

Operational Qualification	Doc. No.	L-PLS03-VP&IF-VD-OQ-HVAC-01	Effective Date	28 OCT 2022
	Rev. No.	00	Total Page(s)	1 of 37



OPERATIONAL QUALIFICATION OF HVAC SYSTEM FOR QUALITY CONTROL LABORATORY (AT-REST CONDITION)

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.

Name	Job Title or Role	Signature	Date (dd-mmm-yyyy)
Authored by: Siti Norhana Fatehah	Validation cum QA Executive		26-Oct-2022
Reviewed by: Ahmad Aslam Ahmad	Design & Quality Assistant Manager		26-Oct-2022
Reviewed by: Mohd Suhaimi Ishak	Senior Project Manager		26-Oct-2022

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

Name	Job Title or Role	Signature	Date (dd-mmm-yyyy)
Reviewed by: Mohd Fadhi Bin Jaafar	Head of Technical Service		26-Oct-2022
Reviewed by: Noor Zurahan Mohamad Noor	Head of Project		26-Oct-2022
Reviewed by: Nurul Saadiah	Head of Engineering		26-Oct-2022
Reviewed by: Zuraidah Abd Wahab	Head of Quality Control		28-Oct-2022
Approved by: Abkaniah Azhar	Head of Quality Assurance		28-Oct-2022



• Passion With Perfection • Engineers With Dreams •

Operational Qualification	Doc. No.	L-PLS03-VP&IF-VD-OQ-HVAC-01	Effective Date	28 OCT 2022
	Rev. No.	00	Total Page(s)	2 of 37

Table of Contents

1.0	Reference Documents	3
2.0	Version History	3
3.0	Introduction and Scope	3
4.0	Purpose	3
5.0	Roles & Responsibility	4
6.0	System Description	5
6.1	Heating, Ventilation & Air Conditioning System (HVAC)	5
6.2	Cleanrooms Operating Conditions	6
7.0	System Boundaries	7
8.0	Test Sheets	7
9.0	Testing Rationale	8
10.0	Acceptance Criteria Summary	31
11.0	Test Instrument Record	33
12.0	Signature Record	33
13.0	Post-Execution Approval	34
14.0	Deviation List	35
15.0	List of Attachments	37

28 OCT 2022

Operational Qualification	Doc. No.	L-PLS03-VP&IF-VD-OQ-HVAC-01	Effective Date	
	Rev. No.	00	Total Page(s)	3 of 37

1.0 Reference Documents

No.	Document No.	Document Title
1.	URS-083-R02	User Requirement Specification (HVAC System for Quality Control Laboratories)
2.	L-PLS03-VP&IF-VD-FSDS-HVAC-01	Functional Specification and Design Specification for HVAC System (Quality Control Laboratory)
3.	L-PLS03-VP&IF-VD-DQ-HVAC-01	Design Qualification for HVAC System (Quality Control Laboratory)
4.	L-PLS03-VP&IF-VD-IQ-HVAC-01	Installation Qualification for HVAC System (Quality Control Laboratory)

2.0 Version History

Revision No.	Date	Revised By	Reason for Revision
00	28 OCT 2022	Siti Norhana Fatehah	New

3.0 Introduction and Scope

This document qualifies the new HVAC system installation for the Pharmaniaga Halal Vaccine Manufacturing Facility, Quality Control Laboratory, Administrative Building and Insulin Manufacturing Facility at Pharmaniaga LifeScience Sdn. Bhd. Cleanrooms is to be in compliance with the principle of Good Manufacturing Practices (cGMP) of the Pharmaceutical Inspection Co-operation Scheme (PIC/S), ISO clean room guidelines, and World Health Organization (WHO) guidelines on 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). The system has been assessed and categorized as "Direct Impact".

4.0 Purpose

This document is created to verify the ability of all the critical components in the HVAC system to operate as per the measures in the approved design and specifications.

Operational Qualification	Doc. No.	L-PLS03-VP&IF-VD-OQ-HVAC-01	Effective Date	28 OCT 2022
	Rev. No.	00	Total Page(s)	4 of 37

5.0 Roles & Responsibility

The following personnel have been designated to prepare, execute, review and approve the protocol.

Company	Job Title	Responsibility
Pharmaniaga LifeScience Sdn. Bhd.	Client Representative	To provide approval to the submitted protocol/ report.
		To ensure all relevant technical specifications in vendor's documents are correct.
		To review the validation protocol/ report.
Lufte Sdn. Bhd.	Project Manager Project Engineer Validation Executive	To evaluate vendor's design against the URS.
		To execute the approved validation protocol.
		To prepare and ensure the validation protocol is reviewed and approved before execution.
TecnicAire Services Sdn. Bhd.	3 rd Party NEBB Tester	To conduct cleanroom performance testing in accordance to NEBB standards.
		To provide cleanroom performance testing report and certification.

Operational Qualification	Doc. No.	L-PLS03-VP&IF-VD-OQ-HVAC-01	Effective Date	28 OCT 2022
	Rev. No.	00	Total Page(s)	5 of 37

6.0 System Description

6.1 Heating, Ventilation & Air Conditioning System (HVAC)

The HVAC System designed to serve the Grade D area consists of one (1) unit of AHU which is AHU-F3a.

AHU-F3a consists of two separate sections. The first section draws in fresh air and forces it through the primary (grade G4-washable) filter for the first stage of filtration. The fresh air is then conditioned in the chilled-water pre-cooling coil to reduce its temperature and moisture content. In the second section of the AHU unit, the conditioned air is allowed to mix with the return air before passing through a set secondary (grade G4-washable and F9) filter. Following the second stage of filtration, the mixed air will then be further cooled down at the chilled-water post-cooling coil section. After that, the post-cooled air will flow through an electrical heater to be heated to the required before exiting the AHU unit.

The supply air enters the grade D cleanrooms via a network of ducting/branch ducts and flexible duct then further filtrated by HEPA (grade H14) (efficiency of >99.995%) filters at the HEPA Filter Terminal before being released into the rooms.

Air exiting from Sterility Room (L218) served by these AHUs will return to the AHU to be recirculated except for the Personnel Airlock In/ Out (L217) where the air will be exhausted out via room exhaust. AHUs supply recirculated air to the rooms as listed in Table 1.

For AHU, air control devices like aluminum blade volume control dampers are strategically installed along the main duct and branch duct to throttle the supply, return air as well as the exhaust air. Manual dampers are installed at each of the supply air diffusers and return air grilles for fine adjustment.



• Passion With Perfection • Engineers With Dreams •

Operational Qualification	Doc. No.	L-PLS03-VP&F-VD-OQ-HVAC-01	Effective Date	28 OCT 2022
	Rev. No.	00	Total Page(s)	
			6 of 37	

6.2 Cleanrooms Operating Conditions

Table 1 below shows the cleanroom parameters designed to meet the design parameters required for Grade D areas as stated in the URS document (URS-083-R02; under section 4.3) and as per existing condition with latest room name given by Pharmaniaga LifeScience Sdn. Bhd.

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-F3a	Personnel Airlock In/Out	L217	D	20	50-60	18-24	≥ 20	20
	Sterility	L218	D	25	50-60	18-24	≥ 20	25

Table 1: Cleanroom parameter

Operational Qualification	Doc. No.	L-PLS03-VP&IF-VD-OQ-HVAC-01	Effective Date	28 OCT 2022
	Rev. No.	00	Total Page(s)	7 of 37

7.0 System Boundaries

The airflow schematic diagram (L-PLS03-VP&IF-AF-02-R02) illustrates the components which comprise the HVAC System and the airflow direction.

The operational qualification covers at the minimum the following equipment/components:

- Air Parameter for AHU
- Terminal HEPA Filters

The test carried out for the rooms in this Operational Qualification will be classified as either "as-built", "at-rest" or "in-operation" as define below:

- As-built – Condition where the cleanroom is complete with all services connected and functioning but with no equipment, furniture, materials or personnel present.
- At-rest – Condition where the cleanroom is complete with equipment installed and operating in a manner agreed upon, but with no personnel present.
- In-operation – Condition where the cleanroom is complete with equipment installed and operating in a manner agreed upon with the presence of personnel.

8.0 Test Sheets

This section details the checks to be carried out in support of the system.

A/C Ref.	Test Sheet Title	Test No.
1	Documentation – Document Review	OQ-01
2	Performance Verification – Air Change Rates (Room)	OQ-02
3	Performance Verification – Differential Pressure (Room)	OQ-03
4	Performance Verification – Temperature Monitoring (Room)	OQ-04
5	Performance Verification – Relative Humidity Monitoring (Room)	OQ-05
6	Performance Verification – Particle Count Verification – Non-Viable (Room)	OQ-06
7	Performance Verification – Total Microbial Count (Room)	OQ-07
8	Performance Verification – Airflow Visualization Test (Room)	OQ-08
9	Performance Verification – Recovery Test (Room)	OQ-09
10	Support – Procedure Verification	OQ-10
11	Support – Change Control Record	OQ-11

Operational Qualification	Doc. No.	L-PLS03-VP&IF-VD-OQ-HVAC-01	Effective Date	28 OCT 2022
	Rev. No.	00	Total Page(s)	8 of 37

9.0 Testing Rationale

Ref.	Acceptance Criteria	Rationale
1	The previous stages of commissioning & qualification have been completed; any unresolved snags/deviations must be documented and have no impact on the tests in this protocol.	To provide documented evidence that all necessary commissioning/qualification required prior to the operation of this system have been completed.
2	Air Change Rate (ACR) in all rooms are within the acceptable range specified in the design specification	To provide documented evidence that the Air Change Rate (ACR) in all rooms meets the design requirements.
3	Differential pressure in all rooms is within the acceptable range specified in the design specification.	To provide documented evidence that the differential pressure in all rooms meets the design requirements.
4	Temperature in all rooms is within the acceptable range specified in the design specification.	To provide documented evidence that the room temperature in all rooms meets the design requirements.
5	Relative humidity (RH) in all rooms is within the acceptable range specified in the design specification.	To provide documented evidence that the relative humidity in all rooms meets the design requirements.
6	Air particle count in all rooms is within the acceptable range specified in the design specification.	To provide documented evidence that the air particle count in all rooms meets the design requirements.
7	Total microbial count in all rooms is within the acceptable range specified in the design specification.	To provide documented evidence that the total microbial count in all rooms meets the design requirements.
8	Airflow direction for all rooms is according to the design specification.	To provide documented evidence that the airflow direction for the room meets the design requirements.
9	Recovery rate (time taken) for all rooms to reach specified steady state cleanliness level after contamination or system shut down is within acceptable range specified in the design specification.	To provide documented evidence that the recovery rate to reach specified steady state cleanliness levels of all rooms after contamination or system shut down meets the design requirements.
10	Operation, maintenance and cleaning documentations have been completed and available.	To provide documented evidence that all documentations required for operation, maintenance and cleaning are complete and available.
11	Records are available for all changes made to the system throughout the execution of this checking procedure.	To provide documented records of all changes made to the system upon installation.



28 OCT 2022
9 of 37

Test No: OQ-01



• Passion With Perfection • Engineers With Dreams •

Operational Qualification		Doc. No. Rev. No.	L-PLS03-VP&IF-VD-OQ-HVAC-01 00	Effective Date Total Page(s)	28 OCT 2022 10 of 37
---------------------------	--	----------------------	-----------------------------------	---------------------------------	-------------------------

Title:	Documentation – Protocol Review	Test No: OQ-01
--------	---------------------------------	----------------

Comments/Deviations/Supporting Documentation:

N / A

Overall Test Outcome (PASS/FAIL)	Verified By (Signature):	Date:
PASS	 	31 - Oct - 2022 31 - Oct - 2022



• Passion With Perfection • Engineers With Dreams •

Operational Qualification		Doc. No. Rev. No.	L-PLS03-VP&F-VD-OQ-HVAC-01 00	Effective Date Total Page(s)	28 OCT 2022 11 of 37
---------------------------	--	----------------------	----------------------------------	---------------------------------	-------------------------

Title:	Performance Verification – Air Change Rates (Room)	Test No: OQ-02
---------------	---	-----------------------

Objective:

To provide documented evidence that the Air Change Rate (ACR) in all rooms meets the design specification.

Pre-requisites:

System commissioning and balancing has been completed.

Method:

1. Confirm HVAC system is fully commissioned. Measure the dimensions of the room and calculate the volume.
2. Using a calibrated barometer or alternative flow instrument measure all terminal supply volumes. Summate all terminal volumes to give the total supplied airflow into the room.
3. Divide the total supplied air by the room free volume to give the hourly volumetric air change rate.

Note:

1. In some cases machinery volumetric presence may be subtracted from the total room volume to give an actual room free volume.
2. Room volume $m^3 = L \times W \times H$
3. For areas with negative pressures, air change rates should be calculated from room extract fan.
4. Hourly room air change rates $(Ac/h) = m^3/h$ (supply air)/ m^3 (room volume)

Acceptance Criteria:

Air Change Rate (ACR) in all rooms is within the acceptable range specified in the design specification.

Results:

AHU	Room Name	Expected Results	Actual Result		Initial & Date
		Design Air Change Rate (/hr)	Measured Room Volume (ft ³)	Total Measured Area Supply (cfm) Calculated Air Change Rate (/hr)	
AHU-F3a	Personnel Airlock In/ Out (L217)	≥20	458	223	than 31-Oct-2022
	Sterility Room (L218)	≥20	1,957	843	than 31-Oct-2022

Operational Qualification		Doc. No. Rev. No.	L-PLS03-VP&IF-VD-OQ-HVAC-01 00	Effective Date Total Page(s)	28 OCT 2022 12 of 37
Title: Performance Verification – Air Change Rates (Room) Test No: OQ-02					
Comments/Deviations/Supporting Documentation: Refer to Attachment 1 : Raw Data Refer to Attachment 2 : Specifications & Summary of Test Results					
Overall Test Outcome (PASS/FAIL)		Verified By (Signature):		Date:	
PASS		 		31- Oct - 2022 31- Oct - 2022	



• Passion With Perfection • Engineers With Dreams •

Operational Qualification		Doc. No.	L-PLS03-VP&F-VD-OQ-HVAC-01	Effective Date	28 OCT 2022
		Rev. No.	00	Total Page(s)	13 of 37

Title:		Performance Verification – Differential Pressure (Room)		Test No: OQ-03	
Objective/Purpose:					
To provide documented evidence that the differential pressure in all rooms meets the design requirements.					
Pre-requisites:					
System commissioning and balancing has been completed.					
Method:					
1. Using calibrated micro manometer (record details) zero the instrumentation and connect the rubber tube to the micro manometer positive connection.					
2. Lay the tube into the higher-pressure room under the door separating the areas, ensuring that any induced air leakage is minimized and that the tube end and instrument are respectively as far from the door as possible i.e., minimum of 2 meters.					
3. Allow reading to stabilize and record actual pressure.					
Acceptance Criteria:					
Differential pressure in all rooms is within the acceptable range specified in the design specification.					
Results:					
Room Ref.	Airflow Directions	Expected Results		Actual Results	
		Adjacent Room Ref.	Design Differential Pressure (Pa)	Actual Differential Pressure (Pa)	Initial & Date
Sterility Room (L218)	→	Personnel Airlock In/ Out (L217)	≥ 5	6.8	HA 31-Oct-2022
Personnel Airlock In/ Out (L217)	→	Personnel Airlock In/ Out (L216)	≥ 15	25.9	HA 31-Oct-2022

Operational Qualification		Doc. No. Rev. No.	L-PLS03-VP&F-VD-QQ-HVAC-01 00	Effective Date Total Page(s)	28 OCT 2022 14 of 37
Title:		Performance Verification – Differential Pressure (Room)			Test No: OQ-03
Comments/Deviations/Supporting Documentation					
Refer to Attachment 1 : Raw Data					
Refer to Attachment 2 : Specifications & Summary of Test Results					
Overall Test Outcome (PASS/FAIL)		Verified By (Signature):		Date:	
PASS		Han 		31 - Oct - 2022 31 - Oct - 2022	



• Passion With Perfection • Engineers With Dreams •

Operational Qualification		Doc. No.	L-PLS03-VP&IF-VD-OQ-HVAC-01	Effective Date	28 OCT 2022
		Rev. No.	00	Total Page(s)	15 of 37

Title:	Performance Verification - Temperature Monitoring (Room)	Test No: OQ-04
---------------	---	-----------------------

Objective/Purpose:
To provide documented evidence that the room temperature in all rooms meets the design requirements.

Pre-requisites:
All monitoring equipment such as sensors and other devices have been fully calibrated.

Method:
1. Check that the HVAC system has been fully commissioned and operated continuously for at least 24 hours prior to the commencement of the test.
2. Using fully calibrated test equipment (record details), place a temperature sensor on a suitable surface. Indicate the location of the temperature sensor logger on a diagram of the area under test and record the condition of the room (as-built, at-rest or in-operation). Record the date and time of test.

Acceptance Criteria:
1. Temperature in all rooms is within the acceptable range specified in the design specification.
2. Other details such as the test location, room condition, date and time when the test was conducted must be recorded.

Results:

AHU	Room Ref.	Expected Result	Actual Result		Initial & Date
		Design Temperature (°C)	Test Location Recorded	Room Condition	
AHU-F3a	Personnel Airlock In/ Out (L217)	18-24	Refer to Attachment I	At-rest	At-rest 31-Oct-2022
	Sterility Room (L218)	18-24	Refer to Attachment I	At-rest	At-rest 31-Oct-2022



• Passion With Perfection • Engineers With Dreams •

Operational Qualification		Doc. No. Rev. No.	L-PLS03-VP&IF-VD-OQ-HVAC-01 00	Effective Date Total Page(s)	28 OCT 2022 16 of 37
---------------------------	--	----------------------	-----------------------------------	---------------------------------	-------------------------

Title:	Performance Verification - Temperature Monitoring (Room)	Test No: OQ-04
--------	--	----------------

Comments/Deviations/Supporting Documentation:

Refer to Attachment 1 : Raw Data

Refer to Attachment 2 : Specifications & Summary of Test Results

Overall Test Outcome (PASS/FAIL)	Verified By (Signature):	Date:
PASS	HCH JHCH	31 - Oct - 2022 31 - Oct - 2022



• Passion With Perfection • Engineers With Dreams •

Operational Qualification		Doc. No.	L-PLS03-VP&IF-VD-OQ-HVAC-01	Effective Date	28 OCT 2022
		Rev. No.	00	Total Page(s)	17 of 37

Title:	Performance Verification - Relative Humidity Monitoring (Room)	Test No: OQ-05
---------------	---	-----------------------

Objective/Purpose:
To provide documented evidence that the relative humidity in all rooms meets the design requirements.

Pre-requisites:

1. System commissioning and balancing has been completed.
2. All monitoring equipment such as sensors and other devices have been fully calibrated.

Method:

1. Check that the HVAC system has been balanced and operated continuously for at least 24 hours prior to the commencement of the test.
2. Using fully calibrated test equipment (record details), place humidity sensor on a suitable surface. Indicate the location of the humidity sensor on a diagram of the area under test and record the condition of the room (as built, at-rest or in-operation). Record the date and time of test.

Acceptance Criteria:

1. Relative humidity (RH) in all rooms is within the acceptable range specified in the design specification.
2. Other details such as the test location, room condition, date and time when the test was conducted must be recorded.

AHU	Room Ref.	Expected Result	Actual Result		Initial & Date
		Design Relative Humidity (%)	Test Location Recorded	Room Condition	
AHU-F3a	Personnel Airlock In/ Out (L217)	50-60	Refer to Attachment I	At-rest	Hea 31-Oct-2022
	Sterility Room (L218)	50-60	Refer to Attachment I	At-rest	Hea 31-Oct-2022



• Passion With Perfection • Engineers With Dreams •

Operational Qualification		Doc. No. Rev. No.	L-PLS03-VP&IF-VD-OQ-HVAC-01 00	Effective Date Total Page(s)	28 OCT 2022 18 of 37
---------------------------	--	----------------------	-----------------------------------	---------------------------------	-------------------------

Title:	Performance Verification - Relative Humidity Monitoring (Room)				Test No: OQ-05
--------	--	--	--	--	----------------

Comments/Deviations/Supporting Documentation:

Refer to Attachment 1 : Raw Data

Refer to Attachment 2 : Specifications & Summary of Test Results

Overall Test Outcome (PASS/FAIL)	Verified By (Signature):	Date:
PASS	 	31 - Oct - 2022 31 - Oct - 2022



• Passion With Perfection • Engineers With Dreams •

Operational Qualification	Doc. No.	L-PLS03-VP&IF-VD-OQ-HVAC-01	Effective Date	28 OCT 2022
	Rev. No.	00	Total Page(s)	

19 of 37

Performance Verification – Particle Count Verification – Non-Viable (Room)				Test No: OQ-06
--	--	--	--	----------------

Objective:

To provide documented evidence that the air particle count in all rooms meets the design requirements.

Pre-requisites:

System commissioning and balancing has been completed.

Method:

1. Check that HVAC is fully commissioned and any additional air moving devices in the area have also been fully commissioned and set to operate normally.
2. Calculate the number of sampling points per room using the test method in section ISO 14644-1:2015 (E). Divide the floor equally into the number of zones indicated and locate the particle counter in the center of each zone.
3. With the particle counter at a height of 1 m and the sampling probe pointing in the direction of airflow, set the counter to the manufacturer's specifications to count 0.5 µm and 5.0 µm particles. Sample time was set to 1 minute for Grade D per sample with counters' sample rate at 28.3 lpm. At center of each grid take at least 1 sample, at a height of 1 meter above the floor for cleanroom. When the count was greater than 75% of the allowable count limit, 3 samples was taken at that sample location.
4. The average was computed from the collected data.

Acceptance Criteria:

Air particle count in all rooms is within the acceptable range specified in the design specification.

Results:

Room Ref.	Design Classification	Room Condition	Mean Particle Count/m ³ (Particle size ≥0.5 µm)		Mean Particle Count/m ³ (Particle size ≥5 µm)		Initial & Date
			Expected	Actual	Expected	Actual	
Personnel Airlock In/ Out (L217)	Grade D	At-rest	≤3,520,000	8,593	≤29,300	283	4th 31-Oct-2022
Sterility Room (L218)	Grade D	At-rest	≤3,520,000	4,662	≤29,300	201	4th 31-Oct-2022



• Passion With Perfection • Engineers With Dreams •

Operational Qualification	Doc. No.	L-PLS03-VP&IF-VD-OQ-HVAC-01	Effective Date	28 OCT 2022
	Rev. No.	00	Total Page(s)	

20 of 37

Title:	Performance Verification – Particle Count Verification – Non-Viable (Room)	Test No: OQ-06
--------	--	----------------

Comments/Deviations/Supporting Documentation:

Refer to Attachment 1 : Raw Data

Refer to Attachment 2 : Specifications & Summary of Test Results

Overall Test Outcome (PASS/FAIL)

PASS

Verified By (Signature):

han
Jhuw

Date:

31 - Oct - 2022
31 - Oct - 2022

Operational Qualification		Doc. No.	L-PLS03-VP&IF-VD-OQ-HVAC-01	Effective Date	28 OCT 2022
		Rev. No.	00	Total Page(s)	21 of 37

Title:	Performance Verification – Total Microbial Count (Room)	Test No: OQ-07
---------------	--	-----------------------

Objective:

To provide documented evidence that the total microbial count in all rooms meets the design requirements.

Pre-requisites:

System commissioning and balancing has been completed.

Method:

1. The airborne viable micro-organism monitoring is conducted by using impaction technique (air sampling) followed by laboratory incubation on sampled test media recover and promote the micro-organism.
2. Total bacteria count is enumerated by using Tryptic Soy Agar (TSA) incubated at 35°C for five (5) days.
3. Total fungal count is enumerated by using Sabouraud Dextrose Agar (SDA) incubated at 25°C for seven (7) days.
4. A pre-set sampler volumetric impact flow of 100 liters/ min was used to expose the media and the respective plates incubated at the specific condition above.
5. Calculate the summation of the number of colony form unit (cfu) present on both media plates at the end of the incubation cycle.

Acceptance Criteria:

Total microbial count in all rooms is within the acceptable range specified in the design specification.

Results:

Room Ref.	Design Classification	Room Condition	Total Number of Colony Form Unit from Air Sample (cfu/m ³)		Initial & Date
			Expected	Actual	
Personnel Airlock In/ Out (L217)	Grade D	At-rest	≤200	6	Heh 14-Nov-2022
Sterility Room (L218)	Grade D	At-rest	≤200	3	Heh 14-Nov-2022

Operational Qualification	Doc. No.	L-PLS03-VP&IF-VD-OQ-HVAC-01	Effective Date	28 OCT 2022 22 of 37
	Rev. No.	00	Total Page(s)	

Title:	Performance Verification – Total Microbial Count (Room)	Test No: OQ-07
---------------	--	-----------------------

Comments/Deviations/Supporting Documentation:

Refer to Attachment 2 : Specifications & Summary of Test Results

Overall Test Outcome (PASS/FAIL)	Verified By (Signature):		Date:
	PASS	han Amir	14 - Nov - 2022 14 - NOV - 2022



• Passion With Perfection • Engineers With Dreams •

Operational Qualification	Doc. No. Rev. No.	L-PLS03-VP&IF-VD-OQ-HVAC-01 00	Effective Date Total Page(s)	28 OCT 2022 23 of 37
---------------------------	----------------------	-----------------------------------	---------------------------------	-------------------------

Title:		Performance Verification – Airflow Visualization Test (Room)			Test No: OQ-08
Objective:					
To provide documented evidence that the airflow direction for the room meets the design requirements.					
Pre-requisites:					
System commissioning and balancing has been completed.					
Method:					
1. This test to be conducted after airflow velocity has been performed. 2. Position the fogger nozzle horizontally 150 mm below the filter face and at the working level of cleanroom. 3. At 300 mm from the cleanroom return grille, apply the smoke from the top to bottom, identify any sign of the back flow. 4. Position the fogger nozzle at top of the door, move the nozzle from top to bottom, the smoke shall be move from positive to negative area. 5. Allow the vapor to free flow downward and use the video camera to capture the flow pattern.					
Acceptance Criteria:					
Airflow direction for room is according to design specification.					
Results:					
Room Ref.	Design Classification	Room Condition	Airflow Direction		Initial & Date
			Acceptance Criteria	Actual Result	
Personnel Airlock In/ Out (L217)	Grade D	At-rest	i. Free from back-flow and no turbulence at return grille ii. No pressure back-flow from adjacent room	i) Free from back-flow and no turbulence at return grille ii) No pressure back-flow from adjacent room	Hta 31-Oct-2022
Sterility Room (L218)	Grade D	At-rest	i. Free from back-flow and no turbulence at return grille ii. No pressure back-flow from adjacent room	i) Free from back-flow and no turbulence at return grille ii) No pressure back-flow from adjacent room	Hta 31-Oct-2022

Operational Qualification	Doc. No.	L-PLS03-VP&IF-VD-OQ-HVAC-01	Effective Date	28 OCT 2022
	Rev. No.	00	Total Page(s)	24 of 37

Title:	Performance Verification – Airflow Visualization Test (Room)	Test No: OQ-08
---------------	---	-----------------------

Comments/Deviations/Supporting Documentation:

Refer to Attachment 2: Specifications & Summary of Test Results

Overall Test Outcome (PASS/FAIL)	Verified By (Signature):	Date:
PASS	han Jhu	31 - Oct - 2022 31 - Oct - 2022

Operational Qualification	Doc. No. Rev. No.	L-PLS03-VP&IF-VD-OQ-HVAC-01 00	Effective Date	28 OCT 2022
			Total Page(s)	25 of 37

Title:	Performance Verification – Recovery Test (Room)	Test No: OQ-09
---------------	--	-----------------------

Objective:

To provide documented evidence that the recovery rate to reach specified steady state cleanliness levels of room after contamination or system shut down meets the design requirements.

Pre-requisites:

System commissioning and balancing has been completed.

Method:

1. The cleanrooms were operated until the cleanliness level reaches a steady state level with all the room differential pressure direction was balanced.
2. At the strategic location within the cleanrooms the particle count was measured. These readings served as the target steady state cleanliness level.
3. Once the steady state cleanliness was established, the PAO generator was turned on to introduce particles of nominal size 0.5µm, around the vicinity of the test location.
4. The counts at the strategic location were measured. The targeted counts at this location were to reach at least 10 times for Grade D to the steady state cleanliness level.
5. Once the targeted counts were achieved, the PAO generator was turned off. The particle counts were continually measured until they reached its initial cleanliness level.
6. The particle count level for a moving average of 60 seconds samples was plotted against time and the recovery time was determined from the data.

Acceptance Criteria:

Recovery rate (time taken) for room to reach specified steady state cleanliness level after contamination or system shut down is within acceptable range specified in the design specification.

Operational Qualification	Doc. No.	L-PLS03-VP&IF-VD-OQ-HVAC-01	Effective Date	28 OCT 2022
	Rev. No.	00	Total Page(s)	26 of 37

Performance Verification – Room Recovery Test					Test No: OQ-06
Results:					
Room Ref.	Design Classification	Room Condition	Recovery Time (minutes)		Initial & Date
			Acceptance Criteria	Actual Result	
Personnel Airlock In/ Out (L217)	Grade D	At Rest	< 20	6	han 31-Oct-2022
Sterility Room (L218)	Grade D	At-rest	< 20	3	han 31-Oct-2022
Comments/Deviations/Supporting Documentation:					
Refer to Attachment 1 : Raw Data					
Refer to Attachment 2 : Specifications & Summary of Test Results					
Overall Test Outcome (PASS/FAIL)		Verified By (Signature):		Date:	
PASS		han Date		31-Oct-2022 31-Oct-2022	

Operational Qualification		Doc. No.	L-PLS03-VP&IF-VD-OQ-HVAC-01	Effective Date	28 OCT 2022
		Rev. No.	00	Total Page(s)	27 of 37

Title:		Support – Procedure Verification		Test No: OQ-10	
Objective: To provide documented evidence that all documentations required for operation, maintenance and cleaning of the system are complete and available.					
Pre-requisites: None					
Method: Review the Operation and Maintenance procedures available for the system. Record the document title, document reference and issue date.					
Acceptance Criteria: Operation and maintenance documentations have been completed and available.					
Results:					
Document Title		Document Reference	Issue Date	Verified by (Initial & Date)	
Operation and Maintenance Manual for QC Lab HVAC system		L-PLS03 - VP & IF - VD - O & M - HVAC - R00	01 - Apr - 2022	thn 31 - Oct - 2022	



• Passion With Perfection • Engineers With Dreams •

Operational Qualification		Doc. No. Rev. No.	L-PLS03-VP&IF-VD-OQ-HVAC-01 00	Effective Date Total Page(s)	28 OCT 2022 28 of 37
---------------------------	--	----------------------	-----------------------------------	---------------------------------	-------------------------

Title:	Support – Procedure Verification	Test No: OQ-10
--------	----------------------------------	----------------

Comments/Deviations/Supporting Documentation:

Refer to Attachment ⁷ : Operation and Maintenance Manual for QC Lab HVAC System
the 31-Oct-2022

Overall Test Outcome (PASS/FAIL)	Verified By (Signature):	Date:
PASS	han Jana	31-Oct-2022 31-Oct-2022

Operational Qualification		Doc. No. Rev. No.	L-PLS03-VP&IF-VD-OQ-HVAC-01 00	Effective Date Total Page(s)	28 OCT 2022 29 of 37
---------------------------	--	----------------------	-----------------------------------	---------------------------------	-------------------------

Title:	Support – Change Control Record	Test No: OQ-11
---------------	--	-----------------------

Objective:

To provide documented records of all changes made to the system upon installation.

Pre-requisites:

All approved change form must be attached.

Method:

1. Record each change made to the system during the completion of the protocol. Record the change reference, a brief description of the change and the date of the change. Clearly and concisely outline what needs to be changed, so the impacted areas can review and analyze.
2. Review the changes made to the system and determine whether further testing is required. If further testing is required determine whether this has been completed satisfactorily.

Acceptance Criteria:

1. Records are available for all changes made to the system throughout the execution of this checking procedure.
2. Further tests required after the changes made have been conducted.

Results:

Change Ref.	Description of Change	Date of Change	Further Testing Required (Yes/No)	Further Testing Completed (Yes/No)	Initial & Date
		thc N/A			
		31-Oct-2022			



Operational Qualification		Doc. No.	L-PLS03-VP&IF-VD-OQ-HVAC-01	Effective Date	28 OCT 2022
		Rev. No.	00	Total Page(s)	30 of 37

Title:	Support - Change Control Record	Test No: OQ-11
--------	---------------------------------	----------------

Comments/Deviations/Supporting Documentation:

N/A

Overall Test Outcome (PASS/FAIL)	Verified By (Signature):	Date:
PASS	han Avis	31 - Oct - 2022 31 - Oct - 2022

Operational Qualification	Doc. No.	L-PLS03-VP&IF-VD-OQ-HVAC-01	Effective Date	28 OCT 2022
	Rev. No.	00	Total Page(s)	31 of 37

10.0 Acceptance Criteria Summary

This section, detailing system specific Acceptance Criteria (A/C), should be completed following a review of the test sheets, within Section 8, and supporting data, contained within the referenced project files.

Pre-requisite

Ref. No.	Acceptance Criteria	A/C Met? (Yes/No)	Deviation Ref.	Initial & Date
1	The previous stages of commissioning & qualification have been completed; any unresolved snags/deviations must be documented and have no impact on the tests in this protocol.	Yes	N/A	Ha 31-Oct-2022

Operational

Ref. No.	Acceptance Criteria	A/C Met? (Yes/No)	Deviation Ref.	Initial & Date
2	Air Change Rate (ACR) in all rooms is within the acceptable range specified in the design specification	Yes	N/A	Ha 31-Oct-2022
3	Differential pressure in all rooms is within the acceptable range specified in the design specification.	Yes	N/A	Ha 31-Oct-2022
4	Temperature in all rooms is within the acceptable range specified in the design specification.	Yes	N/A	Ha 31-Oct-2022
5	Relative humidity (RH) in all rooms is within the acceptable range specified in the design specification.	Yes	N/A	Ha 31-Oct-2022
6	Air particle count in all rooms is within the acceptable range specified in the design specification.	Yes	N/A	Ha 31-Oct-2022
7	Total microbial count in all rooms is within the acceptable range specified in the design specification.	Yes	N/A	Ha 14-Nov-2022
8	Airflow direction for all rooms is according to the design specification.	Yes	N/A	Ha 31-Oct-2022
9	Recovery rate (time taken) for the room to reach specified steady state cleanliness level after contamination or system shut down is within acceptable range specified in the design specification.	Yes	N/A	Ha 31-Oct-2022



• Passion With Perfection • Engineers With Dreams •

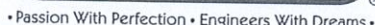
Operational Qualification	Doc. No.	L-PLS03-VP&IF-VD-OQ-HVAC-01	Effective Date	28 OCT 2022
	Rev. No.	00	Total Page(s)	32 of 37

Support

Ref. No.	Acceptance Criteria	A/C Met? Yes/No	Deviation Ref.	Initial & Date
10	Operation, maintenance and cleaning documentations have been completed and available.	Yes	N/A	Ha 31-Oct-2022

Additional

Ref. No.	Acceptance Criteria	A/C Met? Yes/No	Deviation Ref.	Initial & Date
11	Records are available for all changes made to the system throughout the execution of this checking procedure.	Yes	N/A	Ha 31-Oct-2022



28 OCT 2022

11.0 Test Instrument Record

A record of all test instruments used during Operational Qualification, ensuring all instruments have valid calibration certificates.

Test Instrument Description	Instrument Serial No.	Calibration Date	Calibration Frequency	Calibration Certificate No.	Calibration Cert. Location	Initial & Date
Anemometer	T83801315011	07-Dec-2021	Yearly	SM21960892	Attachment 3	31-Oct-2022
Temperature & Humidity Meter	180708916	29-Nov-2021	Yearly	PSYP-21078238	Attachment 4	31-Oct-2022
Airborne Particle Counter	120804004	11-Aug-2022	Yearly	CR220811-0633MA	Attachment 5	31-Oct-2022
Bio-Culture Calibration Head	W27ADKM-204	02-Oct-2022	Yearly	N/A	Attachment 6	31-Oct-2022
			then N/A			
			31-Oct-2022			

12.0 Signature Record

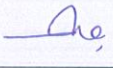
A record of all key personnel(s) involved in the completion of the Operational Qualification.

[illegible]

28 OCT 2022

Operational Qualification	Doc. No.	L-PLS03-VP&IF-VD-OQ-HVAC-01	Effective Date	28 OCT 2022
	Rev. No.	00	Total Page(s)	34 of 37

13.0 Post-Execution Approval

CONDITIONAL ACCEPTANCE			
The system operational checks have been reviewed. All testing associated during Operational Qualification are completed with all criteria being met. Any deviations that were noted (if any) have been resolved and closed out.			
Name	Job Title or Role	Signature	Date (dd-mmm-yyyy)
Reviewed by: Mohd Fadhli Bin Joafar	Head of Technical Service		09-Dec-2022
Reviewed by: Noor Zuraihan Mohamad Noor	Head of Project		09-Dec-2022
Reviewed by: Nurul Sabariah	Head of Engineering		13-Dec-2022
Reviewed by: Zuraidah Abd Wahab	Head of Quality Control		14-Dec-2022
Approved by: Abkariah Azhari	Head of Quality Assurance		15-Dec-2022



• Passion With Perfection • Engineers With Dreams •

Operational Qualification	Doc. No.	L-PLS03-VP&IF-VD-OQ-HVAC-01	Effective Date	28 OCT 2022
	Rev. No.	00	Total Page(s)	36 of 37

DEVIATION REPORT

Report no.:

A. Description of Deviation:

Documented By:

Date:

RESPONSE

A. Reason of Deviation

B. Correction/ preventive action to be taken

N/A Hta

14 - NOV - 2022

Evaluation by:

Signature

Date (dd-mmm-yyyy)

Reviewed By:

ACCEPTANCE

C. Corrective/ preventive action taken:

Performed by:

Signature

Date (dd-mmm-yyyy)

Reviewed By:

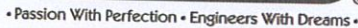
Reviewed By:

Reviewed By:

Reviewed By:

Approved By:

Note: This page to be re-printed as required



28 OCT 2022

15.0 List of Attachments

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

N/A
Ha 14-Nov-2022