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OPERATIONAL QUALIFICATION OF HVAC SYSTEM

PROJECT: NEW HOTLAB AT SUBANG JAYA MEDICAL CENTRE,
SUBANG JAYA, SELANGOR DARUL EHSAN.

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 Luffer Sdn. Bhd.			
Name	Job Title or Role	Signature	Date (dd-mmm-yyyy)
Authored by: Wong Peng Peng	Validation Executive		17- Oct - 2022
Reviewed by: Ahmad Aslam	Assistant Manager		17- Oct - 2022
Reviewed by: Koh Soon Yong	Project Manager		17- Oct - 2022
By signing below, Subang Jaya Medical Centre 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: Quek Kiat Hae	Deputy Chief Pharmacist		11- NOV - 2022
Reviewed by:			
Approved by: Steven	Manager		21 NOV 2022

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1.0 REFERENCE DOCUMENTS

No.	Document No.	Document Title
1.	L-SJMC02-HTL-VD-URS-R00	User Requirement Specification - New Hotlab at Subang Jaya Medical Centre, Subang Jaya, Selangor Darul Ehsan.
2.	L-SJMC02-HTL-VD-DQ-R00	Design Qualification, New Hotlab at Subang Jaya Medical Centre, Subang Jaya, Selangor Darul Ehsan.
3.	L-SJMC02-HTL-VD-IQ-HVAC-01-R00	Installation Qualification for HVAC System, New Hotlab at Subang Jaya Medical Centre, Subang Jaya, Selangor Darul Ehsan.

2.0 VERSION HISTORY

Revision No.	Date	Revised By	Reason for Revision
00	21 NOV 2022	Peng Peng	New

3.0 INTRODUCTION AND SCOPE

This document qualifies the new HVAC system operation for the New Hotlab within the Subang Jaya Medical Centre, Subang Jaya, Selangor Darul Ehsan. Cleanrooms is to be in compliance with the principle of Current 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, Heating and Refrigeration Institute (AHRI), 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 (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.

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5.0 ROLES & RESPONSIBILITY

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

Company	Job Title	Responsibility
Subang Jaya Medical Centre	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.
Lufter 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.

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6.0 ABBREVIATIONS

No.	Term/Abbreviation	Definition
1.	A/C	Acceptance Criteria
2.	ACR	Air Change Rate
3.	AHU	Air Handling Unit
4.	AHRI	Air-Conditioning, Heating and Refrigeration Institute
5.	ASHRAE	American Society of Heating, Refrigerating, and Air-Conditioning Engineers
6.	BIBO	Bag in/Bag out
7.	c/w	Come With
8.	Cert	Certificate
9.	CFU	Colony-Forming Unit
10.	CPP	Critical Process Parameter
11.	CQA	Critical Quality Attributes
12.	DQ	Design Qualification
13.	cGMP	Current Good Manufacturing Practices
14.	HFC	HEPA filter Chamber
15.	HEPA	High-Efficiency Particulate Air
16.	HVAC	Heating, Ventilation and Air Conditioning
17.	IQ	Installation Qualification
18.	ISO	International Standardization for Organization
19.	NC	Not Controlled
20.	No	Number
21.	NEBB	National Environmental Balancing Bureau
22.	OQ	Operational Qualification
23.	PIC/S	Pharmaceutical Inspection Co-Operation Scheme
24.	Ref	Reference
25.	RH	Relative Humidity
26.	SDA	Saboraud Dextrose Agar
27.	SMACNA	Sheet Metal and Air Conditioning Contractors' National Association
28.	TSA	Tryptic Soy Agar
29.	UNCL	Unclassified
30.	URS	User Requirement Specification
31.	WHO	World Health Organization

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7.0 SYSTEM DESCRIPTION

7.1 Heating, Ventilation & Air Conditioning System (HVAC)

The HVAC System designed for the classified cleanroom consists of two (2) units of new AHU which are designed to supply condition air to the cleanroom of the New Hotlab as per Table 2 under Section 8.2.

The new AHU-1 unit consists of two separate sections. The first section draws in the fresh air passes through a primary (grade G4-bag) filter and secondary (grade F9) filter. 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 air will be further cooled down at the chilled water post cooling coil section. Before exiting the AHU unit, the post-cooled air will flow through an electric heater to be heated to the required temperature as stated in the URS. The air exiting the AHU will be further filtered by H14 HEPA filter at the HEPA filter terminal before being released into the rooms.

The new AHU-2 unit consists of two separate sections. The first section draws in the fresh air passes through a primary (grade G4-bag) filter and secondary (grade F9) filter. 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 air will be further cooled down at the chilled water post-cooling coil section. Before exiting the AHU unit, the post-cooled air will flow through an electric heater to be heated to the required temperature as stated in the URS. The air exiting the AHU will be further filtered by H13 HEPA filter at the HEPA Filter Chamber before being released into the rooms.

For AHU-1 and AHU-2, the supply air enters the cleanroom via a network of ducting/branch ducts and flexible duct. Air control devices like aluminum blade volume control dampers are strategically installed along the main duct and branch duct to throttle the supply, and exhaust air. Manual dampers will be installed at each of the supply air diffusers and exhaust air grilles for fine adjustment.

Air exiting from all cleanrooms served by AHU-1 and AHU-2 will then pass through the BIBO filtration system and exhaust fan system before being exhausted out to atmosphere from the chimney.

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7.2 Cleanrooms Operating Conditions

Table 1 below shows the cleanroom parameters designed to meet the design parameters required as stated in the URS document (L-SJMC02-HTL-VD-URS-R00; under section 8.2).

AHU/ Exhaust Fan	Room Description	Room No.	Room ISO Classification	Pressure (Pa) (ref. atmosphere)	Relative Humidity (RH) (%)	Temperature (°C)	Air Change
AHU-1	PET/CT Hotlab	HL01	ISO 5	55	50 - 60	18 - 22	≥ 120
	SPECT/CT Hotlab	HL02	ISO 5	55	50 - 60	18 - 22	≥ 95
	Airlock 1	HL03	ISO 5	0	50 - 60	18 - 22	≥ 40
	Clean Corridor	HL04	ISO 5	40	50 - 60	18 - 22	≥ 40
	Gown Room	HL05	ISO 5	30	50 - 60	18 - 22	≥ 110
	Component Prep. Room	HL06	ISO 7	30	50 - 60	18 - 22	≥ 35
AHU-2	Change Room 1	HL07	ISO 7	15	50 - 60	18 - 22	≥ 35
	Radioiodine	HL08	ISO 8	5	50 - 60	18 - 22	≥ 60
	Change Room 2	HL09	ISO 8	20	50 - 60	18 - 22	≥ 45
	QC Room	HL10	UNCL	-5	NC	20 - 24	≥ 20
EF-4	Transfer Room	HL11	ISO 8	20	50 - 60	18 - 22	≥ 50
	Decay Room	HL12	NC	-5	NC	NC	≥ 10

Table 1: Cleanroom Parameter

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8.0 SYSTEM BOUNDARIES

The airflow schematic diagram (L/SJMC02/HTL/DC/HVAC/06, L/SJMC02/HTL/DC/HVAC/07, L/SJMC02/HTL/DC/HVAC/08) 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 the AHU
- Centralised and Terminal HEPA Filters
- BIBO System

The test carried out for the rooms in this Operational Qualification are 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.

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9.0 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 Verification– Protocol Review	OQ-01
2	Device Functionality – Filter Integrity Verification (HEPA Filter)	OQ-02
3	Performance Verification – Total Air Change Rates	OQ-03
4	Performance Verification – Room Differential Pressure	OQ-04
5	Performance Verification – Room Temperature Monitoring	OQ-05
6	Performance Verification – Room Relative Humidity Monitoring	OQ-06
7	Performance Verification – Particle Count Verification – Non-Viable	OQ-07
8	Performance Verification – Total Microbial Count Test	OQ-08
9	Performance Verification – Airflow Visualization Test (ISO 5 & 7)	OQ-09
10	Performance Verification – Room Recovery Test (ISO 5 & 7)	OQ-10
11	Support – Procedure Verification	OQ-11
12	Support - Change Control Record	OQ-12

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10.0 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	The HEPA filter system is properly installed with no bypass leakage and the installed filters are free of defects and pinhole leaks.	To provide documented evidence that the HEPA filters have pass the leak test and meet the design requirements.
3	Air Change Rate (ACR) in all rooms is 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.
4	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.
5	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.
6	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.
7	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.
8	Total microbial count (cfu/m ³) in all rooms is within the recommended limits for microbiological monitoring of cleanrooms according to PIC/S_PE 009-16 Annexes 1.	To provide documented evidence that the total microbial count in all rooms is within limits according to PIC/S_PE 009-16 Annexes 1 standards.
9	Airflow direction of all rooms are according to design specification.	To provide documented evidence that the airflow direction in all rooms meets the design requirements.
10	Recovery rate (time taken) for all the 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.
11	Operation, maintenance and cleaning documentations have been completed and available. Equipment logbooks are also available.	To provide documented evidence that all documentations required for operation, maintenance and cleaning are complete and available.
12	Records are available for all changes made to the system throughout the execution of this checking procedure and further tests required after the changes made have been conducted.	To provide documented records of all changes made to the system upon installation.

[illegible]



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Title: Documentation Verification- Protocol Review

Comments/Deviations/Supporting Documentation:

NIL

Test No: OQ-01

Overall Test Outcome (PASS/FAIL)

Verified By (Signature):

Date:

13-Mar-2023



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Title: Device Functionality – Total Filter Integrity Verification (HEPA Filter)					
Objective: To provide documented evidence that the HEPA filters have pass the leak test and meet the design requirements.					
Pre-requisites: System commissioning and balancing has been completed.					
Method: 1. Set up the aerosol photometer and aerosol generator according to manufacturer's instructions. 2. Introduce the PAO-4 aerosol at the upstream from the filter(s) using the aerosol generator. 3. Measure the upstream concentration in µg/liter, immediately upstream of the filter(s) being tested. Adjustment made, if necessary, to ensure concentration is within preferred range of ≥ 10 µg/liter. 4. Measure the downstream penetration % with the digital aerosol photometer. 5. Scan the filter(s) using a rectangular sampling probe by holding the probe approximately 25mm from frame and filter(s) surface at a rate of approximately 50mm/s. 6. Record the maximum downstream penetration % measured.					
Acceptance Criteria: The HEPA filter system is properly installed with no bypass leakage and the installed filters are free of defects and pinhole leaks.					

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Title: Device Functionality – Total Filter Integrity Verification (HEPA Filter)		Test No: OQ-02
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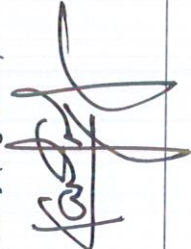
Results:

AHU/EF	Filter Ref.	Location	Acceptance Criteria	Actual Result		Verified By (Initial & Date)
				Upstream Challenge	Downstream Penetration %	
AHU-1	THF-01	PET/CT Hotlab	Downstream penetration % is ≤0.01% of upstream concentration	14	media : 0.002 Gasket : 0.004	13-Mar-2023
	THF-02	SPECT/CT Hotlab		16	media : 0.003 Gasket : 0.006	13-Mar-2023
	THF-03	Airlock 1		17	media : 0.002 Gasket : 0.005	13-Mar-2023
	THF-04	Clean Corridor		23	media : 0.002 Gasket : 0.004	13-Mar-2023
	THF-05	Clean Corridor		27	media : 0.003 Gasket : 0.005	13-Mar-2023
	THF-06	Gown Room		14	media : 0.005 Gasket : 0.006	13-Mar-2023
	THF-07	Component Prep. Room		17	media : 0.003 Gasket : 0.005	13-Mar-2023
	THF-08	Change Room 1		21	media : 0.003 Gasket : 0.006	13-Mar-2023
AHU-2	HFC-2-01	AHU-2 HEPA Filter Chamber	Downstream penetration % is ≤0.1% of upstream concentration	10	media : 0.002 Gasket : 0.005	13-Mar-2023
AHU-1	HF-BIBO-1-S1	BIBO-1		21	0.044	13-Mar-2023
	HF-BIBO-1-S2					
AHU-1	HF-BIBO-2A	BIBO-2A		11	0.071	13-Mar-2023



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Title: Device Functionality – Total Filter Integrity Verification (HEPA Filter)					Test No: OQ-02	
AHU/EF	Filter Ref.	Location	Acceptance Criteria	Actual Result		Verified By (Initial & Date)
				Upstream Challenge	Downstream Penetration %	
AHU-2	HF-BIBO-3	BIBO-3	Downstream penetration % is $\leq 0.01\%$ of upstream concentration	15	0.013	 13-Mar-2023
EF-4	HF-BIBO-4	BIBO-4	Downstream penetration % is $\leq 0.1\%$ of upstream concentration	16	0.023	 13-Mar-2023
Comments/Deviations/Supporting Documentation: NIL						
Overall Test Outcome (PASS/FAIL)				Verified By (Signature): 	Date: 13-Mar-2023	



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Title: Performance Verification – Total Air Change Rates					Test No: OQ-03
Objective: To provide documented evidence that the Air Change Rate (ACR) in all rooms meets the design requirements.					
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 $(Ac/h) = m^3/h \text{ (supply air)}/m^3 \text{ (room volume)}$					
Acceptance Criteria: Air Change Rate (ACR) in all rooms is within the acceptable range specified in the design specification.					



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Performance Verification – Total Air Change Rates					Test No: OQ-03
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Results:

AHU	Room Name	Acceptance Criteria	Actual Result		Verified By (Initial & Date)
		Design Air Change Rate (/hr)	Measured Room Volume (ft ³)	Total Measured Area Supply (cfm) Calculated Air Change Rate (/hr)	
AHU-1	PET/CT Hotlab	≥120	385	786 122	HA 13-Mar-2023
	SPECT/CT Hotlab	≥95	493	798 97	HA 13-Mar-2023
	Airlock 1	≥40	132	103 47	HA 13-Mar-2023
	Clean Corridor	≥40	673	578 52	HA 13-Mar-2023
	Gown Room	≥110	128	275 129	HA 13-Mar-2023
	Component Prep. Room	≥35	461	323 42	HA 13-Mar-2023
AHU-2	Change Room 1	≥35	281	193 41	HA 13-Mar-2023
	Radioiodine	≥60	761	778 61	HA 13-Mar-2023
	Change Room 2	≥45	333	283 51	HA 13-Mar-2023
	Transfer Room	≥50	276	266 58	HA 13-Mar-2023



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Title:	Performance Verification – Total Air Change Rates	Test No: OQ-03
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Comments/Deviations/Supporting Documentation:

NIL

Overall Test Outcome (PASS/FAIL)	Verified By (Signature): 	Date: 13-Mar-2023
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Title: Performance Verification – Room Differential Pressure				Test No: OQ-04
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: - Using calibrated micro manometer (record details) zero the instrumentation and connect the rubber tube to the micro manometer positive connection. - 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. - 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.				



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Performance Verification – Room Differential Pressure					Test No: OQ-04
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Results:

Room Ref.	Airflow Directions	Adjacent Room Ref.	Acceptance Criteria		Actual Results	Verified By (Initial & Date)
			Design Differential Pressure (Pa)			
Change Room 1	→	Med Prep Area	≥ 15		32.8	<i>[Signature]</i> 13-Mar-2023
Gown Room	→	Change Room 1	≥ 15		16.2	<i>[Signature]</i> 13-Mar-2023
Gown Room	→	Airlock 1	≥ 30		34.3	<i>[Signature]</i> 13-Mar-2023
Component Prep. Room	→	Change Room 1	≥ 15		21.4	<i>[Signature]</i> 13-Mar-2023
PET/CT Hotlab	→	Clean Corridor	≥ 15		30.4	<i>[Signature]</i> 13-Mar-2023
Clean Corridor	→	Airlock 1	≥ 40		60.5	<i>[Signature]</i> 13-Mar-2023
SPECT/CT Hotlab	→	Clean Corridor	≥ 15		32.6	<i>[Signature]</i> 13-Mar-2023
Change Room 2	→	Radioiodine	≥ 15		24.6	<i>[Signature]</i> 13-Mar-2023
Change Room 2	→	Med Prep Area	≥ 20		34.8	<i>[Signature]</i> 13-Mar-2023
Transfer Room	→	Radioiodine	≥ 15		23.9	<i>[Signature]</i> 13-Mar-2023
Transfer Room	→	Med Prep Area	≥ 20		31.1	<i>[Signature]</i> 13-Mar-2023

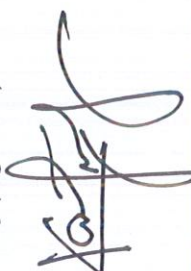


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Title:	Performance Verification – Room Differential Pressure	Test No: OQ-04
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Comments/Deviations/Supporting Documentation
NIL

Overall Test Outcome (PASS/FAIL)	Verified By (Signature): 	Date: 13-Mar-2023
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Title:	Performance Verification – Room Temperature Monitoring	Test No: OQ-05
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 and set-up as per site operating procedures.	
Method:	1. Check that the HVAC system has been fully commissioned and has been running in automatic mode. 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.	

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Title: Performance Verification – Room Temperature Monitoring

Test No: OQ-05

Results:

AHU	Room Ref.	Acceptance Criteria	Actual Result			Verified By (Initial & Date)
		Design Temperature (°C)	Test Location Recorded	Room Condition	Temp Recorded (°C)	
AHU-1	PET/CT Hotlab	18-22	Refer to CPT report	At rest	20.4	✓ 13-Mar-2023
	SPECT/CT Hotlab	18-22	Refer to CPT report	At rest	20.4	✓ 13-Mar-2023
	Airlock 1	18-22	Refer to CPT report	At rest	19.3	✓ 13-Mar-2023
	Clean Corridor	18-22	Refer to CPT report	At rest	19.4	✓ 13-Mar-2023
	Gown Room	18-22	Refer to CPT report	At rest	19.2	✓ 13-Mar-2023
	Component Prep. Room	18-22	Refer to CPT report	At rest	20.9	✓ 13-Mar-2023
AHU-2	Change Room 1	18-22	Refer to CPT report	At rest	21.6	✓ 13-Mar-2023
	Radiiodine	18-22	Refer to CPT report	At rest	19.7	✓ 13-Mar-2023
	Change Room 2	18-22	Refer to CPT report	At rest	19.8	✓ 13-Mar-2023
	Transfer Room	18-22	Refer to CPT report	At rest	19.5	✓ 13-Mar-2023

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Title:	Performance Verification – Room Temperature Monitoring	Test No: OQ-05
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Comments/Deviations/Supporting Documentation:

NIL

Overall Test Outcome (PASS/FAIL)		Verified By (Signature):	Date:
			13-Mar-2023

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Title:	Performance Verification – Room Relative Humidity Monitoring				
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 and set-up as per site operating procedures.				
Method:	1. Check that the HVAC system has been fully commissioned and has been running in automatic mode. 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.				

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Title:	Performance Verification – Room Relative Humidity Monitoring				Test No: OQ-06
Results:					

AHU	Room Ref.	Acceptance Criteria	Actual Result			Verified By (Initial & Date)
		Design Relative Humidity (%)	Test Location Recorded	Room Condition	Relative Humidity Recorded (%)	
AHU-1	PET/CT Hotlab	50-60	Refer to CPT report	At rest	52.6	13-Mar-2023
	SPECT/CT Hotlab	50-60	Refer to CPT report	At rest	52.0	13-Mar-2023
	Airlock 1	50-60	Refer to CPT report	At rest	56.0	13-Mar-2023
	Clean Corridor	50-60	Refer to CPT report	At rest	54.7	13-Mar-2023
	Gown Room	50-60	Refer to CPT report	At rest	56.7	13-Mar-2023
	Component Prep. Room	50-60	Refer to CPT report	At rest	51.5	13-Mar-2023
AHU-2	Change Room 1	50-60	Refer to CPT report	At rest	51.5	13-Mar-2023
	Radioiodine	50-60	Refer to CPT report	At rest	55.2	13-Mar-2023
	Change Room 2	50-60	Refer to CPT report	At rest	56.9	13-Mar-2023
	Transfer Room	50-60	Refer to CPT report	At rest	54.2	13-Mar-2023

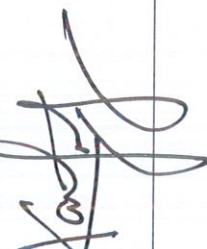


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Title:	Performance Verification – Room Relative Humidity Monitoring	Test No: OQ-06
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Comments/Deviations/Supporting Documentation:
Nil

Overall Test Outcome (PASS/FAIL)	Verified By (Signature): 	Date: 13 - Mar - 2023
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Title:	Performance Verification – Particle Count Verification – Non-Viable	Test No: OQ-07
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 (record these devices in the comments section). 2. Calculate the number of sampling points per room using the test method in section B.4.1 of EN ISO 14644-1:1999. Divide the floor equally into the number of zones indicated and locate the particle counter in the center of each zone. Show zones and particle counter location on a diagram of the area. 3. With the particle counter at a height of 1m 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 volume and time should be set in accordance with section B.4.2 of EN ISO 14644-1:1999. At each point take at least 1 sample. Where only one sample location is required, take a minimum of 3 single samples at that location. A statistical analysis carried out on each room according to section B.5 of EN ISO 14644-1:1999 and all data should be attached/referenced below.	
Acceptance Criteria:	Air particle count in all rooms is within the acceptable range specified in the design specification.	

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Title:	Performance Verification – Particle Count Verification – Non-Viable				Test No: OQ-07
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)		Verified By (Initial & Date)
			Acceptance Criteria	Actual	Acceptance Criteria	Actual	
PET/CT Hotlab	ISO 5	At Rest	≤3,520	330	Not specified	0	13-Mar-2023
SPECT/CT Hotlab	ISO 5	At Rest	≤3,520	141	Not specified	0	13-Mar-2023
Airlock 1	ISO 5	At Rest	≤3,520	2,107	Not specified	0	13-Mar-2023
Clean Corridor	ISO 5	At Rest	≤3,520	733	Not specified	0	13-Mar-2023
Gown Room	ISO 5	At Rest	≤3,520	2,355	Not specified	0	13-Mar-2023
Component Prep. Room	ISO 7	At Rest	≤352,000	8,600	≤2,930	98	13-Mar-2023
Change Room 1	ISO 7	At Rest	≤352,000	7,428	≤2,930	24	13-Mar-2023
Radioiodine	ISO 8	At Rest	≤3,520,000	5,059	≤29,300	239	13-Mar-2023
Change Room 2	ISO 8	At Rest	≤3,520,000	30,230	≤29,300	412	13-Mar-2023
Transfer Room	ISO 8	At Rest	≤3,520,000	7,028	≤29,300	577	13-Mar-2023



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Title:	Performance Verification – Particle Count Verification – Non-Viable	Test No: OQ-07
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Comments/Deviations/Supporting Documentation:
NIL

Overall Test Outcome (PASS/FAIL)		Verified By (Signature): 	Date: 13-Mar-2023
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Title: Performance Verification – Total Microbial Count Test		Test No: OQ-08
Objective: To provide documented evidence that the total microbial count in all the rooms is within limits according to PIC/S_PE 009-16 Annexes 1 standards.		
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 for micro-organism growth if any. 2. Total bacteria count is enumerated by using Tryptic Soy Agar (TSA) incubated at 35°C for 5 days. 3. Total fungal count is enumerated by using Sabouraud Dextrose Agar (SDA) incubated at 25°C for 7 days. 4. A pre-set sampler volumetric impact flow of 100 liters/min is used to expose the media and the respective plates incubated at the specific condition above. 5. At the end of the incubation cycle, the number of colony form unit (cfu) present on the media plate is counted and expressed in cfu/m³ using Feller's Statistical Correction formula. 6. The results obtained are compared against the prevailing standard adopted from PIC/S_PE 009-16 Annexes 1 for Total Viable Micro-organism (cfu/m³). 7. The microbial certificates of analysis will be out on the 9 days of both bacterial and fungal counts result obtained.		
Acceptance Criteria: Total microbial count (cfu/m ³) in all the rooms is within the recommended limits for microbiological monitoring of cleanrooms according to PIC/S_PE 009-16 Annexes 1.		

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Title:		Performance Verification – Total Microbial Count Test		Test No: OQ-08	
Results:					

Room Ref.	Design Classification	Room Condition	Total Microorganism Count (cfu/m ³)		Verified By (Initial & Date)
			Acceptance Criteria	Actual Result	
PET/CT Hotlab	ISO 5	At Rest	≤ 10	2	<i>At</i> 13-Mar-2023
SPECT/CT Hotlab	ISO 5	At Rest	≤ 10	4	<i>At</i> 13-Mar-2023
Airlock 1	ISO 5	At Rest	≤ 10	3	<i>At</i> 13-Mar-2023
Clean Corridor	ISO 5	At Rest	≤ 10	3	<i>At</i> 13-Mar-2023
Gown Room	ISO 5	At Rest	≤ 10	< 1	<i>At</i> 13-Mar-2023
Component Prep. Room	ISO 7	At Rest	≤ 100	3	<i>At</i> 13-Mar-2023
Change Room 1	ISO 7	At Rest	≤ 100	< 1	<i>At</i> 13-Mar-2023
Radiiodine	ISO 8	At Rest	≤ 200	3	<i>At</i> 13-Mar-2023
Change Room 2	ISO 8	At Rest	≤ 200	9	<i>At</i> 13-Mar-2023
Transfer Room	ISO 8	At Rest	≤ 200	4	<i>At</i> 13-Mar-2023



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Title: Performance Verification – Total Microbial Count Test		Test No: OQ-08
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Comments/Deviations/Supporting Documentation:
NIL

Overall Test Outcome (PASS/FAIL)

Verified By (Signature):

Date: 13-Mar-2023



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Operational Qualification		Doc. No. Rev. No.	L-SJMC02-HTL-VD-OQ-HVAC-01 00	Effective Date Total Page(s)	21 NOV 2022 34 of 51
Title: Performance Verification – Airflow Visualization Test (ISO 5 & 7) Test No: OQ-09					
Objective: To provide documented evidence that the airflow direction for all the rooms meets the design requirements.					
Pre-requisites: Airflow velocity test has been performed.					
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 all the rooms is according to design specification.					

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Title:	Performance Verification – Airflow Visualization Test (ISO 5 & 7)	Test No: OQ-09
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Results:

Room Ref.	Design Classification	Room Condition	Airflow Direction		Verified By (Initial & Date)
			Acceptance Criteria	Actual Result	
PET/CT Hotlab	ISO 5	At Rest	i. Free from death spot and turbulence. ii. No sign of back-flow at return grille.	Airflow moves from high to low pressure and disperse, smoke freely exhausted out through return grilles.	<i>HA</i> 13-Mar-2023
SPECT/CT Hotlab	ISO 5	At Rest	i. Free from death spot and turbulence. ii. No sign of back-flow at return grille.	Airflow moves from high to low pressure and disperse, smoke freely exhausted out through return grilles.	<i>HA</i> 13-Mar-2023
Airlock 1	ISO 5	At Rest	i. Free from death spot and turbulence. ii. No sign of back-flow at return grille.	Airflow moves from high to low pressure and disperse, smoke freely exhausted out through return grilles.	<i>HA</i> 13-Mar-2023
Clean Corridor	ISO 5	At Rest	i. Free from death spot and turbulence. ii. No sign of back-flow at return grille.	Airflow moves from high to low pressure and disperse, smoke freely exhausted out through return grilles.	<i>HA</i> 13-Mar-2023
Gown Room	ISO 5	At Rest	i. Free from death spot and turbulence. ii. No sign of back-flow at return grille.	Airflow moves from high to low pressure and disperse, smoke freely exhausted out through return grilles.	<i>HA</i> 13-Mar-2023
Component Prep. Room	ISO 7	At Rest	i. Free from death spot and turbulence. ii. No sign of back-flow at return grille.	Airflow moves from high to low pressure and disperse, smoke freely exhausted out through return grilles.	<i>HA</i> 13-Mar-2023



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Title: Performance Verification – Airflow Visualization Test (ISO 5 & 7)					Test No: OQ-09
Room Ref.	Design Classification	Room Condition	Airflow Direction		Verified By (Initial & Date)
			Acceptance Criteria	Actual Result	
Change Room 1	ISO 7	At Rest	i. Free from death spot and turbulence. ii. No sign of back-flow at return grille.	Airflow moves from high to low pressure and disperse, smoke freely exhausted out through.	 13-Mar-2023
Comments/Deviations/Supporting Documentation: NIL					
Overall Test Outcome (PASS/FAIL)			Verified By (Signature): 	Date: 13-Mar-2023	



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Title: Performance Verification – Room Recovery Test (ISO 5 & 7)		Test No: OQ-10
Objective: To provide documented evidence that the recovery rate to reach specified steady state cleanliness levels of all the rooms 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. 2. At the strategic location within the cleanrooms (mutually agreed by the relevant parties), 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 100 times for ISO 5 and ISO 7 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 all the rooms to reach specified steady state cleanliness level after contamination or system shut down is within acceptable range specified in the design specification.		

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Title:	Performance Verification – Room Recovery Test (ISO 5 & 7)				Test No: OQ-10
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Results:

Room Ref.	Design Classification	Room Condition	Recovery Time (minutes)		Verified By (Initial & Date)
			Acceptance Criteria	Actual Result	
PET/CT Hotlab	ISO 5	At Rest	< 20	3	<i>HA</i> 13-Mar-2023
SPECT/CT Hotlab	ISO 5	At Rest	< 20	4	<i>HA</i> 13-Mar-2023
Airlock 1	ISO 5	At Rest	< 20	4	<i>HA</i> 13-Mar-2023
Clean Corridor	ISO 5	At Rest	< 20	4	<i>HA</i> 13-Mar-2023
Gown Room	ISO 5	At Rest	< 20	3	<i>HA</i> 13-Mar-2023
Component Prep. Room	ISO 7	At Rest	< 20	6	<i>HA</i> 13-Mar-2023
Change Room 1	ISO 7	At Rest	< 20	5	<i>HA</i> 13-Mar-2023



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Title:	Performance Verification – Room Recovery Test (ISO 5 & 7)	Test No: OQ-10
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Comments/Deviations/Supporting Documentation:

NIL

Overall Test Outcome (PASS/FAIL)	Verified By (Signature): 	Date: 13-Mar-2023
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Title:	Support – Procedure Verification	Test No: OQ-11
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Objective:
To provide documented evidence that all documentations required for operation, maintenance and cleaning of the system are complete and available.

Pre-requisites: Operation & Maintenance Manual should be available.

Method:
Review the Operation, Maintenance and Cleaning procedures and equipment logbooks available for the system. Record the document title, document reference and issue date.

Acceptance Criteria:
1. Operation, maintenance and cleaning documentations have been completed and available.
2. Equipment logbooks are also available.

Results:

Document Title	Document Ref.	Issue Date	Verified by (Initial & Date)
Operation and Maintenance Manual	L-SJMC02-HTL-VD-02M-R00	01-Mar-2023	13-Mar-2023
	N/A		



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Title: Support – Procedure Verification		Test No: OQ-11
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Comments/Deviations/Supporting Documentation:
NIL

Overall Test Outcome (PASS/FAIL)	Verified By (Signature): 	Date: 13-Mar-2023
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Test No: OQ-12

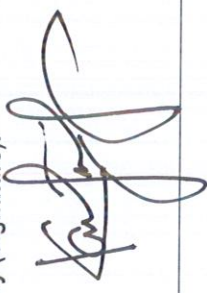


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Title:	Support – Change Control Record	Test No: OQ-12
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Comments/Deviations/Supporting Documentation:
NIL

Overall Test Outcome (PASS/FAIL)	Verified By (Signature): 	Date: 13-Mar-2023
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11.0 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

A/C Ref.	Acceptance Criteria (A/C)	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	<i>[Signature]</i> 13-Mar-2023

Operational

A/C Ref.	Acceptance Criteria (A/C)	A/C Met? Yes/No	Deviation Ref.	Initial & Date
2	The HEPA filter system is properly installed with no bypass leakage and the installed filters are free of defects and pinhole leaks.	Yes	N/A	<i>[Signature]</i> 13-Mar-2023
3	Air Change Rate (ACR) in all rooms is within the acceptable range specified in the design specification	Yes	N/A	<i>[Signature]</i> 13-Mar-2023
4	Differential pressure in all rooms is within the acceptable range specified in the design specification.	Yes	N/A	<i>[Signature]</i> 13-Mar-2023
5	Temperature in all rooms is within the acceptable range specified in the design specification.	Yes	N/A	<i>[Signature]</i> 13-Mar-2023
6	Relative humidity (RH) in all rooms is within the acceptable range specified in the design specification.	Yes	N/A	<i>[Signature]</i> 13-Mar-2023
7	Air particle count in all rooms is within the acceptable range specified in the design specification.	Yes	N/A	<i>[Signature]</i> 13-Mar-2023
8	Total microbial count (cfu/m ³) in all rooms is within the recommended limits for microbiological monitoring of cleanrooms according to PIC/S_PE 009-16 Annexes 1.	Yes	N/A	<i>[Signature]</i> 13-Mar-2023
9	Airflow direction of all rooms are according to design specification.	Yes	N/A	<i>[Signature]</i> 13-Mar-2023
10	Recovery rate (time taken) for all the rooms 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	<i>[Signature]</i> 13-Mar-2023



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Support

A/C Ref.	Acceptance Criteria (A/C)	A/C Met? Yes/No	Deviation Ref.	Initial & Date
11	Operation, maintenance and cleaning documentations have been completed and available. Equipment logbooks are also available.	Yes	N/A	 13-Mar-2023

Additional

A/C Ref.	Acceptance Criteria (A/C)	A/C Met? Yes/No	Deviation Ref.	Initial & Date
12	Records are available for all changes made to the system throughout the execution of this checking procedure and further tests required after the changes made have been conducted.	Yes	N/A	 13-Mar-2023

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12.0 TRAINING VERIFICATION

Training attendance record of end-user and/or other relevant personnel(s) who underwent training by Lufter Sdn. Bhd. on the system operations, maintenance and brief troubleshooting methods.

Name of Trainee	Description of Training Provided	Date of Training	Training Cert. Ref.
	Refer to Training Attendance List.		

13.0 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 Cert. No.	Calibration Cert. Location	Initial & Date
Digital Aerosol Photometer	23084	26-Apr-2022	Yearly	CFS6-A1KAC-24-22-035	Refer to CPT report	13-Mar-2023
Balometer	T83801315011	14-Dec-2022	Yearly	PSYN-22081570	Refer to CPT report	13-Mar-2023
Balometer	T83801315011	13-Jan-2023	Yearly	PSYN-22081572	Refer to CPT report	13-Mar-2023
Balometer	T83801315011	07-Dec-2022	Yearly	PSYP-22081575	Refer to CPT report	13-Mar-2023
Balometer	T83801315011	30-Jan-2023	Yearly	PSYP-23003340	Refer to CPT report	13-Mar-2023
Airborne Particle Counter	120804004	11-Aug-2022	Yearly	CR220811-0633MB	Refer to CPT report	13-Mar-2023
Anemometer	2203130021	29-Mar-2022	Yearly	446492203130021	Refer to CPT report	13-Mar-2023
		N/A				13-Mar-2023



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14.0 SIGNATURE RECORD

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

[illegible]



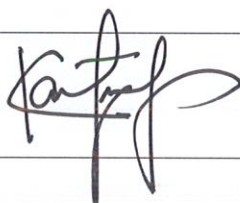
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15.0 POST-EXECUTION APPROVAL

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:			
Reviewed by:		N/A 13-mmr-xxxx	
Approved by: Steven	Manager		13-mmr-xxxx



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16.0 DEVIATION LIST

Record each of the deviations raised during the completion of the protocol and the date that the deviation was resolved.

[illegible]



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DEVIATION REPORT	Report no.:
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A. Description of Deviation:	
Documented By:	Date:

RESPONSE		
A. Reason of Deviation:		
B. Correction/preventive action to be taken:		
Evaluation by:	N/A Signature	Date (dd-mmm-yyyy)
Reviewed By:	13-mmr-2022	

ACCEPTANCE		
C. Corrective/preventive action taken:		
Performed by:	Signature	Date (dd-mmm-yyyy)
Performed By:		
Reviewed By:		
Approved By:		

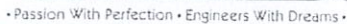
Note: This page to be re-printed as required

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17.0 LIST OF ATTACHMENTS

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

[illegible]

[illegible]