VERIFICATION OF OPERATING PARAMETERS THROUGH SCADA SYSTEM
FOR
BUILDING MANAGEMENT SYSTEM

System Name	Building Management System
System ID	
Location	BMS Room
Effective Date	

CONTENTS

	PHARMA DEVILS
	QUALITY ASSURANCE DEPARTMENT

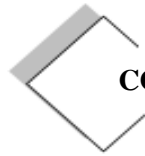| Title	Verification of Operating Parameters Through SCADA System for Building Management System				
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1.0.0   PRE-APPROVAL SIGNATURES:

The signatures below indicate pre approval of this verification of operating parameters and it is ready for execution. Any changes or modifications to the intent or the acceptance criteria of this verification of operating parameters document, following approval, requires the generation of an amendment which must be approval prior to execution.

Prepared By:

Functional Area	Name	Sign/Date
Validation Engineer		

Reviewed By (………………..):

Functional Area	Name	Designation	Sign/Date
Engineering			
Production			
Quality Assurance			

Approved By (………………..):

Functional Area	Name	Sign/Date
Head Quality Assurance		

2.0.0   PURPOSE:

The purpose of this verification of operating parameters document is to demonstrate and document that the BMS system is operating and fulfill its intended use when it's placed in its intended environment.

The purpose of the verification of operating parameters is to provide documented evidence to demonstrate that the BMS system is operated as per the functional specifications.

2.1.0   SCOPE:

This verification of operating parameters will be performed on BMS system which is located in "Service Floor".

It ensures that the operation performed by meets the master documentations. (manuals, URS etc.)

This verification of operating parameters document describes the BMS system hardware and software, test procedures, documentation, references and acceptance criteria used to establish that BMS system has been installed and operated in accordance with the master documentations. Verify document compliance to GAMP-5.

2.2.0 BACKGROUD:

The Building Management System is a purchased specifically for use at ………………..

2.3.0 REVISION HISTORY:

Version No.	Effective Date	Reason for Change
00		**New Document**

2.4.0 VALIDATION TEAM:

Validation team is responsible for the execution of verification of operating parameters for BMS system. Validation team comprises.

Name	Department	Designation	Sign & Date
	New Tech. Solution		
	Engineering		
	Production		
	Quality Assurance		

2.5.0   RESPONSIBILITY:

❖ **New Tech. Solution:**

  ➢ Collect all manuals, electrical wiring diagram and documentary or any other data necessary for the preparation, execution of verification of operating parameters document from M/S …………..

  ➢ Preparation and execution of verification of operating parameters document.

  ➢ Initiate Verification study in coordination with Production, Quality Assurance and Engineering.

  ➢ Provide training to the persons, who present during execution, of this document.

Engineering	Production	Quality Assurance
➢ Co-ordinate during execution of Verification activities.	➢ Co-ordinate during execution of Verification activities.	➢ Co-ordinate during execution of Verification activities.
➢ To provide utilities for Verification activity.	➢ Provide personnel for facilitating the execution of Verification activity.	➢ To Review and approve the verification of operating parameters document.
➢ To check the verification of operating parameters document.	➢ Check that test requirements are completed. ➢ To check the verification of operating parameters document.	

2.6.0   REFERENCES:

The tests and execution procedures within the scope of this Verification document are consistent with the following references:

S.No.	Test Name	Require as per guideline
1.	Master test instrument verification	GAMP 5
2.	Verification of calibration certificate of sensors	GAMP 5
3.	Verification of LED indication of DDC system processor	GAMP 5
4.	Verification of DDC system inputs/outputs	GAMP 5
5.	Verification of security levels	GAMP 5
6.	Verification of SCADA Screen	GAMP 5
7.	Verification of range of set parameters	GAMP 5
8.	Verification of power loss recovery condition	GAMP 5
9.	Verification of communication fails recovery condition	GAMP 5
10.	Verification of alarms and interlocks	GAMP 5
11.	Verification of trends test for BMS	GAMP 5
12.	Verification of data backup and restoration for SCADA system	GAMP 5
13.	Verification of 21 CFR Part 11 clauses	GAMP 5
14.	Verification of an integrated control loop test	GAMP 5

2.7.0   BMS SYSTEM DESCRIPTION:

The Building Management System is used to control, monitor and record various parameter of HVAC system. Building Management System consists of Software PC, Interfacing Device, DDC Panels, Field instruments for monitoring various parameters of AHU's.

The BMS handles all the functions that enable system monitoring and controlling of field equipment. The Desigo Insight V2.35 software of BMS system serves as an interface to allow operator interaction with the system.

The Building Management System (BMS) is to collect data from field instrumentation (Temperature, Relative Humidity, Pressure differential of room, Filter Status etc.) which is installed in different Air handling Units through DDC panel and NCRS interfacing unit. BMS software are checked this data with predefined limits. If data not found within limits then BMS will create alarm.

The Building Management System (BMS) is recorded all data in form of Trends and audit trial.

The Building Management System (BMS) controlled all following parameter through DDC panel and interfacing unit.

- AHU Return Air and Room Temperature
- AHU Return Air % RH
- AHU Supply and return Air fan static pressure
- Pre Filter and HEPA filter status
- Auto / Manual fan Status
- Chilled water valve and HW valve opening status
- AHU fan running status
- Return air Damper opening status

 Return temperature of Chilled and Hot water On / Off Status of Duct heater

2.8.0   BMS SYSTEM SCHEMATIC DIAGRAM:

3.0.0   TRAINING RECORD:

Following persons have been trained on this Verification document and will execute/ help in execution of this Verification document.

Duration and time 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	Designation	Signature

3.1.0   VERIFICATION OF MASTER TEST INSTRUMENTS:

Purpose   :   To verify master test instruments which is going to use for validation.

Scope   :   To verify and record of the Master Test Instrument details.

Procedure   :   ➢   Verify the details of master test instruments with the appropriate calibration certificates.

➢   Record all the details of master test instruments, which are given below, from calibration certificates.

- Instrument Name
- Instrument ID
- Calibration date
- Calibration Due date

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 No	Calibration Date	Calibration Due Date	Meets acceptance criteria	Sign. & date
1					Yes ( ) No ( )	
2					Yes ( ) No ( )	

Comments/ Remarks:

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Function	Name	Department	Sign. & Date
Done by		**Engineering**	
Checked by		**Engineering**	
Verified by		**QA**	

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3.2.0   VERIFICATION OF CALIBRATION CERTIFICATES OF SENSORS:

Purpose   :   Verify the calibration certificates of critical sensors in BMS 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 BMS 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 BMS system must be calibrated.

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3.2.1 DATA TABLE OF CALIBRATION CERTIFICATES OF SENSORS:

Sr. No.	Sensor Name	Sensor ID No	Calibration Date	Calibration Due Date	Sign. & date
		AHU-18			
1	Pressure Gauge	AHU-T1-2-PG-1			
2	Pressure Gauge	AHU-T1-2-PG-2			
3	Pressure Gauge	AHU-T1-2-PG-3			
4	Pressure Gauge	AHU-T1-2-PG-4			

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Verified by		QA	

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3.3.0   VERIFICATION OF LED INDICATION OF DDC SYSTEM:

Purpose	:	To verify LED indication of DDC system in working condition
Scope	:	To check and record of LED Indication of DDC system
Procedure	:	➢ Switch "ON" the main power supply of DDC panel ➢ Check and record the behavior of LED in DDC system
Discrepancy	:	If any Discrepancy is encountered which prevent completion of the report as originally intended, document the Discrepancy Report.
Acceptance Criteria	:	All LED indication of DDC system must have been properly visualized, checked and should be same as the expected results.

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3.3.1 DATA TABLE OF DDC SYSTEM LED INDICATION IN OFF CONDITION:

LED	Expected state of LED	Actual state of LED	Meets acceptance criteria	Sign. & date
DDC PROCESSOR				
RUN	OFF		Yes ( ) No ( )	
STA	OFF		Yes ( ) No ( )	
INFO	OFF		Yes ( ) No ( )	
TX	OFF		Yes ( ) No ( )	

3.3.2 DATA TABLE OF DDC SYSTEM LED INDICATION IN ON CONDITION:

LED	Expected state of LED	Actual state of LED	Meets acceptance criteria	Sign.& date
DDC PROCESSOR				
RUN	ON		Yes ( ) No ( )	
STA	ON		Yes ( ) No ( )	
INFO	OFF		Yes ( ) No ( )	
TX	OFF		Yes ( ) No ( )	

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Comments/ Remarks:

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Function	Name	Department	Sign. & Date
Done by		Engineering	
Checked by		Engineering	
Verified by		QA	

3.4.0   VERIFICATION OF DDC SYSTEM INPUTS/ OUTPUTS:

Purpose : Verify the entire inputs/outputs of the DDC system, checking the connections to the cards of the DDC system.

Scope : To check and record the function of all DDC 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 DDC system.
Digital Outputs	➢ Force each digital output ON/OFF. ➢ Verify and record the status of digital outputs LED indication in DDC system
Analog Inputs/ Outputs	➢ Feed 4-20mA current or appropriate Ohms signal to DDC system using calibrated Universal Calibrator. ➢ Simultaneously check the reading in SCADA. ➢ Verify and record the reading of it.
Analog Output	➢ Measure appropriate current signal from output terminal of DDC 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 DDC 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.

3.4.1 DATA TABLE OF DDC SYSTEM DIGITAL INPUTS:

Input Address	Description	Expected state of LED	Actual state of LED	Meets acceptance criteria	Sign. & date
**AHU T1-2 (Super Universal TXM1.8X) Module**					
UT-1	Return Air Temp./ AHU-T1-2	ON		Yes ( ) No ( )	
		OFF		Yes ( ) No ( )	
UT-2	Return Air RH AHU-T1-2	ON		Yes ( ) No ( )	
		OFF		Yes ( ) No ( )	
UT-3	AHU-T1-2 Chilled Water Return Temp.	ON		Yes ( ) No ( )	
		OFF		Yes ( ) No ( )	
UT-4	Supply Air temp.	ON		Yes ( ) No ( )	
		OFF		Yes ( ) No ( )	
UT-5	Spare	NA		Yes ( ) No ( )	
UT-6	Supply Air RH AHU-T1-2	ON		Yes ( ) No ( )	
		OFF		Yes ( ) No ( )	
UT-7	Frequency AHU-T1-2 Feedback	ON		Yes ( ) No ( )	
		OFF		Yes ( ) No ( )	
UT-8	Supply Air Velocity AHU-T1-2	ON		Yes ( ) No ( )	
		OFF		Yes ( ) No ( )	

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Input Address	Description	Expected state of LED	Actual state of LED	Meets acceptance criteria	Sign. & date
AHU T1-2 (Digital Input TXM1.8D) Module					
DI.1	AHU-T1-2 Auto/manual	ON		Yes ( ) No ( )	
		OFF		Yes ( ) No ( )	
DI.2	AHU-T1-2 Pre. Filter Status	ON		Yes ( ) No ( )	
		OFF		Yes ( ) No ( )	
DI.3	AHU-T1-2 Post Filter Status	ON		Yes ( ) No ( )	
		OFF		Yes ( ) No ( )	
DI.4	Spare	NA		Yes ( ) No ( )	
DI.5	Spare	NA		Yes ( ) No ( )	
DI.6	AHU-T1-2 Fan Status	ON		Yes ( ) No ( )	
		OFF		Yes ( ) No ( )	
DI.7	Spare	NA		Yes ( ) No ( )	
DI.8	Spare	NA		Yes ( ) No ( )	

3.4.2 DATA TABLE OF DDC SYSTEM DIGITAL OUTPUTS:

Output Address	Description	Expected state of LED	Actual state of LED	Meets acceptance criteria	Sign. & date
**AHU T1-2 (Digital Outputs TXM1.6 R)**					
DO-1	AHU-T1-2 VFD Enable Command	ON		Yes ( ) No ( )	
		OFF		Yes ( ) No ( )	
DO-2	AHU-T1-2 Danper On/off	ON		Yes ( ) No ( )	
		OFF		Yes ( ) No ( )	
DO-3	AHU-T1-2 Damper Command	ON		Yes ( ) No ( )	
		OFF		Yes ( ) No ( )	
DO-4	Spare	NA		Yes ( ) No ( )	
DO-5	Spare	NA		Yes ( ) No ( )	
DO-6	Spare	NA		Yes ( ) No ( )	

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3.4.3 DATA TABLE OF DDC SYSTEM ANALOG INPUTS/OUTPUTS:

Input Address	Details	Input Signal	Expected Process Reading	Actual Process Reading	Meets acceptance criteria	Sign. & date
AHU T1-2 (Analog Input TXM1.8U)						
AO-1	AHU-T1-2 Frequency Modulation	4.000mA	0%		Yes ( ) No ( )	
		12.000mA	50%		Yes ( ) No ( )	
		20.000mA	100%		Yes ( ) No ( )	
AO-2	Chilled water Valve AHU-T1-2	4.000mA	0%		Yes ( ) No ( )	
		12.000mA	50%		Yes ( ) No ( )	
		20.000mA	100%		Yes ( ) No ( )	
AO-3	AHU-T1-2/Hot water Valve Modulation	4.000mA	0%		Yes ( ) No ( )	
		12.000mA	50%		Yes ( ) No ( )	
		20.000mA	100%		Yes ( ) No ( )	
AO-4	Spare	NA	NA		Yes ( ) No ( )	
AO-5	Spare	NA	NA		Yes ( ) No ( )	
AO-6	Spare	NA	NA		Yes ( ) No ( )	
AO-7	Spare	NA	NA		Yes ( ) No ( )	
AO-8	Spare	NA	NA		Yes ( ) No ( )	

Comments/ Remarks:

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Function	Name	Department	Sign. & Date
Done by		**Engineering**	
Checked by		**Engineering**	
Verified by		**QA**	

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3.5.0   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 SCADA.

Procedure : ➢ Switch ON the SCADA.
➢ Challenge all the parameters with entering different level user passwords.
➢ Record the warning messages from SCADA.

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.

3.5.1 DATA TABLE OF SCADA ACCESS:

Operator					
Details	**Expected result**	**Actual result**	**Ref. OQ Attachemnt-03**	**Meets acceptance criteria**	**Sign. & date**
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 an correct combination of user name and password for operator levels	User should able to access the system			Yes ( ) No ( )	
Supervisor					
Details	**Expected result**	**Actual result**	**Ref. OQ Attachemnt-03**	**Meets acceptance criteria**	**Sign. & date**
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 an correct combination of user name and password for Supervisor levels	User should able to access the system			Yes ( ) No ( )	

Admin					
Details	**Expected result**	**Actual result**	**Ref. OQ Attachemnt-03**	**Meets acceptance criteria**	**Sign. & date**
Attempt to gain access with an incorrect combination of user name and password for Admin levels	User should not able to access the system			Yes ( ) No ( )	
Attempt to gain access with an correct combination of user name and password for Admin levels	User should able to access the system			Yes ( ) No ( )	

3.5.2   DATA TABLE OF FUNCTION CONFIGURATION:

Function	Operator		Supervisor		Administrator		Meets acceptance criteria	Sign. & Date
	Ref. OQ Attachment-4		Ref. OQ Attachment-4		Ref. OQ Attachment-4			
Login Screen	☐		☐		☐		Yes ( ) No ( )	
Plant Viewer	☐		☐		☐		Yes ( ) No ( )	
AHU Layouts	☐		☐		☐		Yes ( ) No ( )	
AHU Room	☐		☐		☐		Yes ( ) No ( )	
Insight Menu	☐		☐		☐		Yes ( ) No ( )	
Connections Site	☐		☐		☐		Yes ( ) No ( )	
Lock, Log off, Shut down and restart	☐		☐		☐		Yes ( ) No ( )	
Alarm Viewer	☐		☐		☐		Yes ( ) No ( )	
Trend Viewer	☐		☐		☐		Yes ( ) No ( )	
Log Viewer	☐		☐		☐		Yes ( ) No ( )	

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Function	Operator		Supervisor		Administrator		Meets acceptance criteria	Sign. & Date
	Ref. OQ Attachment-4		Ref. OQ Attachment-4		Ref. OQ Attachment-4			
Object viewer	☐		☐		☐		Yes ( ) No ( )	
Data Base Import Utility	☐		☐		☐		Yes ( ) No ( )	
System Configurator	☐		☐		☐		Yes ( ) No ( )	
System Information	☐		☐		☐		Yes ( ) No ( )	
Help Screen	☐		☐		☐		Yes ( ) No ( )	

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Function	Name	Department	Sign. & Date
Done by		Engineering	
Checked by		Engineering	
Verified by		QA	

3.6.0 VERIFICATION OF SCADA SCREENS:

Purpose : To verify each function of SCADA Screens, function keys.

Scope : Verify and record all SCADA screens and function keys.

(Take backup of SCADA program if possible)

Procedure :
- ➤ Take program backup of SCADA and verify with the actual function screens.
- ➤ If backup not possible then take photo of each function screen or 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 SCADA with actual machine conditions and record the actual results.
- ➤ Open a screen; check values displayed on SCADA 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.

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3.6.1 DATATABLE OF SCADA SCREENS:

S.No.	Screen Name	Available Yes/No	Ref. OQ Attachment-5	Meets acceptance criteria	Sign. & date
01	Login Screen			Yes ( ) No ( )	
02	Home Screen			Yes ( ) No ( )	
03	Plant Viewer Screen			Yes ( ) No ( )	
04	AHU T1-2 (Tablet Compression-1) Screen			Yes ( ) No ( )	
05	AHU T2 Commands Screen			Yes ( ) No ( )	
06	Set Point Values AHU T2 Screen			Yes ( ) No ( )	
07	T1-2 CFD Parameters Screen			Yes ( ) No ( )	
08	Chilled Water Valve AHU Screen			Yes ( ) No ( )	
09	Hot Water Valve AHU Screen			Yes ( ) No ( )	
10	Psychometric Chart for AHU T-2 Screen			Yes ( ) No ( )	
11	VFD Enable Command Screen			Yes ( ) No ( )	
12	AHU Layout Screen			Yes ( ) No ( )	
13	Ground Floor AHU Allocation Screen			Yes ( ) No ( )	
14	Basement AHU Allocation Screen			Yes ( ) No ( )	
15	Layout Pressure Ground Floor Screen			Yes ( ) No ( )	

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S.No.	Screen Name	Available Yes/No	Ref. OQ Attachment-5	Meets acceptance criteria	Sign. & date
16	Layout Pressure BM Screen			Yes ( ) No ( )	
17	Layout T/RH-GF Screen			Yes ( ) No ( )	
18	Layout T&RH-BM Screen			Yes ( ) No ( )	
19	Status Screen			Yes ( ) No ( )	
20	AHU Status Screen			Yes ( ) No ( )	
21	VFD Status Screen			Yes ( ) No ( )	
22	Chiller Plant Screen			Yes ( ) No ( )	
23	Hot Water Generator Screen			Yes ( ) No ( )	
24	Air Washer Screen			Yes ( ) No ( )	
25	Desigo insight Screen			Yes ( ) No ( )	
26	Site Connection Screen			Yes ( ) No ( )	
27	Lock, log off and Shut down Screen			Yes ( ) No ( )	
28	Alarm Viewer Screen			Yes ( ) No ( )	
29	Trend Viewer Screen			Yes ( ) No ( )	
30	Log Viewer Screen			Yes ( ) No ( )	
31	Object Viewer Screen			Yes ( ) No ( )	
32	Alarm Router Screen			Yes ( ) No ( )	

S.No.	Screen Name	Available Yes/No	Ref. OQ Attachment-5	Meets acceptance criteria	Sign. & date
33	Database Import Utility Screen			Yes ( ) No ( )	
34	System Configurator Screen			Yes ( ) No ( )	
35	System information (Supervisor) Screen			Yes ( ) No ( )	
36	System Information (Device Status) Screen			Yes ( ) No ( )	
37	System information (Modem Status) Screen			Yes ( ) No ( )	
38	Desigo insight information Screen			Yes ( ) No ( )	
39	System (Project information) Screen			Yes ( ) No ( )	
40	Help Screen			Yes ( ) No ( )	
41	1 Site Connect Screen			Yes ( ) No ( )	
42	Page Setup Screen			Yes ( ) No ( )	

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Function	Name	Department	Sign. & Date
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Checked by		Engineering	
Verified by		QA	

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3.7.0   VERIFICATION OF THE RANGE OF SET PARAMETERS:

Purpose   :   To check and verify the range of set parameters in SCADA 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.

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

> For Integer Value
> Reject Value (minimum) = Acceptable Value (minimum) – 1
> Reject Value (Maximum) = Acceptable Value (maximum) + 1

> For Decimal Value
> Reject Value (minimum) = Acceptable Value (minimum) - 0.1
> Reject Value (Maximum) = Acceptable Value (maximum) + 0.1

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3.7.1 DATA TABLE OF RANGE AND BOUNDARY OF SET PARAMETERS:

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
Set point Value AHU T1-2											
Set point temp. (Deg. C)	0.0 to 100.0		Yes ( ) No ( )		Yes ( ) No ( )		Yes ( ) No ( )		Yes ( ) No ( )	Yes ( ) No ( )	
Set point RH (%)	0.0 to 100.0		Yes ( ) No ( )		Yes ( ) No ( )		Yes ( ) No ( )		Yes ( ) No ( )	Yes ( ) No ( )	
Set point CFM	-0.4 to 100000.0		Yes ( ) No ( )		Yes ( ) No ( )		Yes ( ) No ( )		Yes ( ) No ( )	Yes ( ) No ( )	
Chilled Water Valve (%)	0.0 to 100.0		Yes ( ) No ( )		Yes ( ) No ( )		Yes ( ) No ( )		Yes ( ) No ( )	Yes ( ) No ( )	
Hot water valve (%)	0.0 to 100.0		Yes ( ) No ( )		Yes ( ) No ( )		Yes ( ) No ( )		Yes ( ) No ( )	Yes ( ) No ( )	

Comments/ Remarks:

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Function	Name	Department	Sign. & Date
Done by		Engineering	
Checked by		Engineering	
Verified by		QA	

3.8.0   VERIFICATION OF POWER LOSS RECOVERY CONDTION

Purpose   :   Verify and testing of power loss recovery condition.

Scope   :   Record value of process set-parameters after the power fails.

Procedure   :   ➢   Switch "ON" the BMS system.

➢   Enter value in set parameter field in SCADA screen and record it.

➢   Start the machine.

➢   Cut power supply during machine is in "ON" condition.

➢   Restore power supply after 300 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.

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	QUALITY ASSURANCE DEPARTMENT

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3.8.1   DATA TABLE OF POWER LOSS RECOVERY CONDITION:

Parameter Description	Value Before power loss	Value after power recovery	Expected Result	Meets acceptance criteria	Sign. & date
Date & Time Before Power Loss:_____					
Date & Time After Power Recovery:_____					
Set point Value AHU T1-2					
Set point temp. (Deg. C)			Value remains same	Yes ( ) No ( )	
Set point RH (%)			Value remains same	Yes ( ) No ( )	
Set point CFM			Value remains same	Yes ( ) No ( )	
Chilled Water Valve (%)			Value remains same	Yes ( ) No ( )	
Hot water valve (%)			Value remains same	Yes ( ) No ( )	

Comments/ Remarks:

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Function	Name	Department	Sign. & Date
Done by		**Engineering**	
Checked by		**Engineering**	
Verified by		**QA**	

3.9.0   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 SCADA system.

➢ Enter value in set parameter field in IPT screen and record it.

➢ Start the machine in auto mode.

➢ While the machine is in running condition, unplug the communication link cable between DDC and SCADA.

➢ Take a screen shot or photograph of communication link failure message.

➢ Try to change recipe in SCADA screen.

➢ Records the result or error message, if no message appears then write "recipe cannot be changed".

➢ Reconnect the communication link cable after 300 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 SCADA 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.

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3.9.1   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 DDC – SCADA communication cable	Err message should display in SCADA screen and System should not stop.		Yes ( ) No ( )	
Reconnect the DDC – SCADA communication cable	Message should remove from SCADA screen.		Yes ( ) No ( )	

Parameter Description	Value Before Communication unplug	Value after Communication link reconnect	Expected Result	Meets acceptance criteria	Sign. & date
Date & Time Before Communication Unplug:_____					
Date & Time After Communication Reconnect:_____					
Set point Value AHU T1-2					
Set point temp. (Deg. C)			Value remains same	Yes ( ) No ( )	
Set point RH (%)			Value remains same	Yes ( ) No ( )	
Set point CFM			Value remains same	Yes ( ) No ( )	
Chilled Water Valve (%)			Value remains same	Yes ( ) No ( )	
Hot water valve (%)			Value remains same	Yes ( ) No ( )	

Comments/ Remarks:

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Function	Name	Department	Sign. & Date
Done by		**Engineering**	
Checked by		**Engineering**	
Verified by		**QA**	

3.10.0 VERIFICATION OF A TRENDS TEST FOR BMS:

Purpose : Verify the all trends of BMS.

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.
- ➢ 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 : SCADA system should able to control the set process parameter within the specified limit

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3.10.1 DATA TABLE OF TRENDS IN BMS:

S.No.	Specified	Actual Observation	Meet Acceptance Criteria
1.	System RUN status, Chilled and hot water valve status trends should be available		Yes ( ) No ( )
2.	Temperature and RH status trends should be available		Yes ( ) No ( )
3.	AHU room DP status trends should be available		Yes ( ) No ( )
4.	AHU HEPA DP status trends should be available		Yes ( ) No ( )

Comments/ Remarks:

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Function	Name	Department	Sign. & Date
Done by		**Engineering**	
Checked by		**Engineering**	
Verified by		**QA**	

3.11.0 VERIFICATION OF ALARMS AND INTERLOCKS:

Purpose   : Verify that all alarms and interlocks of the BMS 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 SCADA.
- ➢ 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.

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3.11.1 DATA TABLE OF ALARMS AND INTERLOCKS:

(AHU T1-2)

Cause	Expected Result	Actual Result	Correction	Meets acceptance criteria	Sign. & date
When AHU T1-2 temp. greater than set value	**"AHU T1-2 Temp. High"** Alarm message should display in SCADA Screen.		Check the temperature of and maintain the temperature.	Yes ( ) No ( )	
When AHU T1-2 temp. greater than set value	**"AHU T1-2 Temp. Low"** Alarm message should display in SCADA Screen.		Check the temperature and maintain the temperature.	Yes ( ) No ( )	

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Cause	Expected Result	Actual Result	Correction	Meets acceptance criteria	Sign. & date
When AHU T1-2 RH greater than set value	**"AHU T1-2. RH High"** Alarm message should display in SCADA Screen.		Check the RH of AHU T1-2 and maintain the RH.	Yes ( ) No ( )	
When AHU T1-2 RH greater than set value	**"AHU T1-2. RH Low"** Alarm message should display in SCADA Screen.		Check the RH of AHU T1-2 and maintain the RH.	Yes ( ) No ( )	

Comments/ Remarks:

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Function	Name	Department	Sign. & Date
Done by		Engineering	
Checked by		Engineering	
Verified by		QA	

3.12.0 VERIFICATION OF CONTROL SYSTEM SOFTWARE.

Purpose	:	Verify the SCADA System Software.

Scope	:	Check and record of control system software for SCADA System.

Procedure :

➢ Open the SCADA System in normally.

➢ Login with higher level id and password.

➢ Verify all the points as per the test table clause wise & record.

Discrepancy : If any Discrepancy is encountered which prevent completion of the report as originally intended, document the Discrepancy Report.

Acceptance Criteria : System should complies control system software requirements.

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3.12.1 TEST DATA TABLE OF CONTROL SYSTEM SOFTWARE AS PER 21 CFR PART 11:

S.No. (As per clause)	Question	Testing procedure and requirement.	Actual Result	Meet Acceptance Criteria	Sign. & Date
11.10(a)	Is it possible to discern invalid or altered records?	Try to change the possibilities of the record alteration in Process Data file. System should not allow altering record. Try to enter Invalid character or Value in the system.		Yes ( ) No ( )	

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S.No. (As per clause)	Question	Testing procedure and requirement.	Actual Result	Meet Acceptance Criteria	Sign. & Date
11.10(b)	Is the system capable of producing accurate and complete copies of electronic records on paper?	Take batch printout and Verify Print out of Data Recorded. Data display and Print should be match.		Yes ( ) No ( )	
11.10(c)	Are the records readily retrievable throughout their retention period?	Verify data backup location and data retrieving facilities. Check data retention period. It should be documented in DATA Backup SOP.		Yes ( ) No ( )	

S.No. (As per clause)	Question	Testing procedure and requirement.	Actual Result	Meet Acceptance Criteria	Sign. & Date
11.10 (d)	Is the system access is authorized to individuals?	Try to access the system by entering invalid user ID and Password for All Level for operating System and Application software. Check access rights of each level. System should not allow unauthorized person.		Yes ( ) No ( )	

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S.No. (As per clause)	Question	Testing procedure and requirement.	Actual Result	Meet Acceptance Criteria	Sign. & Date
11.10(e)	Is there a secure, computer generated, time stamped audit trail that records the date and time of operator entries and actions that create, modify or delete electronic records?	Try to change or modify the set parameter and check for audit trail generated by the system. Audit Trail should be available for any modification		Yes ( ) No ( )	
11.10(e)	Is an electronic record's audit trail retrievable throughout the record's retention period?	Verify that audit trail is available till data retention period.		Yes ( ) No ( )	

S.No. (As per clause)	Question	Testing procedure and requirement.	Actual Result	Meet Acceptance Criteria	Sign. & Date
11.10(f)	If the sequence of system steps or events is important, is this enforced by the system (e.g. As would be the case in a process control system)?	Check sequence of operation of Application software as per operation procedure. System should be operates as per sequence written in SOP.		Yes ( ) No ( )	
11.10 (g)	Does the system ensure that only authorized individuals can use the system, electronically sign records, access the operation, or computer system input or output device, alter a record or perform other operations?	Try to access the system by entering invalid user ID and Password for Application software. Check access rights of each level. Minimum 2 level is required in Application software System should not allow unauthorized person.		Yes ( ) No ( )	

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S.No. (As per clause)	Question	Testing procedure and requirement.	Actual Result	Meet Acceptance Criteria	Sign. & Date
11.10(h)	If it is a requirement of the system that input data or instructions can only come from certain input devices (e.g. Terminals) does the system check the validity of the source of any data or instructions received?	Verify system input data come from calibrated sensors and Transmitters.		Yes ( ) No ( )	

S.No. (As per clause)	Question	Testing procedure and requirement.	Actual Result	Meet Acceptance Criteria	Sign. & Date
11.10 (k)	System operation and maintenance documentation controlled?	Verify and review System Operation and Maintenance Document		Yes ( ) No ( )	
11.10 (k)	Is there a formal change control procedure for system documentation that maintains a time sequenced audit trail for those changes made by the pharmaceutical organization?	Verify the sop of change control, data backup, access control and maintenance.		Yes ( ) No ( )	

Comments/ Remarks:

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Function	Name	Department	Sign. & Date
Done by		Engineering	
Checked by		Engineering	
Verified by		QA	

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3.13.0 VERIFICATION OF DATA BACKUP AND RESTORATION:

Purpose   :   Verify the data backup and restoration system

Scope   :   Check and verify the data backup and restoration system

Procedure   :   ➢ Verify the data backup policy.

➢ Verify the data backup and restoration path for the SCADA system

➢ Verify the data backup and restoration procedure

Discrepancy   :   If any Discrepancy is encountered which prevent completion of the report as originally intended, document the Discrepancy Report.

Acceptance Criteria   :   Data should be remain unchanged during Data backup and after data restoration.

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3.13.1 DATA TABLE OF DATA BACKUP AND RESTORATION PATH:

Software storage path	Specified	Actual Observation	Meets acceptance criteria	Sign. & date
Software backup and restoration path	C:\program Files		Yes ( ) No ( )	
Formats backup and restoration Path	C:\BMS Projects\pharmadevils		Yes ( ) No ( )	
Audit trail backup and restoration Path	E:\desigo Software		Yes ( ) No ( )	

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Comments/ Remarks:

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Function	Name	Department	Sign. & Date
Done by		Engineering	
Checked by		Engineering	
Verified by		QA	

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3.14.0 VERIFICATION OF AN INTEGRATED CONTROL LOOP TEST:

Purpose   :   Verify the performance of integrated SCADA 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.

➢ 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   :   SCADA system should able to control the set process parameter within the specified limit

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3.14.1 DATA TABLE OF CONTROL LOOP TEST:

Parameter	Specified	Actual Result	Meet Acceptance Criteria	Sign. & Date
AHU No-01				
Frequency feedback (%)	Numeric		Yes ( ) No ( )	
Return air Temp. (Deg. C)	Numeric		Yes ( ) No ( )	
Return air RH (%)	Numeric		Yes ( ) No ( )	
Supply Air Temp. (Deg. C)	Numeric		Yes ( ) No ( )	
Supply air RH (%)	Numeric		Yes ( ) No ( )	
Set point temp. (Deg. C)	0.0 to 100.0		Yes ( ) No ( )	
Set point RH (%)	0.0 to 100.0		Yes ( ) No ( )	
Set point CFM	-0.4 to 100000.0		Yes ( ) No ( )	
Chilled Water Valve (%)	0.0 to 100.0		Yes ( ) No ( )	
Hot water valve (%)	0.0 to 100.0		Yes ( ) No ( )	

Comments/ Remarks:

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Function	Name	Department	Sign. & Date
Done by		**Engineering**	
Checked by		**Engineering**	
Verified by		**QA**	

4.0.0   DEVIATION REPORT AND DISCREPANCY REPORT:

Description of deficiency and its classification*

S.No.	Deficiency	Category

Recommended corrective action, Responsible person

S.No.	Recommended corrective action	Responsibility	Assigned date

Provisional approval to proceed further (For Category B Deficiencies):

_____   _____
Engineering   Quality Assurance
(Sign and date)   (Sign and date)

Corrective actions taken (For Category C deficiency)

S.No.	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 B deficiency):

Recommended corrective actions taken (Action taken within stipulated period)

S.No.	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:

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Function	Name	Department	Sign. & Date
Done by		Engineering	
Checked by		Engineering	
Verified 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 Verification (IQ):**

Document evidence that verify the equipment and its sub-system has been installed properly as per the specification.

❖ **Verification of operating parameters (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.

❖ **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:

S.No.	Reference	Description Of Attachment
1.	Attachment – 01	Calibration Certificates of Master Test Instruments
2.	Attachment -02	Calibration Certificates of Sensors
3.	Attachment -03	Right Wrong Password Challenge
4.	Attachment -04	User Access Rights
5.	Attachment -05	SCADA Screens
6.	Attachment -06	Power Fails Recovery Condition
7.	Attachment -07	Communication Fails Recovery Condition
8.	Attachment – 08	Trend
9.	Attachment – 09	21 CFR part 11 Screen Shots
10.	Attachment – 10	Data Backup and Restoration
11.	Attachment – 11	Login Print Report

8.0.0   LISTS OF ANNONYMS:

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

OQ   →   **O**perational **Verification**

DDC   →   **D**irect **D**igital **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

SCADA   →   **S**upervisory **C**ontrol **A**nd **D**ata **A**cquisition

BMS   →   **B**uilding **M**anagement **S**ystem

9.0.0   POST APPROVAL SIGNATURES:

The signatures below indicate post approval of this verification of operating parameters document and it is executed properly. All variations or discrepancies have been satisfactorily resolved.

Executed By:

Functional Area	Name	Sign/Date
Validation Engineer		

Reviewed By:

Functional Area	Name	Designation	Sign/Date
Engineering			
Production			
Quality Assurance			

Approved By:

Functional Area	Name	Sign/Date
Head Quality Assurance		