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FUNCTIONAL SPECIFICATION AND DESIGN SPECIFICATION FOR HVAC SYSTEM (QUALITY CONTROL LABORATORY)

PROJECT: ESTABLISHMENT OF PHARMANIAGA HALAL VACCINE
MANUFACTURING FACILITY, QUALITY CONTROL LABORATORY,
ADMINISTRATIVE BUILDING AND INSULIN MANUFACTURING FACILITY FOR
MESSRS PHARMANIAGA LIFESCIENCE SDN. BHD. (PUCHONG)

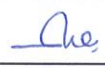
APPROVAL OF PROTOCOL

Signatures below signify that both vendor and client have read, understand, and agree with the content of this document. Approval of protocol must be granted by both parties before its execution.

This document was prepared and approved by the below representatives from Lufter Sdn. Bhd.

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By signing below, Pharmaniaga LifeScience Sdn. Bhd. confirms that all their requirements for this project have been reflected in this document.

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1.0 Reference Documents

No.	Document No.	Document Title
1.	URS-083-R02 (160322)	User Requirement Specification (HVAC System for Quality Control Laboratory)
2.	L-PLS03-VP&IF-DT-01-R2	Design Table (AHU-F3)
3.	L-PLS03-VP&IF-DT-02-R2	Design Table (AHU-F3a)
4.	L-PLS03-VP&IF-DT-03-R2	Design Table (AHU-F5)
5.	L-PLS03-VP&IF-AF-01-R2	Airflow Schematic (AHU-F3)
6.	L-PLS03-VP&IF-AF-02-R2	Airflow Schematic (AHU-F3a)
7.	L-PLS03-VP&IF-AF-03-R2	Airflow Schematic (AHU-F5)

2.0 Version History

Revision No.	Date	Revised By	Reason for Revision
00	16 JUN 2022	Siti Norhana Fatehah	New



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3.0 Introduction

Lufter Sdn. Bhd. is the contractor awarded to install, commission and validate the entire HVAC system for the Pharmaniaga Halal Vaccine Manufacturing Facility, Quality Control Laboratory, Administrative Building and Insulin Manufacturing Facility at Pharmaniaga LifeScience Sdn. Bhd.

4.0 General Design Considerations

The HVAC system is designed and constructed to meet the current ISO clean room guidelines, and Pharmaceutical Inspection Co-operation Scheme (PIC/S) guidelines in accordance to Good Manufacturing Practice (GMP). The HVAC is designed with reference to the HVAC standard for Air-Conditioning and Refrigeration Institute (ARI), American Society of Heating, Refrigerating and Air-Conditioning Engineers (ASHRAE), American Society for Testing and Materials (ASTM), The American Society of Mechanical Engineers (ASME) and Sheet Metal and Air Conditioning Contractors' National Association, Inc. (SMACNA) and Good Engineering Practices (GEP).



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5.0 Abbreviations

No.	Term/Abbreviation	Definition
1.	AHU	Air Handling Unit
2.	CFC	Chlorofluorocarbons
3.	CNC	Clean Non-Classified / Controlled Non-Classified
4.	DQ	Design Qualification
5.	EMS	Environmental Management System
6.	FSDS	Functional Specification Design Specification
7.	GAMP	Good Automated Manufacturing Practice
8.	GI	Galvanized Iron
9.	GMP	Good Manufacturing Practice
10.	HEPA	High-Efficiency Particulate Air
11.	HVAC	Heating, Ventilation & Air-Conditioning
12.	N/A	Not Applicable
13.	N/D	Not Defined
14.	PIC/S	Pharmaceutical Inspectorate Convention Scheme
15.	PLS	Pharmaniaga LifeScience Sdn. Bhd.
16.	Psi	Pounds per Square Inch
17.	SMACNA	Sheet Metal and Air Conditioning Contractors' National Association
18.	TDC	Transverse Duct Connection
19.	URS	User Requirement Specification
20.	OA	Outside Air
21.	CHW	Chilled Water
22.	VSD	Variable Speed Drive
23.	ESP	External Static Pressure
24.	kW	Kilowatt
25.	EH	Electric Heater
26.	DB	Dry Bulb
27.	WB	Wet Bulb
28.	Pa	Pascal

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6.0 Design Criteria

The criteria as per URS (URS-083-R02) and as per existing condition with latest room name given by Pharmaniaga LifeScience Sdn. Bhd. have been taken into consideration during the design stage.

a) Temperature & Relative Humidity

The temperature & humidity parameters for Grade D and CNC cleanroom area as below:

AHU	Room/Area	Room No.	Room Grade	Pressure (Pa) (reference atmosphere)	Relative Humidity (%)	Temperature (°C)	Minimum Air Change Required	Design Air Change (As Per Consultant Approval)
AHU-F3	Microbiology Laboratory	L209	CNC	-	< 80	< 25	≥ 10	11
	Sample Receipt Room	L210	CNC	-	< 80	< 25	≥ 10	38
	Hot, Wash & Decontamination Room	L211	CNC	-	< 80	< 25	≥ 10	31
	Glassware Room	L212	CNC	-	< 80	< 25	≥ 10	16
	Media Preparation Room	L213	CNC	-	< 80	< 25	≥ 10	38
	MLT	L214	CNC	-	< 80	< 25	≥ 10	20
	Incubation	L215	CNC	-	< 80	< 25	≥ 10	22
	Personnel Airlock In/Out	L216	CNC	5	< 80	< 25	≥ 10	17
	Personnel Airlock In/Out	L217	D	20	50-60	18-24	≥ 20	20
	Sterility Room	L218	D	25	50-60	18-24	≥ 20	25

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AHU	Room/Area	Room No.	Room Grade	Pressure (Pa) (reference atmosphere)	Relative Humidity (%)	Temperature (°C)	Minimum Air Change Required
AHU-F5	Quality Control Office	B201	CNC	-	< 80	< 25	≥ 10
	General Chemistry Laboratory	L201	CNC	-	< 80	< 25	≥ 10
	FTIR / Balance Room	L202	CNC	-	≤ 65	< 25	≥ 10
	ICP-OES / AAS Room	L203	CNC	-	< 80	< 22	≥ 10
	Hot & Wash Room	L204	CNC	-	< 80	< 25	≥ 10
	Glassware Room	L205	CNC	-	< 80	< 25	≥ 10
	Biochemistry Laboratory	L206	CNC	-	< 80	< 25	≥ 10
	Chemical / Solvent Room	L207	CNC	-	< 80	< 25	≥ 10
	Quality Control Corridor	L208	CNC	-	< 80	< 25	≥ 10
	Fume Hoods Room	L220	CNC	-	< 80	< 25	≥ 10

Table 1: Temperature & Humidity Parameters



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b) Room Pressurization and Airflow Direction

The room pressurization and airflow direction for the cleanroom area are as below:

Adjacent Room		Air Differential Pressure (Pascal)
From	To	
Sterility Room (L218)	Personnel Airlock In/Out (L217)	≥ 5
Personnel Airlock In/Out (L217)	Personnel Airlock In/Out (L216)	≥ 15
Personnel Airlock In/Out (L216)	Microbiology Laboratory (L209)	≥ 5

Table 2: Pharmaniaga Design Room Differential Pressure

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7.0 Design Considerations for AHU Design

7.1 External Design Conditions

The design of the system is done with reference to the latest version of ASHRAE and the current tropical climate condition as listed below:

Country: Malaysia
 Location: Kuala Lumpur, INTL
 Max Out Door Condition: 34.0°C DB / 27.3°C WB
 (DB = Dry Bulb; WB = Wet Bulb)

7.2 Design for Air Handling Unit

No.	AHU
1.	AHU-F3
2.	AHU-F3a
3.	AHU-F5

The above external design conditions shall be treated as the worst-case scenario. The air conditioning output fluctuates as the external condition changes, and this will subsequently impact on system performance, causing the room condition to run out of the design limit. To prevent this from occurring, cooling coils are installed in selected AHUs to cool the fresh air intake. This cooling capacity can be adjusted by controlling the chilled water flow in the coil.

For area where relative humidity is required to be under control, air moisture will be removed by the cooling coil system in variable rate to achieve the required relative humidity. This can be done by controlling the chilled water flow rate to set the off coil designed condition. The change of internal load in the room will be controlled by the chilled water flow rate in the cooling coil to eventually achieve the design condition as specified in the URS.

AHU-F3, AHU-F3a and AHU-F5 has 2 sections comprised of chilled-water pre-cooling and post-cooling coil.

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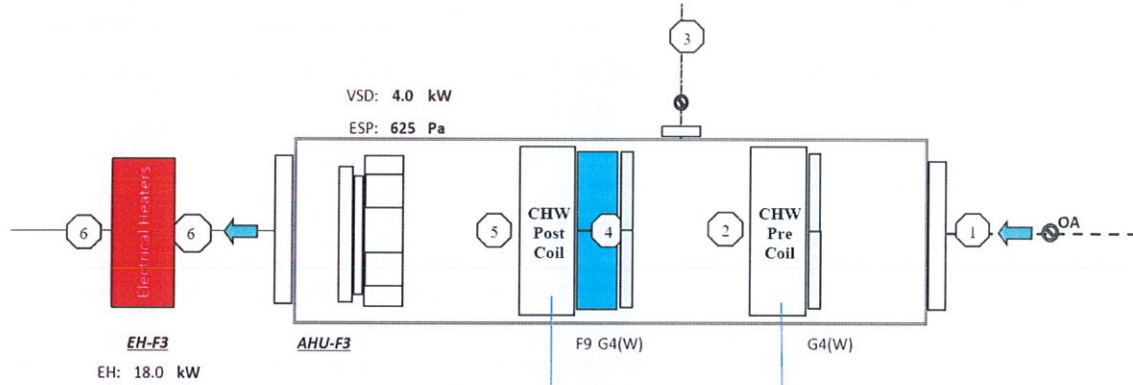


Diagram 1: AHU-F3 P&ID

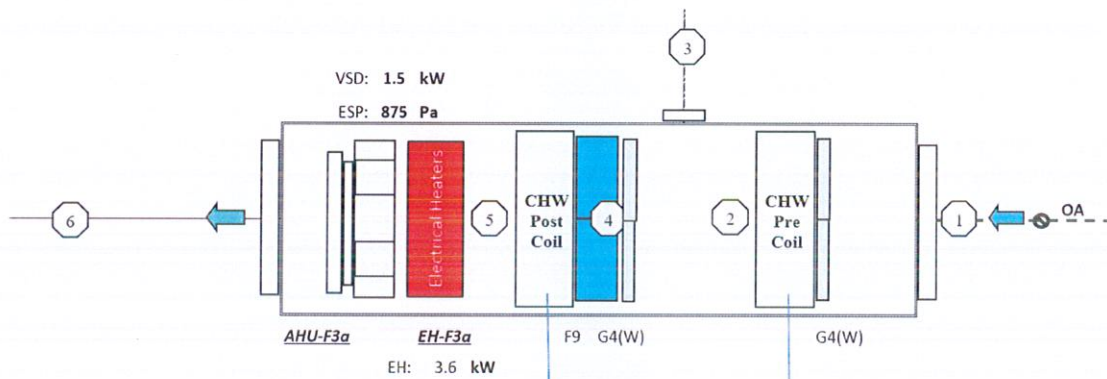


Diagram 2: AHU-F3a P&ID

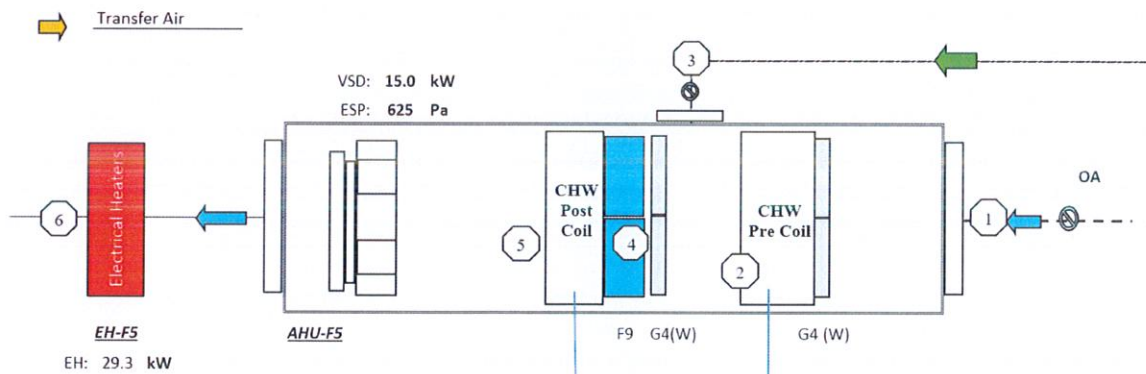


Diagram 3: AHU-F5 P&ID

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7.3 Design for AHU Supply Air Flow

The amount of supply air from AHU is dependent on the room cleanliness grade. Air circulation rate in terms of Air Change per hour is the basic guideline to obtain the desired room grade. A higher air change rate will have higher room recovery as the room is being flushed more frequently. The air change rate increases as the room grade increases (for example Grade CNC to Grade D). Sufficient air circulation and air distribution is part of the consideration. The load for each room has been assessed to give a minimum airflow based upon the fresh air requirement, heat gains, minimum air change rate or extract equipment make-up whichever is the larger.

7.4 Design for Pre-Cool Fresh Air Flow and Room Pressurization

The fresh air requirement is determined by the required room pressure, human fresh air needs and the rate of air being exhausted from the room. Usually, the amount of fresh air required to pressurize the room is much greater than the human fresh air need, hence the latter is negligible. The fresh air heat and moisture load is taken into consideration by the pre-cooled coil system.

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7.5 Design for Process Equipment Heat Gain

Machine motors are some common heat sources in a production facility. This room internal heat load must be taken into consideration in the heat change calculation while designing a HVAC system. The system must be designed in such a way that it is capable of overcoming the room internal heat load when the heat load is at its highest level. It is important that all required machine data such as the heat dissipation rate and frequency of machine usage are provided by the process owner for accurate design calculations.

Machine and room heat dissipation calculation is based on assumptions.

If the frequency of machine usage with the diversity factor based on the estimated machine heat load falls within our HVAC design safety factor, we can then assume the machine heat load dissipation is negligible.

In other cases, the production machine heat load dissipation helps to increase the room sensible heat, thus the sizing of reheat HVAC system can be reduced.

7.6 Design to Achieve Room Cleanliness

No.	AHU
1.	AHU-F3
2.	AHU-F3a
3.	AHU-F5

The desired room cleanliness can be achieved by adjusting the air change per hour and the selected filtration stage.

The filtration stages for new HVAC system supplied by AHU-F3, AHU-F3a and AHU-F5 are G4 (washable) for fresh air intake (pre-coil) while G4 (washable) and F9 for room return and fresh air mixing point (post coil).

For all AHU-F3a, terminal HEPA filters H14 with efficiency of removing at least 99.995% of airborne particles 0.3 micrometers (μm) in diameter are installed at all Grade D cleanrooms. The design air change is stated in Section 6(a).

To achieve the required grade, the design approach needs to take into consideration the overall attributes of sufficient air circulation with appropriate filtration system, the air flow pattern, the absolute room pressure, the correct pressure gradient to the adjacent room, the architecture room layout, material selection and minimum air leakage from the room.

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Pharmaceutical cleanroom cleanliness for sterile manufacturing is classified according to the Pharmaceutical Inspection Co-operation Scheme (PIC/S) PE 009-14 as listed below:

Grade	Maximum permitted number of particles/m ³ equal to or greater than the tabulated size			
	At Rest		In Operation	
	0.5 µm	5 µm	0.5 µm	5 µm
A	3,520	20	3,520	20
B	3,520	29	352,000	2,900
C	352,000	2,900	3,520,000	29,000
D	3,520,000	29,000	Not Defined	Not Defined

Table 3: PIC/S permitted number of airborne particles of graded cleanrooms

Grade	Recommended limits for microbial contamination ^(a)			
	Air Sample (cfu/m ³)	Settle plates (diam. 90 mm), cfu/4hours ^(b)	Contact plates (diam. 55 mm), cfu/plate	Glove print 5 fingers cfu/glove
A	<1	<1	<1	<1
B	10	5	5	5
C	100	50	25	-
D	200	100	50	-

Table 4: PIC/S permitted limits for microbiological monitoring of graded cleanrooms

Notes: (a) These are average values

(b) Individual settle plates may be exposed for less than 4 hours

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7.7 Air Circulation Rate

Air circulation rate in terms of Air Change per hour is a basic guideline to achieve the desired room cleanliness. A higher air change rate will result in a higher room recovery as the room is being flushed more frequently. The required air change rate increases as the room grade increases (E.g.: Grade CNC to Grade D). The design of air change rate shall be in accordance to the "rule of thumb" of ventilation rate as stated in the ISPE Good Practice Guide for Heating, Ventilation and Air Conditioning.

Grade	Air Change Rate per Hour (Refer to URS: URS-083-R02)
D	≥ 20
CNC	≥ 10

Air change rate of an area correlates with the airflow volume supplied to the area. To determine the airflow volume required, there is a need to consider the heat gains within the space, the particulate gain within the space under worst case conditions to maintain room-classification and the required recovery time of 15 to 20 minutes (based on Volume 4 EU GMP - Annex 1 Manufacture of Sterile Medicinal Products [November 2008]). Thus, the air change rate of a similar graded area may be different to accommodate for the heat and/or particulate gains of the room. For example, rooms with machinery, greater activity or personnel movement and/or count will need to account for higher heat and particulate gains when designing the air change rate.

The table below shows the air change rate of the respective rooms as per consultant approval:

AHU	Room Description	Room No.	Room Grade	Minimum Air Change Required	Air Change Per Hour (As Per Consultant Approval)
AHU-F3	Microbiology Laboratory	L209	CNC	≥ 10	11
	Sample Receipt Room	L210	CNC	≥ 10	38
	Hot, Wash & Decontamination Room	L211	CNC	≥ 10	31
	Glassware Room	L212	CNC	≥ 10	16
	Media Preparation Room	L213	CNC	≥ 10	38
	Microbial Limit Testing Room	L214	CNC	≥ 10	20
	Incubation Room	L215	CNC	≥ 10	22
AHU-F3a	Personnel Airlock In/Out	L216	CNC	≥ 10	17
	Personnel Airlock In/Out	L217	D	≥ 20	20
	Sterility Room	L218	D	≥ 20	25



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AHU	Room Description	Room No.	Room Grade	Minimum Air Change Required	Air Change Per Hour (As Per Consultant Approval)
AHU-F5	Quality Control Office	B201	CNC	≥ 10	10
	General Chemistry Laboratory	L201	CNC	≥ 10	13
	FTIR / Balance Room	L202	CNC	≥ 10	22
	ICP-OES /AAS Room	L203	CNC	≥ 10	51
	Hot & Wash Room	L204	CNC	≥ 10	15
	Glassware Room	L205	CNC	≥ 10	14
	Biochemistry Laboratory	L206	CNC	≥ 10	21
	Chemical / Solvent Room	L207	CNC	≥ 10	10
	Quality Control Corridor	L208	CNC	≥ 10	13
	Fume Hoods Room	L220	CNC	≥ 10	20

Table 5: HVAC Air Circulation Rate

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7.8 Room Air Distribution

Room air distribution is the design to obtain the best air circulation in any parts of the room. To do so, the circulation needs to be sufficient. Supply air outlet and the return air or exhaust air grilles shall be placed at the strategic place so that air can be distributed evenly to the room.

Type of Return or Exhaust Air Grilles for each room:

Room Description	Room No.	Room Grade	Ceiling Return / Exhaust	Low Level Return / Exhaust
Microbiology Laboratory	L209	CNC	✓	✗
Sample Receipt Room	L210	CNC	✓	✗
Hot, Wash & Decontamination Room	L211	CNC	✓	✗
Glassware Room	L212	CNC	✓	✗
Media Preparation Room	L213	CNC	✓	✗
Microbial Limit Testing Room	L214	CNC	✓	✗
Incubation Room	L215	CNC	✓	✗
Personnel Airlock In/Out	L216	CNC	✓	✗
Personnel Airlock In/Out	L217	D	✗	✓
Sterility Room	L218	D	✗	✓
Quality Control Office	L219	CNC	✓	✗
General Chemistry Laboratory	L201	CNC	✓	✗
FTIR / Balance Room	L202	CNC	✓	✗
ICP-OES / AAS Room	L203	CNC	✓	✗
Hot & Wash Room	L204	CNC	✓	✗
Glassware Room	L205	CNC	✓	✗
Biochemistry Laboratory	L206	CNC	✓	✗
Chemical / Solvent Room	L207	CNC	✓	✗
Quality Control Corridor	L208	CNC	✓	✗
Fume Hoods Room	L220	CNC	✓	✗

Table 6: Type of Return Air

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7.9 Design Consideration for Air Filtration System

Several filtration systems are implemented for the new HVAC system as required. Kindly refer to the Attachment 7 – 9 for further information.

Equipment	Type of Filter	Location
AHU-F3	Pre-Filter (G4-Washable)	AHU pre-cooling section
	Secondary Filter (G4-Washable & F9)	AHU post-cooling section
AHU-F3a	Pre-Filter (G4-Washable)	AHU pre-cooling section
	Secondary Filter (G4-Washable & F9)	AHU post-cooling section
	HEPA Filter (H14)	Grade D rooms
AHU-F5	Pre-Filter (G4-Washable)	AHU pre-cooling section
	Secondary Filter (G4-Washable & F9)	AHU post-cooling section

Table 7: Air Filtration System

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7.10 Control System Description

There are several factors taken into consideration with regards to the design of the control system for the AHUs:

Temperature Control

Room temperature is controlled by step electrical heater and modulating the amount of chilled water to the post cooling coil according to the Room Temperature and Dew point temperature of off coil value. Changes in internal load will signal to the Temperature sensor which will subsequently command the electric heater to meet the desired °C.

Relative Humidity Control

Room relative humidity is controlled by modulating the amount of chilled water to the pre-cooling according to the set pre-cool off coil Dew point temperature value. Changes in dew point temperature value will signal the relative dew point temperature sensor which will subsequently command the motorized valve to meet the desired dew point value.

Airflow Volume Control

Air flow control is separated into two methods. First is to control by using Variable Speed Drive (Manual Input) to balance the main air flow. After balancing the main air flow, room air flow will be manually balanced by using volume control dampers. Kindly refer to Attachment 19 for more information on the Variable Speed Drive.

Refer to the Attachment 1 – 6 for design table and air flow schematic diagram.

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8.0 Duct Work

8.1 Ducting Construction, Testing and Air Diffusers

The ducting construction shall be as follow:

Ducts, plenums and fittings should be constructed of Galvanized Iron (GI) material with medium pressure design with TDC flange joint or flexible duct. Building cavities may not be used as a duct or plenum without a sealed duct board or metal liner. Other materials are authorized if specific uses (e.g., chemical resistance) are required. The inside surface of the ducts must be smooth, except if the specific equipment is required (noise attenuator, damper, etc.).

The design of ducts with circular section is optional. The duct system must be airtight (low leakage). The rectangular sections must be reinforced with folds or reinforcement to resist deformations and vibration. The duct system including elbows, change of section and other equipment must be selected and designed to minimize the static pressure losses and the level of noise. The assembly of the rectangular ducts must be executed with riveted sleeves and retractable adhesive strips. All gap opening must be sealed internally with approved duct sealant, no adhesive tape is used. The connecting of the movable parts (filters) can be executed with semi flexible metallic ducts. Their length must be as short as possible.

Before duct is insulated, the installing contractor should perform leak test on each duct system at 125% of the operating pressure for holding time 15 minutes of test sequence. Kindly refer to the Attachment 10 for DW/143 Guideline.

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9.0 HVAC Equipment

9.1 Air Handling Unit

The AHU shall be constructed with extruded aluminum profile to form a structural frame to house all internal components. Casing shall be of panel construction, double wall type packed with insulation between the walls. External and internal sheet shall be minimum 0.6mm and 0.6mm galvanized steel sheet respectively. The construction of infill panels shall not be less than 60mm and shall be selected to match both the specified sound reduction index of the casing and to prevent condensation on the exterior surfaces under the extremes of operation and ambient conditions. The infill insulation shall be of CFC-free, vermin and rot-proof, non-flammable, sound-absorbing and thermal insulating type. Framework shall be thermal-break and properly insulated to prevent formation of condensation on the exterior and intermediate surfaces of the unit casing under the extremes of operation and ambient conditions. All fixing screws/ bolts shall not result in thermal bridge of casing external/ internal surface. The density shall not be less than 40kg/m³. Thermal conductivity shall not exceed 0.02W/m°C. The insulation shall be adequately supported to prevent collapse and to eliminate the formation of cavities. The frame and the base of the unit must be made by aluminum alloy. The interior design of the panel must have round edge corner for the cleaning purposes which follow the Hygienic Standard, VDI 6022. All unit panels, including the floor panels, shall be double skin and fabricated at factory. The overall casing criteria shall comply in accordance with EN1886 and EUROVENT standard. Kindly refer to Attachment 11 – 13 for more information on the Air Handling Unit.

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9.2 Cooling Coil

Cooling coils are manufactured from copper tubes with aluminium fins bonded to the tubes through mechanical expansion and housed in aluminium / galvanized / stainless steel frame; headers come with threaded male pipe connections and include drain and vent. Coil shall be tested to 375 Psi. Condensate pans will be of the dry pan design to ensure complete condensate removal and made of galvanized steel powder coated insulated with 30mm polyurethane, slope to remove the condensate. AHU coils should be of sufficient size to guarantee sufficient cooling capacity for the HVAC system. As for reference, the cooling coil may have no more than 14 fins per inch and 5-8 rows in single coil. Kindly refer to Attachment 14 for more information.

9.3 Damper

Dampers are designed with profiled damper blades operating in opposite directions with an additional seal mounted on external, reinforced, polyamide, cogged wheels with slide bearings. All dampers to be used TROX minimum leakage dampers type only. Kindly refer to Attachment 15 for more information.

9.4 Fan

Fans are of direct driven type and mounted on anti-vibration supports. The motor with IP55 rating must be calculated with a sufficient over capacity and must be connected through a safety switch placed on AHU. Kindly refer to Attachment 16 – 18 for more information.

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10.0 List of Attachments

List of attachments should include all the supporting evidence and discrepancy reports.

No.	Attachment Title/Description	Number of Pages
01	Design Table (AHU-F3) (L-PLS03-VP&IF-DT-01-R2)	1
02	Design Table (AHU-F3a) (L-PLS03-VP&IF-DT-02-R2)	1
03	Design Table (AHU-F5) (L-PLS03-VP&IF-DT-03-R2)	1
04	Airflow Schematic (AHU-F3) (L-PLS03-VP&IF-AF-01-R2)	1
05	Airflow Schematic (AHU-F3a) (L-PLS03-VP&IF-AF-02-R2)	1
06	Airflow Schematic (AHU-F5) (L-PLS03-VP&IF-AF-03-R2)	1
07	AAF Primary Pleated Washable Filter (G4) Catalogue	2
08	AAF Secondary Filter (F9) Catalogue	2
09	Terminal HEPA Filter (H14) Catalogue (L-PLS03-VP&IF-SD-HVAC-SIT-06)	4
10	HVCA Practical Guide to Duct Leak Testing DW143	18
11	AHU-F3 Data Sheet (L-PLS03-VP&IF-HVAC-SIT-17-R01)	15
12	AHU-F3a Data Sheet (L-PLS03-VP&IF-HVAC-SIT-18-R01)	16
13	AHU-F5 Data Sheet (L-PLS03-VP&IF-HVAC-SIT-19-R01)	15
14	Cooling Coil Certification	1
15	Volume Control Damper Catalogue (L-PLS03-VP&IF-HVAC-SIT-06)	15
16	AHU-F3 Fan Details	1
17	AHU-F3a Fan Details	1
18	AHU-F5 Fan Details	1
19	Mitsubishi Inverter Catalogue (L-PLS03-VP&IF-HVAC-SIT-20)	18
	N/A	
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