DESIGN QUALIFICATION

FOR

HVAC BMS

PHARMA DEVILS	DESIGN QUALIFICATION FOR HVAC BMS	PROTOCOL No.:

PRE -APPROVAL PAGE

DESIGN QUALIFICATION

DOCUMENT No: ……

"HVAC BMS"

REPORT FOR APPROVAL
(……)

Name	Designation	Department	Signature	Date

REPORT APPROVAL FOR EXECUTION
(……)

Name	Designation	Department	Signature	Date

TABLE OF CONTENT

1. INTRODUCTION:

Description of Document:

This document provides Documented evidence for **HVAC BMS** supplied by …… to …… this system will provide facility monitoring at ……

The Scope of Design Qualification document is to ensure that **HVAC BMS** meets the desired specifications as required.

2. SUMMARY SHEET:

Description of Equipment: **HVAC BMS**

Scope Covered By System:

- Wired Control panels
- CFM,RH and Temperature sensors
- Display Panel With inbuilt Alarm Indication
- HVAC BMS software
- Controlling & Monitoring of Temperature, Humidity and CFM

3. USER REQUIREMENT SPECIFICATION (URS):

3.1 PARAMETERS TO BE MONITORED (FOR RESPECTIVE AHU's):

S.No.	Parameters	Limit as per Design	Remark
1.	CFM	CFM is Based on Delta P	Digital out put
2.	Temperature	-40 to +125 °C with 2 decimal point	Digital out put
3.	Relative Humidity	0 to 100% with 2 decimal point	Digital out put

3.2 USER POINT DETAILS: (14 AHU's & Areas)

Device ID No.	Serial No.	Location Details	Device Connected
1.		----	DDC Controller
2.		----	DDC Controller
3.		----	DDC Controller
4.		----	DDC Controller
5.		----	DDC Controller
6.		----	DDC Controller
7.		----	DDC Controller
8.		----	DDC Controller
9.		----	DDC Controller
10.		----	DDC Controller
11.		----	DDC Controller
12.		----	DDC Controller
13.		----	DDC Controller
14.		----	DDC Controller
15.		Tool Room	Room TRH Device
16.		Disinfectant Preparation	Room TRH Device
17.		Filtration	Room TRH Device
18.		Unloading Area	Room TRH Device
19.		Ampoule Filling & Sealing	Room TRH Device
20.		Sterile Corridor	Room TRH Device
21.		Disinfectant Preparation	Room TRH Device
22.		Manufacturing area	Room TRH Device
23.		Unit Preparation	Room TRH Device
24.		RM Day Store	Room TRH Device
25.		PM Day Store	Room TRH Device
26.		Ampoule Washing & Sterilization	Room TRH Device
27.		Ampoule Hold & Buffer Zone	Room TRH Device
28.		SPARE	Room TRH Device
29.		Panel -01	Room Diff. Pressure
30.		Panel -01	Room Diff. Pressure
31.		Panel -01	Room Diff. Pressure
32.		Panel -01	Room Diff. Pressure
33.		Panel -01	Room Diff. Pressure
34.		Panel -01	Room Diff. Pressure
35.		Panel -01	Room Diff. Pressure
36.		Panel -02	Room Diff. Pressure

Device ID No.	Serial No.	Location Details	Device Connected
37.		Panel -02	Room Diff. Pressure
38.		Panel -02	Room Diff. Pressure
39.		Panel -02	Room Diff. Pressure
40.		Panel -02	Room Diff. Pressure
41.		Panel -02	Room Diff. Pressure
42.		Panel -03	Room Diff. Pressure
43.		Panel -03	Room Diff. Pressure
44.		Panel -03	Room Diff. Pressure
45.		Panel -03	Room Diff. Pressure
46.		Panel -03	Room Diff. Pressure
47.		Panel -03	Room Diff. Pressure
48.		Panel -03	Room Diff. Pressure
49.		Panel -04	Room Diff. Pressure
50.		Panel -04	Room Diff. Pressure
51.		Panel -04	Room Diff. Pressure
52.		Panel -04	Room Diff. Pressure
53.		Panel -04	Room Diff. Pressure
54.		Panel -04	Room Diff. Pressure
55.		Panel -04	Room Diff. Pressure
56.		Panel -04	Room Diff. Pressure
57.		Panel -05	Room Diff. Pressure
58.		Panel -05	Room Diff. Pressure
59.		Panel -05	Room Diff. Pressure
60.		Panel -05	Room Diff. Pressure
61.		Spare	Room Diff. Pressure
62.		Spare	Room Diff. Pressure

- **THIS ABOVE PARAMETERS PERFORMANCE IS SUBJECT TO FOLLOWING:**

Instructions as mentioned in System Performance Warranty are followed.

- Preventive maintenance should be carried out as per requirement.
- Process Areas are operated as per given defined parameters and limits for HVAC System.
- Continues ups power supply to all the modules.

4. OBJECTIVE AND SCOPE OF THE WORK

- **Purpose:**

The purpose of this document is to state the necessities of **HVAC BMS** at ……. Descriptions are given in terms of general functions, procedure and capacity. Requirements are defined as paragraphs to facilitate DQ, IQ, OQ and PQ. The document is made by, **…….** Purpose of this document is to provide detailed Technical information of supplied system. If required by **……** will support to identify/resolve the problem

4.1 SCOPE OF WORK:

- **Description:**

The **HVAC BMS** is designed for continuous data logging, monitoring and controlling of defined Parameters (Temperature, Humidity, CFM).

- Proper documentation, including SOP's and periodical reports of all logs and alarms and excursions. (All Software related alarms are as per process related alarms limits (As per defined SOP).
- Process area and AHU have to be equipped with multiple sensors spread evenly throughout the controlled area.
- Continuous recording of data with accuracy of 21 CFR part 11 Compliance supported by Audit trail and history report.
- Auto Corrective action taken, when defined set parameters go outside the specifications.

- **Alarms and Excursions**

HVAC BMS is designed with identification of abnormality which is as below mentioned.

- Start Alarming, if monitored values go outside a predefined value.
- Proposed adequate controlled output from controllers to achieve parameters(Temperature ,Humidity ,CFM)
- Alarms on excursion conditions being breached (usually a set temperature, Humidity and differential pressure for a particular time)
- Recovery of Alarms and Acknowledgment with action taken.

- **Scope of work**

Scope of work includes:

- Supply of Total system according to specification
- Installation of Modules having
  - CFM sensor (Based on ΔP) (factory calibrated) with digital output
  - Differential Pressure sensor (factory calibrated) with digital output
  - Temperature sensor (factory calibrated) with digital output.
  - Relative Humidity sensor (factory calibrated) with digital output.
- Installation, Start-Up and performance test at ……Site.
- Documentation (DQ, IQ and support to OQ & PQ)
- Training shall be given to all the concern persons

4.2 REQUIREMENTS FOR ENVIRONMENT AND OPERATION:

Layout:

The **HVAC BMS** shall be installed at concerned end for display & monitored by Authorised person online.

Physical conditions & Area classification:

System is intended for indoor application. For AHU's CFM, Temperature and Humidity needs to be monitored and maintained.

UTILITIES:

Utility requirements are for the efficient operation of environment Monitoring.

Utilities	Description	Remark
Personal computer, For data logging & monitoring	Intel Core i5 Processor, 16 GB RAM Minimum, Ubuntu OS, 1TB Hard Drive, USB support	User's scope
Printer	Any printer.	User's scope
Power	230 V, 1-phase, 50 Hz. Continues ups power supply	User's scope
User	All the user list with Email ids	Name and in ascending form.

5. SCHEME & SYSTEM DESCRIPTION & DESIGN

5.1 SYSTEM DESCRIPTION: HVAC BMS

The **HVAC BMS** encompasses state-of-the-art technology with the vision of monitoring and controlling AHU parameters within the Concord environment where accurate temperature, humidity and CFM monitoring and controlling are essential. HVAC BMS supplied by **……** having following basic components:

- Our modules in Ms powder Coated Control panel with necessary control outputs , supply and CFM , Temperature ,Humidity Sensors and Real-time Display Console with Alert Indications

- Communication card for PC
- HVAC BMS software

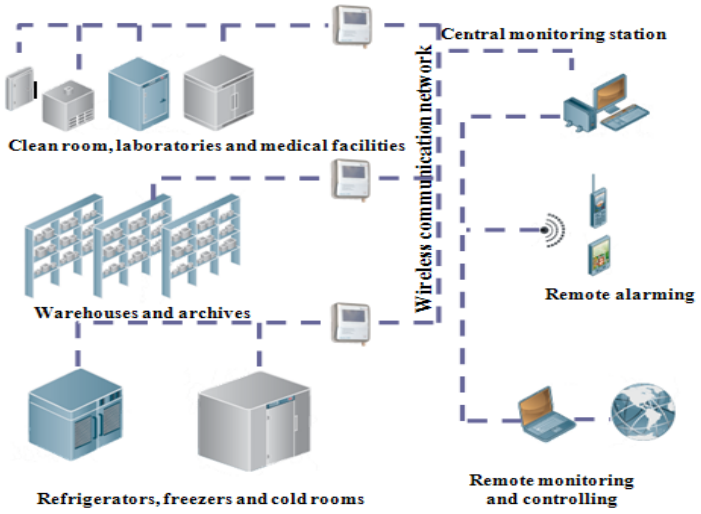
Distinctive Features

- Data monitoring, logging and notification using central base receiver.
- The Internet- and web-enabled remote diagnostics and maintenance
- Controlled access to **HVAC BMS software** based on allocated user privileges.
- Display current temperature ,humidity ,CFM Initiates alarm as per defined parameter limits for each parameters
- Real time monitoring, logging and reporting.
- Best-in-class data analysis tools, including ability to graph and report in standard and user-defined formats.
- Wired module connections to the central computer system.
- Modules are scalable and easy to integrate for fast time-to-market applications.

5.2 OPERATION OF HVAC BMS:

The HVAC BMS **consist module, based on receiver and centralized main computer with** -HVAC BMS software**.**

Each individual module is fully expandable to meet custom requirement of monitoring and controlling based on different AHU's application and specifications.



modules (nodes) can be connected in multiples with wire to a central monitoring, logging and configuration system operating on a server, facility monitoring system combines efficient monitoring and controlling with effective alarming, simplified reporting and secure data records & storage.

5.3 HVAC BMS SOFTWARE:

Series is the online Monitoring system with **HVAC BMS** software support which uses the very latest technology to fully automate temperature, Relative Humidity and Pressure monitoring and recording 24/7 providing effective control over different parameters.

Products has designed and developed the **HVAC BMS software** that shows all parameter values on the PC monitor screen and keep updating and storing them in the computer as per preset time intervals.

It generates log report on bases of time, date and year that can be seen in graphs, tabular reports in PDF form. Data is stored as per pre-defined time interval. Reports are of events based likewise generated errors, modified set values of parameters, email notifications, etc. The software is easy to use and enables real time display, mimic chart, immediate visual display of data (current and historical) in graphical and printable form.

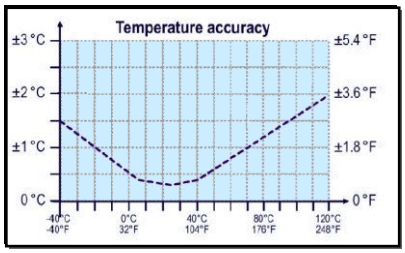
The **HVAC BMS software**, provided with all products, allows to set parameter values, take an action in correspond to out of range value of environmental parameters then generate control output as per the algorithms.

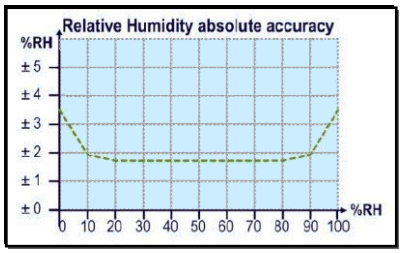
HVAC BMS software exhibit current, minimum and maximum range of all parameters and activates a settable high/low alarm for each parameter. If parameters go high or low, it gives alarm indications

6. MODULE SPECIFICATIONS:

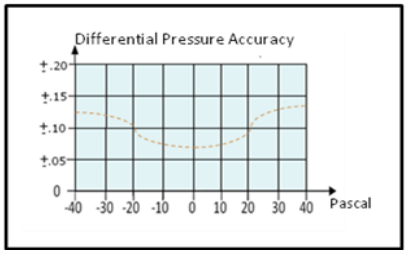
- Body: Ms powder Coated Panels
- Dimensions: 820 mm x 771 mm x 220.22 mm
- Weight: 50 Kg Approx.

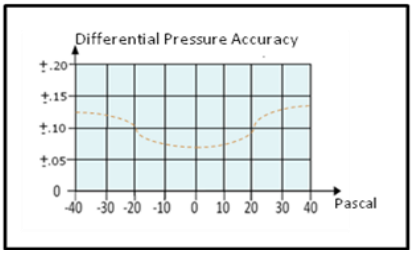
Common feature for Differential Pressure, Temperature and RH sensor:





- Digital signal quality
- Fast response time
- Insensitivity to external disturbances
- Overall temperature accuracy is ± 0.5 °C
- Tiny size and ultra low power consumption
- Highest reliability and excellent long term stability.





Accuracy at different Temperature:

- ±0.5°C, range 0°C to +40°C
- ±1.0°C range +40 to +70°C
- ±1.5°C range + 70 to 100°C

Accuracy at different Differential Pressure:

- ±0.15, range -345 to +345 Pascal

Accuracy at different Relative Humidity:

- ± 3.0 % RH, RH range 0 to 90 %
- ± 3.5 % RH, RH range 0 to 10 %
- ± 3.5 % RH, RH range 90 to 100%

➢ **DISPATCH:**

All Factory manufactured instruments will be cleaned inside and outside and dried before packing for dispatch. All end connections shall be sealed before packing for dispatch.

➢ **CALIBRATION:**

All instruments will be provided with Factory Calibration sensors and Will be in compliance to EQDC Certificate.

7. VALIDATION AND OTHER CONTROL TESTING MEASURES:

- **INSTALLATION CHECK:**

An installation checklist shall be performed before Installation Qualification to ensure that the all instruments have been installed so that IQ can be performed successfully.

8.1 HVAC BMS Software catalogue

HVAC BMS Software is being designed to combine regulatory demands and industries norms for AHU facility. System is the on-line Monitoring system with **HVAC BMS** software support which uses the very latest technology to fully automate process variables such as temperature, relative humidity and pressure.

Accurate Monitoring:

HVAC BMS offers a large array of choices for monitoring the Process area. With the use of **HVAC BMS**.

- Information can be monitored locally, centrally and remotely.
- Access to the system is protected. Each user is assigned with username and password to gain access to functionality, defined by their access level.
- Plant information is supervised through standard and custom displays and includes:
  - Real Time Display

- Data collected from every module are linked together and displayed as trends using online and historical trending within the system. Trended data are available in various groups (Temperature, Humidity. & CFM.)

The monitoring facility also provides the user with access to standard features of the system according to their access level, including:

- Trends
- Alarm set point configuration
- Control parameter configuration

Data Logging, alarming and reporting:

Data logging is a key requirement for **HVAC BMS**. 21 CFR Part 11 requires that logged data will be tamper proof subject to NDA this includes critical facility parameters (temperature, humidity, CFM, and etc.), with audit trails including:

- Accurate time and date stamps
- Alarms and events
- User actions and details (e.g. set point changes as per defined Level of user level) (User Levels are administrator,supervisor,operator)
- User notes
- Login/Logout/Auto Timeout Session

Typically a system comprises of a number of distributed modules where module has its own internal clock. Time synchronization is included to ensure accurate time and date stamps, as required by 21 CFR Part 11, to a known clock source.

The **HVAC BMS** system offers facility such that one can copy data electronically for archive and export them to common packages (e.g. PDF) for viewing of secure records in human readable format.

Alarms and Events Reporting:

A key feature of the **HVAC BMS** is its Alarms and Events functionality. All alarms and events are time stamped and logged for long term retention and
In compliance to 21 CFR Parts 11. Individual plant data can be configured to have one or a combination of the following alarms:

- Critical Alarm selection and set point settings with the appropriate user access level.
- Alarm acknowledgements are automatically logged as required by 21 CFR parts 11.

- All alarms and events are reported and displayed in the Alarm Summary report.
- Audible alarm notification
- Local printing of alarms and events.

Easy to Use, Comprehensive Reporting:

The **HVAC BMS** system provides a comprehensive review and reporting system. The system offers two methods for collecting data

- Local data collection – Data collected locally in a secure format and archived centrally in a filing system
- Central data collection – Data collected in a central server

In this way, the **HVAC BMS** provides the facility to create reports for individual rooms. Information gathered can be automatically transferred and accessed from users define OS

- Real-time and historical trends
- Multiple data plots
- Trend analysis
- Standard and custom queries
- Quick report generation with standard templates

Easy to Operate at every Level:

Security Manager: Security Manager offers significant operation cost savings and ease of use by allowing maintenance of user accounts and passwords from one or multiple locations. If a user needs to change their password they can do so on a local instrument or PC and this will be automatically distributed across all systems to which they have access.

- Change in one place, deploy to many
- Support for multiple security zones
- Built-in audit trail for 21 CFR Part 11

Remote Monitoring:

With the use of **HVAC BMS**; remote users, including off-site, can access plant information via a secure web portal.

- Remote real-time data visualization
- Support for multiple windows
- Integrated information from diverse data sources

Validation:

A key requirement for **HVAC BMS** solutions is validation. Where facility conditions (e.g. temperature, humidity, cfm etc) have a direct impact on product purity, safety, quality or efficiency they need to be monitored against predetermined limits and logged. In this case the system used for collecting and logging the data needs to be validated.

8.2 Module's prominent features

- CFM, Pressure, Temperature and RH. Measurements in one.
- Big LCD display for local display of monitored values.
- Provides 100% guarantee of validation data delivery using factory calibrated measurement sensors.
- High and low alarm for upper and lower limit
- Dry contact or solid state alarm output (O*ptional*)
- Alarm output can be used for simple ON/OFF control
- Visual and Audible alarm notification for operator attention
- User programmable display interval
- Real-time clock(O*ptional*)
- Individual or centralized module data printing
- Serial communication
- Hard wired / wireless communication
- Potential free output for hooter

- User configurable High & Low alarms setup
- Real time display through software

8.3 APPENDIX

S.No.	Title	Checked By	Sign/Date
1.	Software user manual		
2.			
3.			
4.			

9. FINAL REPORT

☐ **Accepted** ☐ **Not-Accepted**

Verified By: Date:

(_____) _____

Reviewed By: _____ Date: _____

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10. DESIGN QUALIFICATION REPORT APPROVAL:

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☐ **Accepted** ☐ **Not-Accepted**

Verified By: Date:

(_____) _____

Reviewed By: _____ Date: _____

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11. GLOSSARY & ABBREVIATION:

DP1	Differential Pressure
TEMP	Temperature
RH	Relative Humidity
CC	Change Control
CGMP	Current Good Manufacturing Practice
DQ	Design Qualification
FAT	Factory Acceptance Tests
I/P	Input
IQ	Installation Qualification
MKT	Mean kinetic Temperature
N/A	Not Applicable
N/Av	Not Available
NABL	National Accreditation Board for Testing and Calibration Laboratories
NMT	Not More Than
O/P	Output
OQ	Operational Qualification
P/N	Part Number
PQ	Performance Qualification
Qty	Quantity
REV	Revision
SAT	Site Acceptance Test
SOP	Statement of Purpose
Spec.	Specifications
TS	Technical Specifications
URS	User Requirement Specification
MOC	Material of construction
PP	Polypropylene
DP	Differential Pressure sensor

TS Temperature sensor

SS Stainless Steel

VFD Variable Frequency Drive

UNITS OF MEASURE:

HP Horsepower
ATM Atmospheric
^{o}C Degree Centigrade
L Liter
ppb Parts per billion
µ Micron
µs/cm Micro siemens per centimeter
cfu /ml Colony Forming Units
KL Kilo Liter
NB Nominal Bore
Kg/cm^2 Kilogram per Square centimeter
M3/hr Cubic meter per hour.
Mtrs Meter
kW Kilo watts