



PHARMA DEVILS

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QUALITY ASSURANCE DEPARTMENT

PROTOCOL No.:

OPERATIONAL QUALIFICATION FOR PLC SYSTEM OF SOFT WATER DISTRIBUTION SYSTEM

**OPERATIONAL QUALIFICATION
FOR PLC SYSTEM OF
SOFT WATER DISTRIBUTION SYSTEM**

Equipment Name	Soft Water Distribution System
Equipment ID	
System Location	
Effective Date	



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1. PRE APPROVALS:

The signature listed below indicates the pre-approval of this operational qualification. This approval is joint responsibility of listed functional areas.

Function	Name	Department	Designation	Signature & Date
Prepared by		Engineering		
Reviewed by		Engineering		
Reviewed by		Quality Assurance		
Approved by		Quality Assurance		



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2. OBJECTIVE:

The objective of operational qualification is to collect the sufficient data pertaining to Programmable logic controller (PLC) and HMI Based system of Soft Water Distribution System installed at M/s., and define the operational qualification requirements and acceptance criteria for the Programmable logic controller (PLC) and HMI Based system of Soft Water Distribution System supporting automation of the system. Successful completion of these operational qualification requirements will provide assurance that the Programmable logic controller (PLC) and HMI Based system of Soft Water Distribution System for the M/s., was functioning properly.

3. SCOPE:

This document is applicable to Programmable logic controller (PLC) and HMI Based system of Soft Water Distribution System is installed at M/s. This operational qualification shall define the documentation, references and acceptance criteria to establish that the Programmable logic controller (PLC) and HMI Based system of Soft Water Distribution System is installed in accordance with the guidelines laid down by the manufacturer of the system.

4. SYSTEM DESCRIPTION:

Equipment Name	:	Soft Water Distribution System
Supplier/Manufacturer	:	
Equipment ID. No.	:	
Location	:	



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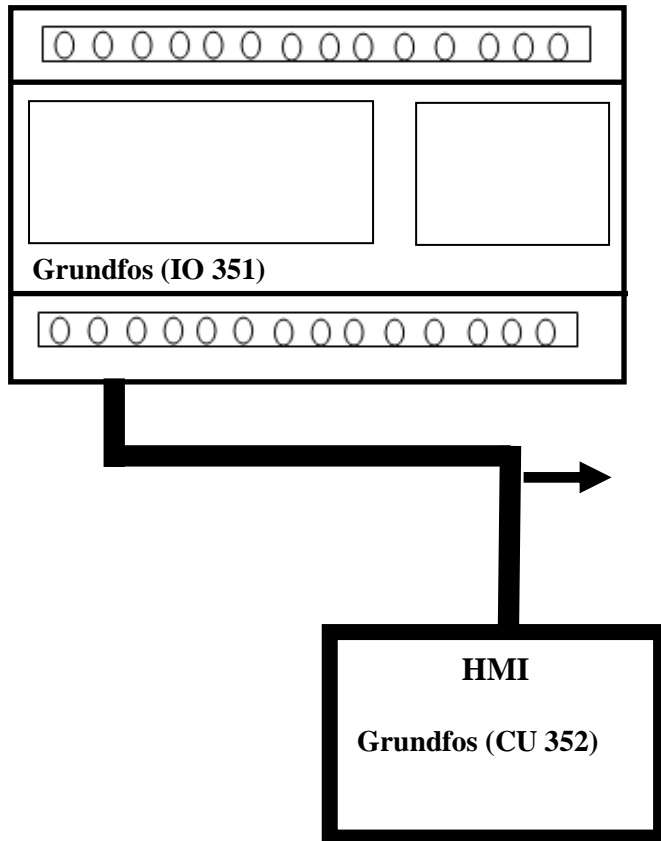
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5. CONTROL SYSTEM SCHEMATIC DIAGRAM:

The PLC System schematic diagram for the “Soft Water Distribution System” automation is given below:





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6. SIGNATURE OF VALIDATION TEAM:

All the executer involved in these documents has to sign within prescribed format given below.

M/s

Name	Designation	Department	Date

M/s

Name	Designation	Department	Signature/Date

7. REVISION HISTORY:

Date	Supersedes	Reason for Revision



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8. ROLE AND RESPONSIBILITY:

The validation team comprising of representative from each of the following departments should be responsible for overall compliance with this validation plan.

Department	Responsibilities
Validation Agency (Instrumentation and Control Solutions)	<ul style="list-style-type: none">➤ To collect the necessary data for operational qualification activities.➤ To prepare and execute the operational qualification in coordination with engineering, validation and quality assurance team.➤ Comply with regulatory / Guidelines / Standards / validation plan requirements throughout the validation life cycle.➤ To submit operational qualification for approval.
Engineering (M/s.)	<ul style="list-style-type: none">➤ To provide the necessary data for operational qualification activities.➤ To review and approve the operational qualification.
Quality Assurance (M/s.)	<ul style="list-style-type: none">➤ To review and approve the operational qualification.



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9. REFERENCES:

The publication listed below form part of this reference documents. Each publication shall have latest revision in effect on the date of this document is approved for execution.

GAMP 5	Good Automated Manufacturing Practices, Version 5, Guideline Document for Automated Systems from International Society of Pharmaceutical Engineering
21 Code of Federal Regulations (CFR), Part 210	Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding off Drugs; General
21 Code of Federal Regulations (CFR), Part 211	Current Good Manufacturing Practice for finished Pharmaceuticals
21 Code of Federal Regulations (CFR), Part 11	21 Code of Federal Regulations (CFR), Part 11 Electronic Records, Electronic Signatures, Final Rule Electronic Submissions; Establishment of Public Docket, Notice
ICH Q9	International Conference of Harmonization (ICH) quality risk assessment Q9
EU GMP	Laying down the principles and guidelines of GMP in respect of medicinal products for human use.
IQ	Installation Qualification

10.

11. DOCUMENTATION PROCEDURE:

- Qualification activities will be performed as defined in the approved document.
- All documentation will be completed during the execution of the qualification.
- Recording of information will be made in permanent ink.
- Fill out complete information in the verification table provided.
- Do not keep any space blank. Mark blank space with a single line throughout the appropriate space with mentioning NA (Not Applicable) and put initial and date.
- Correct the mistakes by drawing a single line through the incorrect data, recording the correct information and then initialing and dating the change.



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12. QUALIFICATION COMPLETION AND APPROVAL:

- Verify that all tests required by qualification are completed and attached.
- Verify that all amendments and discrepancies are documented, approved and attached.
- If all items in the qualification for the Programmable logic controller (PLC) and HMI Based system of Soft Water Distribution System have been reviewed and found to be acceptable, sign the corresponding block in the qualification completion and approval form.

13. ACCEPTANCE CRITERIA:

- Installation of the Programmable logic controller (PLC) and HMI Based system of Soft Water Distribution System with suitable utility connections.
- Installation completion as per manufacturer's recommendations & cGMP requirements.
- Installation of major components as per the design specifications.
- The supply of all necessary documentation from manufacturer.
- The operational capabilities of system demonstrated.
- The system is operating as intended and is under state of control.
- Operational features meet system requirements and system specifications.



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14. 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: Time:

Venue of training:

Date of training:

S.No.	Name of Trainee	Designation of Trainee	Signature of Trainee	Evaluation OK/ To be retrained	Signature of evaluator
Trainer details					
Name		Designation	Signature		



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15. OPERATIONAL VERIFICATION TEST:

15.1 Verification of Field Instruments Calibration Details

Objective : To verify the field instruments certificate.

Tools Required : Not Applicable

Procedure : 1. Verify Instruments Name & ID.
2. Verify Instruments Calibration Done Date & Due Date.

Acceptance Criteria : Fields instruments should be calibrated.

Verification Table:

Refer Attachment No.1						
S.No.	Instruments Name	Instruments ID	Calibration Done Date	Calibration Due Date	Discrepancy? (Yes/No)	Done By Sign & Date
1.						
2.						
3.						
4.						
5.						
6.						
7.						
8.						
9.						
10.						
11.						
12.						
13.						

Remarks:

Meet the acceptance Criteria [] Yes [] No

Checked by : _____

Sign & Date : _____

Verified by : _____

Sign & Date : _____

Reviewed by : _____

Sign & Date : _____



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15.2 Verification of PLC LED's:

Objective : To verify the normal LED'S indication of PLC.

Tools Required : Not Applicable

Procedure : 1. Switch ON the PLC System
2. Record LED indication on PLC.

Acceptance Criteria : LED indication shall match with specified results in verification table.

Verification Table:

Description	LED Indication	Observation	Discrepancy ? (Yes/No)	Done By Sign & Date
PLC				
POWER	ON			

Remarks:

Meet the acceptance Criteria [] Yes [] No

Checked by : _____

Sign & Date : _____

Verified by : _____

Sign & Date : _____

Reviewed by : _____

Sign & Date : _____



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15.3 Verification of PLC Input and Output

Objective : To verify the PLC input and output.

Tools Required : Universal Source

Procedure :

1. Simulate each digital input signal by doing shorting and opening of signal to Control input and record Input Voltage at terminal.
2. Simulate each digital output signal by operating the output using the HMI and record the Output Voltage at terminal.
3. Simulate each analog input signal by giving analog signal from the source and record the value of input on.
4. Simulate each analog output signal by operating the output using the IPC and record the status of output on.

Acceptance Criteria : All inputs and outputs must be verified to meet wiring diagram of Control system and function as per design document.



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15.3.1 Verification Table: Digital Input/ Output

PLC Channel	IO Description	Specified Voltage		Observation Voltage	Discrepancy? (Yes/No)	Done By Sign & Date
Digital Input (CU 352)						
DI1	Remote Control	0 VDC	24 VDC			
DI2	Water Shortage Monitoring	0 VDC	24 VDC			
DI3	Spare	NA	NA			

PLC Channel	IO Description	Specified LED Status		Observation Voltage	Discrepancy? (Yes/No)	Done By Sign & Date
Digital Output (CU 352)						
DO1	Common Alarm Potential Free	0 VDC	24 VDC			
DO2	Common Operation Potential Free	0 VDC	24 VDC			



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14.3.2 Verification Table: Analog Input

Analog Input Module							
PLC Address	Details	Input Signal	Expected Process Reading	Actual Process Reading	Meets acceptance criteria		Sign. & date
					Yes	No	
AI1	Outlet Pressure	4.000 mA	0.0 bar		()	()	
		12.000 mA	5.0 bar		()	()	
		20.000 mA	10.0 bar		()	()	
AI2	Spare	NA	NA		()	()	
AI3	Spare	NA	NA		()	()	

Remarks:

Meet the acceptance Criteria [] Yes [] No

Checked by : _____

Sign & Date : _____

Verified by : _____

Sign & Date : _____

Reviewed by : _____

Sign & Date : _____

15.4 Verification of Password Security

Objective : To verify the password security as defined.

Tools Required : Not Applicable

- Procedure** :
1. Try to login with wrong password.
 2. Login with correct password.
 3. Check all the result with specified data given in verification table.

Acceptance Criteria : All the test result shall match with specified result.



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A.) Verification Table for Password Security:

Refer Attachment No. 2			
Description	Specified	Discrepancy? (Yes/No)	Done By Sign & Date
Wrong User Password Entry at Operator Level	System shall be Generate the wrong password .		
Correct User Password Entry at Operator Level	Operator login the system successfully.		
Wrong User Password Entry at Supervisor Level	System shall be Generate the wrong password .		
Correct User Password Entry at Supervisor Level	Supervisor login the system successfully.		

Remarks:

Meet the acceptance Criteria [] Yes [] No

Checked by : _____ Sign & Date : _____
 Verified by : _____ Sign & Date : _____
 Reviewed by : _____ Sign & Date : _____

15.5 Verification of User Level and Rights.

Objective : To verify the user level and rights as defined.

Tools Required : Not Applicable

Procedure : 1. Verification of User level.
 2. Login with each level and check all rights/screen.
 3. Matched the result with privileges in test verification table.

Acceptance Criteria : All the result shall match with user rights/screen and level.



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Verification Table for User Rights:

Refer Attachment No. 3

Right /Screen	Operator Level	Supervisor Level	Done By Sign & Date
Status Screen	<input type="checkbox"/>	<input type="checkbox"/>	
Operation Screen	<input type="checkbox"/>	<input type="checkbox"/>	
Alarm Screen	<input type="checkbox"/>	<input type="checkbox"/>	
Setting Screen	<input type="checkbox"/>	<input type="checkbox"/>	

Remarks:

Meet the acceptance Criteria [] Yes [] No

Checked by : _____ Sign & Date : _____
 Verified by : _____ Sign & Date : _____
 Reviewed by : _____ Sign & Date : _____

15.6 Verification of HMIScreens

Objective : To verify the HMI screens as defined.

Tools Required : Not Applicable

- Procedure** :
- 1 Check all programmable function keys for their actual response in each screen.
 - 2 Check Function Key Command are properly programmed by operating output devices.
 - 3 Verify the display on HMI with actual machine conditions.
 - 4 List up the screen and attached the screen shot in attachment

Acceptance Criteria : All the programmable function keys and touch keys shall be work as per assign function.



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HMI Screen Verification Table:

Refer Attachment No. 4

S.No.	HMI Screen	Refer Attachment No.4 Screen No.	Discrepancy? (Yes/No)	Done By Sign & Date
1	Status Screen			
2	System Screen			
3	Operating Mode Screen			
4	Set Point Screen			
5	Set Point Influence Screen			
6	Measured Value Screen			
7	Analog Input Screen			
8	Log Graph Screen			
9	Battery Status Screen			
10	Operation Screen			
11	Further Setting Screen			
12	Control Mode Screen			
13	Alternative Set Point Screen			
14	Individual Pump Control Screen			
15	Pump 1 Screen			
16	Pump 2 Screen			
17	Alarm Status Screen			
18	Actual Alarm Screen			
19	Alarm Log Screen			
20	Service Contact Information Screen			
21	Setting Screen			
22	Primary Controller Screen			
23	PI Controller Screen			
24	Alternative Set Point Screen			
25	External Set point influence Screen			
26	Primary Sensor Screen			
27	Secondary Sensor Screen			
28	Clock Program Screen			



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Refer Attachment No. 4

S.No.	HMI Screen	Refer Attachment No.4 Screen No.	Discrepancy? (Yes/No)	Done By Sign & Date
29	Proportional Pressure Screen			
30	S-System Configuration Screen			
31	Set Point Ramp Screen			
32	Pump Cascade Control Screen			
33	Min Time and Max. Number of Starts Screen			
34	Standby Pumps Screen			
35	Forced Pump Changeover Screen			
36	Pump Test Run Screen			
37	Pump Stop Attempt Screen			
38	Pump Start and Stop Speed Screen			
39	Min. Performance Screen			
40	Compensation for Pump start –up Time Screen			
41	Secondary Function Screen			
42	Stop Function Screen			
43	Soft Pressure Build- up Screen			
44	Emergency Run Screen			
45	Digital Inputs Screen			
46	Analog Inputs Screen			
47	Digital Outputs Screen			
48	Min., Max. and User Define duty Screen			
49	Pump Curve Data Screen			
50	Control Source Screen			
51	Fixed Inlet Pressure Screen			
52	Flow Estimation Screen			
53	Reduced Operation Screen			
54	Multisensor Screen			
55	Monitoring Functions Screen			
56	Dry-running Protection Screen			
57	Pressure /Level Switch Screen			



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Refer Attachment No. 4

S.No.	HMI Screen	Refer Attachment No.4 Screen No.	Discrepancy? (Yes/No)	Done By Sign & Date
58	Measurement, Inlet Pressure Screen			
59	Measurement Tank Level Screen			
60	Min. Pressure Screen			
61	Max. Pressure Screen			
62	External Fault Screen			
63	Limit 1 Exceeded Screen			
64	Limit 2 Exceeded Screen			
65	Pump Outside Duty Range Screen			
66	Pressure Relief Screen			
67	Log Valves Screen			
68	Fault, Primary Sensor Screen			
69	Non Return Valve Screen			
70	Adjustment of Counters Screen			
71	Functions,CU352 Screen			
72	Display Language Screen			
73	Units Screen			
74	Date and Time Screen			
75	Password Screen			
76	Ethernet Screen			
77	Genibus Number Screen			
78	Software Status Screen			
79	Status Display Menu Screen			

Remarks:

Meet the acceptance Criteria [] Yes [] No

Checked by : _____

Sign & Date : _____

Verified by : _____

Sign & Date : _____

Reviewed by : _____

Sign & Date : _____



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15.7 Verification of Set Parameter Boundary Condition:

Objective : To verify the set parameter boundary condition as defined.

Tools Required : Not Applicable

Procedure : 1. Enter minimum value for the given span and observe the response.
2. Enter maximum value for the given span and observe the response.
3. Enter value above and below the acceptable span and observe the response

Acceptance Criteria : System must accept value which is within the range and criteria for minimum/maximum reject values are given below

1. For Integer Value

Reject Value (minimum) = Acceptable Value (minimum) – 1

Reject Value (Maximum) = Acceptable Value (maximum) + 1

2. For Decimal Value

Reject Value (minimum) = Acceptable Value (minimum) - 0.1

Reject Value (Maximum) = Acceptable Value (maximum) + 0.1 and so on



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Verification Table:

Parameters	Specified Range	Minimum Range	Value is set in system	Maximum Range	Value is set in system	Below Range setting	Value is not set in system	Upper Range setting	Value is not set in system	Discrepancy? Yes/No	Done By Sign & Date
Operation Screen											
Set Point 1 Closed Loop(bar)	0.0 to 16.0		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		
PL Controller Screen											
Gain Kp	-30.0 to 30.0		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		
Integral Time Ti (S)	0.0 to 1000.0		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		
Alternative Set Point Screen (Set Point 2)											
Set Point 2 Closed Loop(bar)	0.0 to 16.0		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		
Set Point 2 Open Loop%	0 to 100		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		
(Set Point 3)											
Set Point 3 Closed Loop(bar)	0.0 to 16.0		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		
Set Point 3 Open Loop%	0 to 100		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		
(Set Point 4)											
Set Point 4 Closed Loop(bar)	0.0 to 16.0		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		
Set Point 4 Open Loop%	0 to 100		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		
(Set Point 5)											



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Parameters	Specified Range	Minimum Range	Value is set in system	Maximum Range	Value is set in system	Below Range setting	Value is not set in system	Upper Range setting	Value is not set in system	Discrepancy? Yes/(No)	Done By Sign & Date
Set Point 5 Closed Loop(bar)	0.0 to 16.0		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		
Set Point 5 Open Loop%	0 to 100		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		
(Set Point 6)											
Set Point 6 Closed Loop(bar)	0.0 to 16.0		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		
Set Point 6 Open Loop%	0 to 100		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		
(Set Point 7)											
Set Point 7 Closed Loop(bar)	0.0 to 16.0		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		
Set Point 7 Open Loop%	0 to 100		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		
Soft Pressure Build Up Screen (Filling Phase)											
Speed%	0 to 100		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		
No. of Pump	1 to 6		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		
Soft Pressure Build Up Screen (Filling Phase) Continue											
Filling Pressure(bar)	0.0 to 16.0		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		



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Parameters	Specified Range	Minimum Range	Value is set in system	Maximum Range	Value is set in system	Below Range setting	Value is not set in system	Upper Range setting	Value is not set in system	Discrepancy? Yes/No	Done By Sign & Date
Max. Time(s)	0 to 1000		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		
Pressure Build Up Phase											
Ramp Time(s)	0 to 1000		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		
Min & Max User Define Duty (Min. Duty)											
No. of Pump in Operation	1 to 6		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		
Speed of Variable speed Pump in Operation%	0 to 100		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		
Min & Max User Define Duty (Max. Duty)											
No. of Pump in Operation	1 to 6		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		
User Defined Duty Screen											
No. of Pump in Operation	1 to 6		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		



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Parameters	Specified Range	Minimum Range	Value is set in system	Maximum Range	Value is set in system	Below Range setting	Value is not set in system	Upper Range setting	Value is not set in system	Discrepancy? Yes/(No)	Done By Sign & Date
Speed of Variable speed Pump in Operation%	0 to 100		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		Yes <input type="checkbox"/> No <input type="checkbox"/>		

Remarks:

Meet the acceptance Criteria [] Yes [] No

Checked by : _____

Sign & Date : _____

Verified by : _____

Sign & Date : _____

Reviewed by : _____

Sign & Date : _____



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15.8 Verification of Alarms and Interlocks:

Objective : To verify the alarms and interlocks as defined.

Tools Required : Not Applicable

Procedure : 1. Check all the test given in verification table.
2. Record the result in verification table.

Acceptance Criteria : All the test result shall match with expected result.

Verification Table:

Condition	Expected Result	Actual Result	Discrepancy? (Yes/No)	Done By Sign & Date
The Precharge Pressure is Below its Programmable Alarm Limit	“ Water Shortage ” alarm message should display in HMI screen and System should stop			
No Genibus Communication with a device Connected to the CU352	“ Communication Fault ” alarm message should display in HMI screen.			
If Primary Sensor Fault	“ Fault, Primary Sensor ” alarm message should display in HMI screen and System should stop			
If Mains Voltage is low at Start	“ Under voltage ” alarm message should display in HMI screen.			
All pumps set to auto have stopped due to a pump alarm	“ Alarm all Pumps ” alarm message should display in HMI screen and System should stop			
The VFD Signal relay does not release the VFD for Operation	“ VFD not Ready ” alarm message should display in HMI screen.			
The Operating Pressure is above the Programmable High Pressure alarm Limit	“ Pressure High ” alarm message should display in HMI screen and System should stop			



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Condition	Expected Result	Actual Result	Discrepancy? (Yes/No)	Done By Sign & Date
The Operating Pressure is Below the Programmable Low Pressure alarm Limit	“Pressure Low ” alarm message should display in HMI screen and System should stop			
The Terminal box has indicated Over temperature	“(Pump 1) Too High Motor Temperature ” alarm message should display in HMI screen and System should stop			
The Terminal box has indicated Over temperature	“(Pump 2) Too High Motor Temperature ” alarm message should display in HMI screen and System should stop			

Remarks:

Meet the acceptance Criteria [] Yes [] No

Checked by : _____

Sign & Date : _____

Verified by : _____

Sign & Date : _____

Reviewed by : _____

Sign & Date : _____



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15.9 Verification of Power Failure Condition:

Objective : To verify the power failure condition.

Tools Required : Not Applicable

Procedure :

1. Operate the system in run mode.
2. Record the set parameters in the verification table.
3. Shut down the power of the system.
4. Restart the power of the system.
5. Record the set parameters in the verification table.

Acceptance Criteria : After restart the power, the set parameters shall remain unchanged.

Verification Table:

Refer Attachment No. 6				
Date & Time Before Power Loss: _____				
Date & Time After Power Recovery: _____				
Parameter Description	Power Failure		Discrepancy? (Yes/No)	Done By Sign & Date
	Parameter Value Before	Parameter Value After		
Operation Screen				
Set Point 1 Closed Loop(bar)				
PI Controller Screen				
Gain Kp				
Integral Time Ti(S)				



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Parameter Description	Power Failure		Discrepancy? (Y/N)	Done By Sign & Date
	Parameter Value Before	Parameter Value After		
Alternative Set Point Screen (Set Point 2)				
Set Point 2 Closed Loop(bar)				
Set Point 2 Open Loop%				
Alternative Set Point Screen (Set Point 3)				
Set Point 3 Closed Loop(bar)				
Set Point 3 Open Loop%				
Alternative Set Point Screen (Set Point 4)				
Set Point 4 Closed Loop (bar)				
Set Point 4 Open Loop%				
Alternative Set Point Screen (Set Point 5)				
Set Point 5 Closed Loop (bar)				
Set Point 5 Open Loop%				
Alternative Set Point Screen (Set Point 6)				
Set Point 6 Closed Loop (bar)				
Set Point 6 Open Loop%				
Alternative Set Point Screen (Set Point 7)				
Set Point 7 Closed Loop (bar)				
Set Point 7 Open Loop%				



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Parameter Description	Power Failure		Discrepancy? (Y/N)	Done By Sign & Date
	Parameter Value Before	Parameter Value After		
Soft Pressure Build Up Screen (Filling Phase)				
Speed%				
No. of Pump				
Filling Pressure(bar)				
Max. Time(s)				
Pressure Build Up Phase				
Ramp Time(s)				
Min & Max User Define Duty (Min. Duty)				
No. of Pump in Operation				
Speed of Variable speed Pump in Operation%				
Max. Duty				
No. of Pump in Operation				
User Defined Duty Screen				
No. of Pump in Operation				
Speed of Variable speed Pump in Operation%				

Remarks:

Meet the acceptance Criteria [] Yes [] No

Checked by : _____

Sign & Date : _____

Verified by : _____

Sign & Date : _____

Reviewed by : _____

Sign & Date : _____



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15.10 Verification of Communication Failure Condition:

Objective : To verify the communication failure condition.

Tools Required : Not Applicable

- Procedure** :
1. Operate the system in run mode.
 2. Record the set parameters in the verification table.
 3. Disconnect the communication cable from the HMI.
 4. Reconnect the communication cable to the HMI.
 5. Record the set parameters in the verification table.

Acceptance Criteria : After reconnect the communication cable, the set parameters shall remain unchanged.

Verification Table:

Refer Attachment No. 7				
Date & Time Before Communication Failure: _____				
Date & Time After Communication Recovery: _____				
Parameter Description	Communication Failure		Discrepancy? (Yes/No)	Done By Sign & Date
	Parameter Value Before	Parameter Value After		
Operation Screen				
Set Point 1 Closed Loop(bar)				
PI Controller Screen				
Gain Kp				
Integral Time Ti (S)				



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Parameter Description	Communication Failure		Discrepancy? (Y/N)	Done By Sign & Date
	Parameter Value Before	Parameter Value After		
Alternative Set Point Screen (Set Point 2)				
Set Point 2 Closed Loop(bar)				
Set Point 2 Open Loop%				
(Set Point 3)				
Set Point 3 Closed Loop(bar)				
Set Point 3 Open Loop%				
(Set Point 4)				
Set Point 4 Closed Loop(bar)				
Set Point 4 Open Loop%				
(Set Point 5)				
Set Point 5 Closed Loop(bar)				
Set Point 5 Open Loop%				
(Set Point 6)				
Set Point 6 Closed Loop(bar)				
Set Point 6 Open Loop%				
(Set Point 7)				
Set Point 7 Closed Loop(bar)				
Set Point 7 Open Loop%				



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Parameter Description	Communication Failure		Discrepancy? (Y/N)	Done By Sign & Date
	Parameter Value Before	Parameter Value After		
Soft Pressure Build Up Screen (Filling Phase)				
Speed%				
No. of Pump				
Filling Pressure(bar)				
Max. Time(s)				
Pressure Build Up Phase				
Ramp Time(s)				
Min & Max User Define Duty (Min. Duty)				
No. of Pump in Operation				
Speed of Variable speed Pump in Operation%				
(Max. Duty)				
No. of Pump in Operation				
User Defined Duty Screen				
No. of Pump in Operation				
Speed of Variable speed Pump in Operation%				

Remarks:

Meet the acceptance Criteria [] Yes [] No

Checked by : _____

Sign & Date : _____

Verified by : _____

Sign & Date : _____

Reviewed by : _____

Sign & Date : _____



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15.11 Verification of Control Loop Test:

Purpose : Verify the performance of integrated HMI 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.

Acceptance Criteria HMI system should able to control the set process parameter within the specified limit



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Verification Table: Verification of Control Loop Test

Refer Attachment No. 8				
Parameter	Specified	Set Value	Actual Result	Done By Sign & Date
Operation Screen				
Set Point 1 Closed Loop(bar)	0.0 to 16.0			

Remarks:

Meet the acceptance Criteria [] Yes [] No

Checked by : _____

Sign & Date : _____

Verified by : _____

Sign & Date : _____

Reviewed by : _____

Sign & Date : _____

16. OPERATIONAL QUALIFICATION TEST STATUS:

The operational qualification test status is as per below mentioned table.

Test Description	Status (Pass/Fail)	Discrepancy ? (Yes/No)
Verification of Field Instruments Calibration Details		
Verification of PLC LED's.		
Verification of PLC Input and Output.		
Verification of Password Security		
Verification of User Level & Rights		
Verification of HMI Screens.		
Verification of Set Parameter Boundary Condition.		
Verification of Alarms and Interlocks.		
Verification of Power Failure Condition.		
Verification of Communication Failure Condition.		
Verification of Control Loop Test		



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17. DISCREPANCIES HANDLING DURING PLC QUALIFICATION:

- In case of discrepancy observed during qualification, document in the defined column in each table and document the details of the observation in the discrepancy log sheet.
- Inform to production, engineering and quality assurance about discrepancy.
- Investigate the discrepancy and ensure the possible impact.
- If discrepancy does not have potential to impact on operation as well as performance of the system, close the discrepancy with proper justification.
- The production, engineering and QA will decide whether discrepancy is acceptable or not.
- If discrepancy is acceptable, provide conclusion and recommendation if any into respective column.



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18. DISCREPANCY AND CORRECTIVE ACTION FORM:

Protocol Reference	
Discrepancy Number	

DISCREPANCY:

Describe the Discrepancy	
Reported by	Date

CORRECTIVE ACTION:

Describe corrective action taken (Attach additional sheets if necessary)	
Reported by	Date

DISPOSITION ACTION:

Acceptable?	Yes	No
Discussion		
Approved by	Date	

COMPLETION:

Completed by	Date
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19.

20. ABBREVIATION:

Abbreviations	Description
GMP	Good Manufacturing Practices
HMI	Human Machine Interface
PLC	Programable Logic Controller
SRS	System Requirement and Specification
IQ	Installation Qualification
OQ	Operation Qualification
QA	Quality Assurance
SOP	Standard Operating Procedure
ICS	Instrumentation and Control Solutions
NA	Not Applicable
ICH	International Conference of Harmonization
mA	mili Ampere
ACV	Alternate Current Voltage
DCV	Direct Current Voltage
RH	Relative Humidity



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31. POST APPROVALS:

The signature listed below indicates the post approval of this operational qualification. This approval is joint responsibility of listed functional areas.

Function	Name	Department	Designation	Signature & Date
Executed by		Engineering		
Reviewed by		Engineering		
Reviewed by		Quality Assurance		
Approved by		Quality Assurance		