DESIGN QUALIFICATION

OF

BUILDING MANAGEMENT SYSTEM

(BMS)

	PHARMA DEVILS	
	QUALITY ASSURANCE DEPARTMENT	

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1.0 APPROVAL

Prepared By (Vendor Representative):

Department	Name	Designation	Signature	Date

Checked By (Vendor Representative):

Department	Name	Designation	Signature	Date

Reviewed By (Client Representative):

Department	Name	Designation	Signature	Date
User Department				

Approved By (Client Representative):

Department	Name	Designation	Signature	Date
User Department Head				
Engineering Head				
IT Head				
Factory Head				
Quality Head				

2.0   OVERVIEW

2.1   Objective:

Design Qualification is a comprehensive document providing all the details required ensuring that the proposed design of the system is suitable for its intended purpose.

It thus provides documented evidence that quality is built into the design of the equipment.

The objective of this specification is, therefore, to provide the construction and operation requirement of the system on the basis of which it is designed.

2.2   Scope:

This specification will define the responsibilities, acceptance criteria, basis of design, technical specifications, utility requirements, safety and cGMP features and documentation requirements.

3.0   RESPONSIBILITIES

CLIENT:

To provide the URS for the system

MANUFACURER:

To design, engineer and provide the key technical details of the system pertaining to its design qualification viz.

- System Overview

- Specifications of the components and their make, model & quantity,

- Pre-installation requirements,
    - To confirm the safe delivery of the system to the user site
    - To ensure that unauthorized and/or unrecorded design modifications shall NOT take place. If at any point in time, any change is desired in the mutually agreed design, Change Control procedure shall be followed and documented.
    - To ensure the proper installation and commissioning of the system.

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4.0   SYSTEM DESCRIPTION

Brief Description

The design of the System has integration of the smallest sensor to the operator workstations with all function of HVAC services available at the control stations. Integration shall mean all the parts of system are connected together through software and shall share all the information. The integration of all input/output points shall be achieved through software programs, electronic components, hardware packaging and communication through network for BMS.

The Building Management System shall carry out the monitoring & control following. Air Handling Unit

During normal operation, control stations shall carry out their respective functions. This shall be governed by user level password access to prevent interference during normal operation.

The system will allow for operation scheduling, sequencing of various systems, apart from allowing the operational history of various systems to be recorded in the database, which information will be useful for reliability analysis and troubleshooting.

Siemens Building Management System comprise of following:

The BMS is capable of integrating multiple functions including equipment supervision & control, alarm management, historical data collection and archiving.

The BMS consists of the following:

a)   Network able DDC (Direct Digital Control) Controllers.

System operation work station.
a)   Field Sensors (analog/Digital)

b)   Field Output devices/actuators

The system is modular in nature and permits expansion of both capacity and functionality through the addition of sensors, actuators, DDC Controller and operator devices within specified I/O range.

System architectural design eliminates dependence on the network for controlling and storing events. Each DDC Controller operates independently by performing its own specified input and output control and historical data collection. The failure of network connection will not interrupt the execution of control strategies at other operation devices.

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DCC Controllers are able to access any data or send control commands and alarm reports directly to any other DDC Controllers or combination of controllers on the network without dependence upon a central processing device.

Control Logic:

Sequence for AHU Starting:-

Normal Mode: -In normal mode BMS system have two types of operations i.e. Scheduling and Manual Operation

Scheduling: If we schedule the system, AHUs will run as per desired schedule.

Manual Operation: Operator can command the system as per requirement by over-riding the schedule.

Power Fail & Resume: -After resumption of power, normal operation will start**.** When the power is fail there will be no alarm highlighted except Fire Alarm.

VFD Control: - VFD Speed control is based on the DP sensor connected to the VFD for modulation.

Temperature / Humidity Control: -

Chilled Water Control: - The Chilled water valve Actuator operation is based on the present value (PV) and set point (SP) of Return air temperature and Humidity. If AHU is OFF, Actuator will not work. Control Parameter Settings

➢ Integral action time: - 120 Seconds.(Adjustable)

➢ Temperature Set point: - As per Air Flow Deg. C.

➢ Proportional Band: - 2 Deg. C.

➢ Operation before startup: Chilled water valve actuator remain off until AHU is ON.

RAT & RARH PV <= Return Air Temperature & Humidity Set point Deg. C = Chilled Water Valve Actuator will remain 100% closed
RAT or RARH PV > Return Air Temperature or Humidity Set point Deg. C = Chilled Water Valve Actuator will remain 100% open.

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Hot Water Control: -The Hot water valve Actuator operation is based on the present value (PV) and set point (SP) of Return air temperature. If AHU is OFF, Actuator will not work.
Control Parameter Settings.

Control Parameter Settings
- ➢ Integral action time: - 120 Seconds.(Adjustable)

- ➢ Temperature Set point :- As per Air Flow Deg. C

- ➢ Proportional Band :- 2 Deg. C(Adjustable)

RAT PV < Return Air Temperature Set point Deg. C = Hot Water Valve Actuator will remain 100% closed
RAT PV >= Return Air Temperature Set point Deg. C = Hot Water Valve Actuator will remain 100% open.

AHU Safety Interlock:-

- ➢ Door limit switch will be interlocked with electrical panel. System will not run if the door is open.

AHU Alarm Parameters:-

- ➢ Temp high/ Low alarm

- ➢ Humidity high/Low Alarm

Trends Configuration: -

1. RA Temperature
2. RA Humidity
3. System On/Off Status.
4. Dp Status

Interlocking of the systems:

- ➢ All valve actuators will remain OFF till the respective system is OFF.

- ➢ Dehumidifier will remain OFF if the AHU is OFF.

IO Point Summary:

As per attached "**ANNEXURE-I**"

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5.0   TECHNICAL SPECIFICATIONS OF COMPONENTS

Components	Specifications
Duct Temperature Sensor	
Make	Dwyer
Model	BTT D06 2
Range	-40 to 60 °C
Output Signal	DC 0...10 V
Location	At Return Air Duct of AHU
Magnesense ® Differential Pressure Transmitter	
Make	Dwyer
Model	MS311
Range	0…2 kpa
Output Signal	4-20mA
Location	Across Fan
Magnesense ® Differential Pressure Transmitter	
Make	NA
Model	NA
Range	NA
Output Signal	NA
Location	NA
OEM Pressure Transmitter	
Make	NA
Model	NA

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Components	Specifications
Range	NA
Output Signal	NA
Location	NA
Duct Temperature & Humidity Transmitter with Sensor	
Make	Dwyer
Model	RHP3D22
Range	Temperature: -40 to 60 °C, Humidity:0...100 % RH
Output Signal	4-20 mA
Location	At Return Air Duct of AHU
Hazardous Area Temperature & Humidity Transmitter with Sensor	
Make	NA
Model	NA
Range	NA
Output Signal	NA
Location	NA
CHW Actuator	
Make	Danfoss
Model	AME110NL
Closing Force	130 N
Stroke	5 mm
Location	At Chilled Water Outlet Duct
CHW Actuator	
Make	Danfoss

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Components	Specifications
Model	AME435QM
Closing Force	200 N
Stroke	20 mm
Location	At Chilled Water Outlet Duct
Room Display Unit	
Make	Hawkeye RTC
Port	RS485, Isolated
Baud Rate	9600 bps
Protocol	Modbus RTU
Desigo Software	
Make	Siemens
Software	Desigo CC
Firmware Version	3.0
Function	Monitoring of system
DDC Controller	
Make	Siemens
Model	PXC50.E.D with expansion modules& PXC001.ED for MODBUS communication
Location	Second Floor
Power	24V AC (+/- 20%)

6.0   DETAILS OF UTILITIES:

S.No.	Utility	Requirement
1	UPS Power	230V AC , 50 Hz

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7.0 REVIEW/EVALUATION OF VENDOR DESIGN AGAINST USER REQUIREMENTS:

Review the vendor design proposal, against each item, and comment whether, vendor design, meets requirements.

S.No.	Description of Requirement / URS reference	Features		Specification Matches (Yes/No)	Remarks / Actions to be taken (if specification does not match)
		Requirements	Vendor Specifications		
1.	Equipment / System	Building Management System for AHU of the Injection Facility	Building Management System for AHU of the Injection Facility.	Yes	NA
2.	Requirement	The purpose of this requirement definition document is to describe the User Requirement Specification for BMS (Building Management System) which shall be used to: o To Control temperature of Each AHU System o To Control RH of Each AHU System (As applicable)	BMS (Building Management System) shall be used to: o To Control temperature of Each AHU System o To Control RH of Each AHU System (As applicable)	Yes	NA
3.	Equipment Installation	• The System to be installed at AHU of the Injection Facility. • BMS Server PC shall be installed at BMS Room which is also at 2nd Floor. • Return air Temperature + RH sensor shall be installed in return air duct of respective AHU to control temperature and RH of respective AHU. • Differential Pressure transmitter shall be installed in supply air duct of respective AHU. • DDC controller shall be installed in the Electrical Room.	• The System to be installed at AHU of the Injection Facility BMS Server PC shall be installed at BMS Room which is also at 2nd Floor. • Return air Temperature + RH sensor shall be installed in return air duct of respective AHU to control temperature and RH of respective AHU. • Differential Pressure transmitter shall be installed in supply air duct of respective AHU. • DDC controller shall be installed in the Electrical Room.	Yes	NA

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S.No.	Description of Requirement / URS reference	Features		Specification Matches (Yes/No)	Remarks / Actions to be taken (if specification does not match)
		Requirements	**Vendor Specifications**		
	System Specifications	• The BMS shall control the Temperature and Relative Humidity for the areas served by respective HVAC systems. • The BMS shall store logged data, alarms and history trends as specified in the document. • Access to the BMS interface shall be through username and password protection. A hierarchy of configurable user access levels shall be available ranging from "Administrator" rights with full access and control to "user" rights with read only access. • DDC Panel shall run through UPS power. • The system shall be centralized and PC with simple operating techniques and shall be used to control, manage, alarm / report with reference to AHU systems. • Signals from field level devices shall be communicated to DDC which shall communicate information to a central computer. • Editing and controlling of various set points shall be done from the central computer through password protection.	• The BMS shall control the Temperature and Relative Humidity for the areas served by respective HVAC systems. • The BMS shall store logged data, alarms and history trends as specified in the document. • Access to the BMS interface shall be through username and password protection. A hierarchy of configurable user access levels shall be available ranging from "Administrator" rights with full access and control to "user" rights with read only access. • DDC Panel shall run through UPS power. • The system shall be centralized and PC with simple operating techniques and shall be used to control, manage, alarm / report with reference to AHU systems. • Signals from field level devices shall be communicated to DDC which shall communicate information to a central computer. • Editing and controlling	Yes	NA

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		Requirements	**Vendor Specifications**		
			of various set points shall be done from the central computer through password protection.		

8.0   FINAL REPORT

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Summarized By (Sign/Date):

Reviewed By (Sign/Date):

9.0   REFERENCE DOCUMENTS

S.No.	Title
1.	User Requirement Specifications (URS)

10.0   ABBREVIATIONS

S.No.	Abbreviation	Description
1.	%	Percent
2.	°C	Degree Centigrade
3.	AHU	Air Handling Unit
4.	BMS	Building Management System
5.	CFR	Code of Federal Regulations
6.	DDC	Direct Digital Control
7.	DP	Differential Pressure
8.	HVAC	Heating Ventilation and Air Conditioning
9.	LAN	Local Area Network
10.	LED	Light Emitting Diode
11.	Ltd.	Limited
12.	MKT	Mean Kinetic Temperature

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S.No.	Abbreviation	Description
13.	PC	Personal Computer
14.	RH	Relative Humidity
15.	Sr. No.	Serial Number
16.	UPS	Uninterrupted Power Supply
17.	URS	User Requirement Specifications
18.	US FDA	United States Food and Drug Administration
19.	w.r.t.	With respect to

11.0   ATTACHMENT(S) / ANNEXURE(S)

S.No.	Description	Attachment No. / Annexure No.
1.	IO Point Summary	Annexure-I
2.	System Architecture Drawing	Attachment - I
3.	DDC GA Drawings	Attachment - II