	ON		Yes ( ) No ( )	
		OFF		Yes ( ) No ( )	
OUT11	buzzer	ON		Yes ( ) No ( )	
		OFF		Yes ( ) No ( )	
Digital Output Card (OW8)					
OUT00	DUST Extractor	ON		Yes ( ) No ( )	
		OFF		Yes ( ) No ( )	
OUT01	Spare	NA		Yes ( ) No ( )	
OUT02	Spare	NA		Yes ( ) No ( )	
OUT03	Spare	NA		Yes ( ) No ( )	
OUT04	Spare	NA		Yes ( ) No ( )	
OUT05	Spare	NA		Yes ( ) No ( )	
OUT06	Spare	NA		Yes ( ) No ( )	
OUT07	Spare	NA		Yes ( ) No ( )	

3.5.3 DATA TABLE OF ANALOG INPUTS

Analog Input of PLC Processor (Micro Logix 1400)						
Address	**Details**	**Input Signal**	**Expected Process Reading in HMI**	**Actual Process Reading**	**Meets acceptance criteria**	**Sign. & date**
IN1	HYD Press	4.000mA	1 kN		Yes ( ) No ( )	
		12.000mA	50.5 kN		Yes ( ) No ( )	
		20.000mA	100 kN		Yes ( ) No ( )	
IN2	From AC VFD 1	4.000mA	0%		Yes ( ) No ( )	
		12.000mA	50%		Yes ( ) No ( )	
		20.000mA	100%		Yes ( ) No ( )	
IN3	Spare	NA	NA		Yes ( ) No ( )	
IN4	Spare	NA	NA		Yes ( ) No ( )	
Analog Input & output card (IF2OF2)						
IN1	Spare	NA	NA		Yes ( ) No ( )	
IN2	Spare	NA	NA		Yes ( ) No ( )	

3.5.4 DATA TABLE OF PLC ANALOG OUTPUTS

Analog Output of PLC Processor (Micro Logix 1400)						
Address	**Details**	**Set value in HMI**	**Expected Process Reading at PLC/card**	**Actual Process Reading**	**Meets acceptance criteria**	**Sign. & date**
OUT1	Turret Motor Speed Ref.	12RPM	0V		Yes ( ) No ( )	
		36RPM	5V		Yes ( ) No ( )	
		60RPM	10V		Yes ( ) No ( )	
OUT2	Feeder Motor Speed Ref.	10RPM	0V		Yes ( ) No ( )	
		30RPM	5V		Yes ( ) No ( )	
		50RPM	10V		Yes ( ) No ( )	
Analog Input & Output Card (IF2OF2)						
OUT1	Spare	NA	NA		Yes ( ) No ( )	
OUT2	Spare	NA	NA		Yes ( ) No ( )	

Comments/ Remarks:

_____

_____

_____

_____

_____

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

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.

3.6.1 DATA TABLE OF PLC ACCESS

Procedure	Expected result	Actual result	Meets acceptance criteria	Sign. & date
LEVEL-1 (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-2 (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-3 (Manager)				
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 ( )	

3.6.2 DATA TABLE OF FUNCTION CONFIGURATION

Functions	Level			Meets Acceptance Criteria	Sign. & date
	1	2	3		
Main Menu Screen	☐	☐	☐	Yes ( ) No ( )	
Machine Control Screen	☐	☐	☐	Yes ( ) No ( )	
Dozzer Control Screen	☐	☐	☐	Yes ( ) No ( )	
Auxiliary Control Screen	☐	☐	☐	Yes ( ) No ( )	
Recipe Management Screen	☐	☐	☐	Yes ( ) No ( )	
Recipe Delete	☐	☐	☐	Yes ( ) No ( )	
Recipe Download	☐	☐	☐	Yes ( ) No ( )	
Recipe Upload	☐	☐	☐	Yes ( ) No ( )	
Recipe Save	☐	☐	☐	Yes ( ) No ( )	
Batch Data (View)	☐	☐	☐	Yes ( ) No ( )	
Interlock View	☐	☐	☐	Yes ( ) No ( )	

Comments/ Remarks:

_____

_____

_____

_____

_____

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

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

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	Login Screen		Yes ( ) No ( )	
03	Main Menu Screen		Yes ( ) No ( )	
04	Machine Control Screen		Yes ( ) No ( )	
05	Dozer Control Screen		Yes ( ) No ( )	
06	Auxiliary Control Screen		Yes ( ) No ( )	
07	Recipe Management Screen		Yes ( ) No ( )	
08	Recipe Edit Screen		Yes ( ) No ( )	
09	Batch Data screen		Yes ( ) No ( )	
10	Interlock View Screen		Yes ( ) No ( )	

3.7.2 DATATABLE OF HMI DISPLAY

Parameter	Span	Actual Result	Meet Acceptance Criteria	Sign. & Date
Welcome Screen				
Date	DD/MM/YY		Yes ( ) No ( )	
Time	HH:MM:SS		Yes ( ) No ( )	
Machine Controls Screen				
Turret RPM set value (rpm)	1 to 60		Yes ( ) No ( )	
Turret RPM Actual value (rpm)	Numeric		Yes ( ) No ( )	
Feeder force				
Set speed (rpm)	1 to 50		Yes ( ) No ( )	
Auto clutch delay (sec)	1 to 9		Yes ( ) No ( )	
Hydraulics				
Min set pressure (kN)	0.1 to 99.9		Yes ( ) No ( )	
Actual pressure (kN)	0 to 100		Yes ( ) No ( )	
Auto lubrication				
ON time Set (sec)	1 to 9		Yes ( ) No ( )	
ON time Act (sec)	Numeric		Yes ( ) No ( )	
OFF time set (sec)	0 to 9999		Yes ( ) No ( )	
OFF time Act (sec)	Numeric		Yes ( ) No ( )	

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

Parameter	Span	Actual Result	Meet Acceptance Criteria	Sign. & Date
Dozzer control screen				
LHS weight dozer set (mm)	3.0 to 20.0		Yes ( ) No ( )	
LHS weight dozer Act (mm)	Numeric		Yes ( ) No ( )	
RHS weight dozer set (mm)	3.0 to 20.0		Yes ( ) No ( )	
RHS weight dozer Act (mm)	Numeric		Yes ( ) No ( )	
Auxiliary Control screen				
Revolution for initial rejection	1 to 9		Yes ( ) No ( )	
Production rate	Numeric		Yes ( ) No ( )	
Tablet counter	Numeric		Yes ( ) No ( )	
Hour meter	Numeric		Yes ( ) No ( )	
Recipe Management Screen				
Batch Code	Alpha Numeric		Yes ( ) No ( )	
Batch Size	Alpha Numeric		Yes ( ) No ( )	
Operator Name	Alpha Numeric		Yes ( ) No ( )	
Product Name	Alpha Numeric		Yes ( ) No ( )	
Turret Speed (rpm)	1 to 60		Yes ( ) No ( )	
Feeder speed (rpm)	1 to 50		Yes ( ) No ( )	
Hyd. Press. (/ 10kN)	0 to 1500		Yes ( ) No ( )	
Lub. ON time (sec)	1 to 9		Yes ( ) No ( )	

Parameter	Span	Actual Result	Meet Acceptance Criteria	Sign. & Date
Recipe Management Screen Continue				
Lub. OFF time (sec)	1 to 999		Yes ( ) No ( )	
Tablet Thickness	5 to 80		Yes ( ) No ( )	
Tablet weight	1 to 9999		Yes ( ) No ( )	
Tablet hardness	1 to 9999		Yes ( ) No ( )	
Tablet friability	1 to 9999		Yes ( ) No ( )	
INI Rejection	1 to 9		Yes ( ) No ( )	
LHS depth of die fill	30.0 to 20.0		Yes ( ) No ( )	
RHS depth of die fill	30.0 to 20.0		Yes ( ) No ( )	
Batch Data Screen				
Equipment ID	Alpha Numeric		Yes ( ) No ( )	
Batch code	Alpha Numeric		Yes ( ) No ( )	
Batch size	Alpha Numeric		Yes ( ) No ( )	
Operator Name	Alpha Numeric		Yes ( ) No ( )	
Product Name	Alpha Numeric		Yes ( ) No ( )	

Comments/ Remarks:

_____

_____

_____

_____

_____

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

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

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
Machine Controls Screen											
Turret RPM set value (rpm)	1 to 60		Yes ( ) No ( )		Yes ( ) No ( )		Yes ( ) No ( )		Yes ( ) No ( )	Yes ( ) No ( )	
Feeder force											
Set speed (rpm)	1 to 50		Yes ( ) No ( )		Yes ( ) No ( )		Yes ( ) No ( )		Yes ( ) No ( )	Yes ( ) No ( )	
Auto clutch delay (sec)	1 to 9		Yes ( ) No ( )		Yes ( ) No ( )		Yes ( ) No ( )		Yes ( ) No ( )	Yes ( ) No ( )	
Hydraulics											
Min set pressure (kN)	0.1 to 99		Yes ( ) No ( )		Yes ( ) No ( )		Yes ( ) No ( )		Yes ( ) No ( )	Yes ( ) No ( )	
Actual pressure (kN)	0 to 100		Yes ( ) No ( )		Yes ( ) No ( )		Yes ( ) No ( )		Yes ( ) No ( )	Yes ( ) No ( )	

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
Auto lubrication											
ON time Set (sec)	1 to 9		Yes ( ) No ( )		Yes ( ) No ( )		Yes ( ) No ( )		Yes ( ) No ( )	Yes ( ) No ( )	
OFF time set (sec)	0 to 9999		Yes ( ) No ( )		Yes ( ) No ( )		Yes ( ) No ( )		Yes ( ) No ( )	Yes ( ) No ( )	
Dozzer control screen											
LHS weight dozer set (mm)	3.0 to 20.0		Yes ( ) No ( )		Yes ( ) No ( )		Yes ( ) No ( )		Yes ( ) No ( )	Yes ( ) No ( )	
RHS weight dozer set (mm)	3.0 to 20.0		Yes ( ) No ( )		Yes ( ) No ( )		Yes ( ) No ( )		Yes ( ) No ( )	Yes ( ) No ( )	
Auxiliary Control screen											
Revolution for initial rejection	1 to 9		Yes ( ) No ( )		Yes ( ) No ( )		Yes ( ) No ( )		Yes ( ) No ( )	Yes ( ) No ( )	

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
Recipe Management Screen											
Turret Speed (rpm)	1 to 60		Yes ( ) No ( )		Yes ( ) No ( )		Yes ( ) No ( )		Yes ( ) No ( )	Yes ( ) No ( )	
Feeder speed (rpm)	1 to 50		Yes ( ) No ( )		Yes ( ) No ( )		Yes ( ) No ( )		Yes ( ) No ( )	Yes ( ) No ( )	
Hyd. Press. (/ 10kN)	0 to 1500		Yes ( ) No ( )		Yes ( ) No ( )		Yes ( ) No ( )		Yes ( ) No ( )	Yes ( ) No ( )	
Lub. ON time (sec)	1 to 9		Yes ( ) No ( )		Yes ( ) No ( )		Yes ( ) No ( )		Yes ( ) No ( )	Yes ( ) No ( )	
Lub. OFF time (sec)	1 to 999		Yes ( ) No ( )		Yes ( ) No ( )		Yes ( ) No ( )		Yes ( ) No ( )	Yes ( ) No ( )	
Tablet Thickness	5 to 80		Yes ( ) No ( )		Yes ( ) No ( )		Yes ( ) No ( )		Yes ( ) No ( )	Yes ( ) No ( )	

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

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
Recipe Management Screen continue											
Tablet weight	1 to 9999		Yes ( ) No ( )		Yes ( ) No ( )		Yes ( ) No ( )		Yes ( ) No ( )	Yes ( ) No ( )	
Tablet hardness	1 to 9999		Yes ( ) No ( )		Yes ( ) No ( )		Yes ( ) No ( )		Yes ( ) No ( )	Yes ( ) No ( )	
Tablet friability	1 to 9999		Yes ( ) No ( )		Yes ( ) No ( )		Yes ( ) No ( )		Yes ( ) No ( )	Yes ( ) No ( )	
INI Rejection	1 to 9		Yes ( ) No ( )		Yes ( ) No ( )		Yes ( ) No ( )		Yes ( ) No ( )	Yes ( ) No ( )	
LHS depth of die fill	30.0 to 20.0		Yes ( ) No ( )		Yes ( ) No ( )		Yes ( ) No ( )		Yes ( ) No ( )	Yes ( ) No ( )	
RHS depth of die fill	30.0 to 20.0		Yes ( ) No ( )		Yes ( ) No ( )		Yes ( ) No ( )		Yes ( ) No ( )	Yes ( ) No ( )	

Comments/ Remarks:

_____

_____

_____

_____

_____

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

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 Criteria :

- After Power restore the value of process set-parameter should not changed.
- 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.

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
Machine Controls Screen					
Turret RPM set value (rpm)			Value remains same	Yes ( ) No ( )	
Feeder force					
Set speed (rpm)			Value remains same	Yes ( ) No ( )	
Auto clutch delay (sec)			Value remains same	Yes ( ) No ( )	
Hydraulics					
Min set pressure (kN)			Value remains same	Yes ( ) No ( )	
Actual pressure (kN)			Value remains same	Yes ( ) No ( )	
Auto lubrication					
ON time Set (sec)			Value remains same	Yes ( ) No ( )	
OFF time set (sec)			Value remains same	Yes ( ) No ( )	
Dozzer control screen					
LHS weight dozer set (mm)			Value remains same	Yes ( ) No ( )	
RHS weight dozer set (mm)			Value remains same	Yes ( ) No ( )	

Parameter Description	Value Before power loss	Value after power recovery	Expected Result	Meets acceptance criteria	Sign. & date
Auxiliary Control screen					
Revolution for initial rejection			Value remains same	Yes ( ) No ( )	
Recipe Management Screen					
Turret Speed (rpm)			Value remains same	Yes ( ) No ( )	
Feeder speed (rpm)			Value remains same	Yes ( ) No ( )	
Hyd. Press. (/ 10kN)			Value remains same	Yes ( ) No ( )	
Lub. ON time (sec)			Value remains same	Yes ( ) No ( )	
Lub. OFF time (sec)			Value remains same	Yes ( ) No ( )	
Tablet Thickness			Value remains same	Yes ( ) No ( )	
Tablet weight			Value remains same	Yes ( ) No ( )	
Tablet hardness			Value remains same	Yes ( ) No ( )	
Tablet friability			Value remains same	Yes ( ) No ( )	
INI Rejection			Value remains same	Yes ( ) No ( )	
LHS depth of die fill			Value remains same	Yes ( ) No ( )	
RHS depth of die fill			Value remains same	Yes ( ) No ( )	

Comments/ Remarks:

_____

_____

_____

_____

_____

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

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 Criteria :

- In communication link failure condition, message must appear in HMI screen.
- 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.

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 ( )	

Parameter Description	Value Before Communication unplug	Value after Communication link reconnect	Expected Result	Meets acceptance criteria	Sign. & date
Machine Controls Screen					
Turret RPM set value (rpm)			Value remains same	Yes ( ) No ( )	
Feeder force					
Set speed (rpm)			Value remains same	Yes ( ) No ( )	
Auto clutch delay (sec)			Value remains same	Yes ( ) No ( )	
Hydraulics					
Min set pressure (kN)			Value remains same	Yes ( ) No ( )	
Actual pressure (kN)			Value remains same	Yes ( ) No ( )	
Auto lubrication					
ON time Set (sec)			Value remains same	Yes ( ) No ( )	
OFF time set (sec)			Value remains same	Yes ( ) No ( )	
Dozzer control screen					
LHS weight dozer set (mm)			Value remains same	Yes ( ) No ( )	
RHS weight dozer set (mm)			Value remains same	Yes ( ) No ( )	

Parameter Description	Value Before Communication unplug	Value after Communication link reconnect	Expected Result	Meets acceptance criteria	Sign. & date
Auxiliary Control screen					
Revolution for initial rejection			Value remains same	Yes ( ) No ( )	
Recipe Management Screen					
Turret Speed (rpm)			Value remains same	Yes ( ) No ( )	
Feeder speed (rpm)			Value remains same	Yes ( ) No ( )	
Hyd. Press. (/ 10kN)			Value remains same	Yes ( ) No ( )	
Lub. ON time (sec)			Value remains same	Yes ( ) No ( )	
Lub. OFF time (sec)			Value remains same	Yes ( ) No ( )	
Tablet Thickness			Value remains same	Yes ( ) No ( )	
Tablet weight			Value remains same	Yes ( ) No ( )	
Tablet hardness			Value remains same	Yes ( ) No ( )	
Tablet friability			Value remains same	Yes ( ) No ( )	
INI Rejection			Value remains same	Yes ( ) No ( )	
LHS depth of die fill			Value remains same	Yes ( ) No ( )	
RHS depth of die fill			Value remains same	Yes ( ) No ( )	

Comments/ Remarks:

_____

_____

_____

_____

_____

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

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 Criteria : All alarms and interlocks of machine should work properly.

3.11.1 DATA TABLE OF ALARMS AND INTERLOCKS

Cause	Expected Result	Actual Result	Correction	Meets acceptance criteria	Sign. & date
Emergency Push Button Operated					
If emergency push button Is operated.	**"Emergency Push Button Operated"** alarm message should display in HMI screen and system should stop.		Release the emergency push button.	Yes ( ) No ( )	
Turret Motor VFD Trip					
If Turret Motor VFD go in fault mode. And Tripping of OLR of Turret Motor .	**"Turret Motor VFD Trip"** alarm message should display in HMI screen and system should Stop.		Check the turret motor VFD and supply Voltage. reset the OLR of turret Motor.	Yes ( ) No ( )	

Cause	Expected Result	Actual Result	Correction	Meets acceptance criteria	Sign. & date
Hydraulic Pump Motor Overload					
If the tripping of OLR of Hydraulic pump motor and variation in supply voltage.	**"Hydraulic pump motor Overload"** alarm message should display in HMI screen and system should stop.		Reset the OLR of motor and check the supply voltage. check the connection to the VFD.	Yes ( ) No ( )	
Lubrication Oil Level Low					
If the lubricant oil level is less than the set value.	**"Lubrication Oil Level Low"** alarm message should display in HMI Screen and System will Stop.		Ensure the oil level and maintain it	Yes ( ) No ( )	

Cause	Expected Result	Actual Result	Correction	Meets acceptance criteria	Sign. & date
LHS Weight Dozzer Not In Position					
If LHS weight dozer assembly is not set in set position.	**"LHS Weight Dozzer not in position"** alarm message should display in HMI screen and system will Stop		Set the LHS dozer assembly in set position.	Yes ( ) No ( )	
RHS Weight Dozzer Not In Position					
If RHS weight dozer assembly is not set in set position.	**"RHS Weight Dozzer not in position"** alarm message should display in HMI screen and system will Stop		Set the RHS dozer assembly in set position.	Yes ( ) No ( )	

Cause	Expected Result	Actual Result	Correction	Meets acceptance criteria	Sign. & date
LHS Feeder Motor Overload					
If LHS Feeder is Jammed and Tripping Of OLR Of motor.	**"LHS Feeder Motor Overload"** alarm message should display on HMI screen and System Should Stop		Check the LHS feeder properly and reset the OLR of motor.	Yes ( ) No ( )	
RHS Feeder Motor Overload					
If RHS Feeder is Jammed and Tripping Of OLR Of motor.	**"RHS Feeder Motor Overload"** alarm message should display on HMI screen and System Should Stop		Check the RHS feeder properly and reset the OLR of motor.	Yes ( ) No ( )	

Cause	Expected Result	Actual Result	Correction	Meets acceptance criteria	Sign. & date
LHS Dozzer Servo Drive Trip					
If LHS dozer servo drive go in fault condition and Tripping of OLR of motor	**"LHS Dozzer Servo drive Trip"** alarm message should display on HMI screen and System Should Stop		Reset the servo drive and OLR of the motor. Check the connection and supply voltage.	Yes ( ) No ( )	
RHS Dozzer Servo Drive Trip					
If RHS dozer servo drive go in fault condition and Tripping of OLR of motor	**"RHS Dozzer Servo drive Trip"** alarm message should display on HMI screen and System Should Stop		Reset the servo drive and OLR of the motor. Check the connection and supply voltage.	Yes ( ) No ( )	

Cause	Expected Result	Actual Result	Correction	Meets acceptance criteria	Sign. & date
LHS Pre Pressure Overload					
If LHS pre pressure is not proper with compare to the set value.	**"LHS Pre Pressure Overload "** alarm message should display on HMI screen and System Should Stop		Check the LHS pre pressure and maintain it properly.	Yes ( ) No ( )	
RHS Pre Pressure Overload					
If RHS pre pressure is not proper with compare to the set value.	**"RHS Pre Pressure Overload "** alarm message should display on HMI screen and System Should Stop		Check the RHS pre pressure and maintain it properly.	Yes ( ) No ( )	

Cause	Expected Result	Actual Result	Correction	Meets acceptance criteria	Sign. & date
LHS Main Pressure Overload					
If LHS Main pressure is not proper with compare to the set value.	**"LHS Main Pressure Overload "** alarm message should display on HMI screen and System Should Stop		Check the LHS Main pressure and maintain it properly.	Yes ( ) No ( )	
RHS Main Pressure Overload					

If RHS Main pressure is not proper with compare to the set value.	**"RHS Main Pressure Low "** alarm message should display on HMI screen and System Should Stop		Check the RHS Main pressure and maintain it properly.	Yes ( ) No ( )	

Cause	Expected Result	Actual Result	Correction	Meets acceptance criteria	Sign. & date
Machine Front Guard Open					
If machine front Guard is not close properly and machine front guard proximity sensor is not active.	**"Machine Front Guard open"** alarm message should display on HMI screen and System Should Stop		Check the connection proximity sensor of machine front guard and close it properly.	Yes ( ) No ( )	

Machine Rear Guard Open					
If machine Rear guard is not close properly and machine Rear guard proximity sensor is not active.	**"Machine Rear Guard open"** alarm message should display on HMI screen and System Should Stop		Check the connection proximity sensor of machine Rear guard and close it properly.	Yes ( ) No ( )	

Cause	Expected Result	Actual Result	Correction	Meets acceptance criteria	Sign. & date
Machine LHS Guard Open					
If machine LHS guard is not close properly and machine LHS guard proximity sensor is not active.	**"Machine LHS Guard open"** alarm message should display on HMI screen and System Should Stop		Check the connection proximity sensor of machine LHS guard and close it properly.	Yes ( ) No ( )	
Machine RHS Guard Open					
If machine RHS guard is not close properly and machine RHS guard proximity sensor is not active.	**"Machine RHS Guard open"** alarm message should display on HMI screen and System Should Stop		Check the connection proximity sensor of machine RHS guard and close it properly.	Yes ( ) No ( )	

Cause	Expected Result	Actual Result	Correction	Meets acceptance criteria	Sign. & date
Hydraulic Pressure Low					
If the Hydraulic pressure is less than the set level. And low level of oil in the hydraulic pump.	**"Hydraulic Pressure Low"** alarm message should display in HMI Screen and System will Stop.		Maintain the hydraulic pressure by increase the pressure manually. Check the hydraulic oil level and maintain it.	Yes ( ) No ( )	
Hydraulic Pressure High					
If the hydraulic pressure is goes high than set level.	**"Hydraulic Pressure High"** alarm message should display in HMI Screen and System will Stop.		Maintain the hydraulic pressure by decrease the pressure manually from HMI.	Yes ( ) No ( )	

Cause	Expected Result	Actual Result	Correction	Meets acceptance criteria	Sign. & date
LHS Hopper Powder Level Low					
If the There is no powder in the LHS hopper and powder level goes below than Low level powder sensor.	**"LHS Hopper Powder Level Low "** alarm message should display in HMI Screen and System Should Go in Halt Mode.		Maintain the level of powder in hopper and check the low level powder sensor.	Yes ( ) No ( )	
RHS Hopper Powder Level Low					
If the There is no powder in the RHS hopper and powder level goes below than Low level powder sensor.	**"RHS Hopper Powder Level Low "** alarm message should display in HMI Screen and System Should Go in Halt Mode.		Maintain the level of powder in hopper and check the low level powder sensor.	Yes ( ) No ( )	

Comments/ Remarks:

_____

_____

_____

_____

_____

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

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

3.12.1 DATA TABLE OF CONTROL LOOP TEST

Set Parameters	Set Value
Turret Speed. (RPM)	
Feeder Speed. (RPM)	
MIN set pressure (KN)	

Time (min)	Turret speed (RPM)	Feeder Speed (RPM)	Min Set Pressure (KN)	Meets acceptance criteria	Sign. & date
				Yes ( ) No ( )	
				Yes ( ) No ( )	
				Yes ( ) No ( )	
				Yes ( ) No ( )	
				Yes ( ) No ( )	
				Yes ( ) No ( )	

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	

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

5.0.0 SUMMARY REPORT

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

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

7.0.0 LIST OF ATTACHMENTS

Sr. No.	Reference	Description Of Attachment
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

8.0.0 LIST OF ABBREVIATIONS

Acronym		Description
CPU	→	**C**entral **P**rocessing **U**nit
CGMP	→	**C**urrent **G**ood **M**anufacturing **P**ractices
GAMP	→	**G**ood **A**utomated **M**anufacturing **P**ractices
GMP	→	**G**ood **M**anufacturing **P**ractices
ID	→	**I**dentification **N**umber
IO	→	**I**nput **O**utput
RQ	→	**R**e- **Q**ualification
PLC	→	**P**rogrammable **L**ogic **C**ontroller
SOP	→	**S**tandard **O**perating **P**rocedure
UPS	→	**U**ninterruptible **P**ower **S**upply
VAC	→	**V**olts **A**lternating **C**urrent
VDC	→	**V**olts **D**irect **C**urrent
VMP	→	**V**alidation **M**aster **P**lan
HMI	→	**H**uman **M**achine **I**nterface
SMPS	→	**S**table **M**ode **P**ower **S**upply
M/C	→	**M**achine

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**	