INSTALLATION QUALIFICATION PROTOCOL FOR VERTICAL LAMINAR AIR FLOW

Pre - Execution Approval

	Name	Designation	Signature	Date
Prepared By				
Reviewed By				
Reviewed By				
Reviewed By				
Approved By				

1.0 Objective:

- To establish documented evidence which will provide a High degree of assurance and reliability about the performance of the Vertical Laminar flow unit**.**
- To determine that the Vertical Laminar flow unit performs as intended by repeatedly running the system on its intended schedules and recording all relevant information and data. Results must demonstrate that performance consistently meets predefined specifications under normal conditions and where appropriate for worst case situations.

2.0 Scope:

Scope is limited to the following

Equipment / System Name	**Vertical Laminar Flow Unit**
ID Number	**…..**
Location	**Cooling Zone**

INSTALLATION QUALIFICATION PROTOCOL FOR VERTICAL LAMINAR AIR FLOW

3.0 Performance Verification Checklist:

Verify the performance of all the critical process/functions as per their respective procedure. Refer Performance Verification Checklist as per Annexure - I.

4.0 Any Changes/Deviations identified during operating checks:

Refer Annexure - II

5.0 Recommendations and Conclusions:

6.0 References:

Design Qualification

Installation Qualification

Operational Qualification

Standard Operating Procedure

7.0 Annexure

Annexure - I : Performance Verification Checklist

Annexure - II : List of Changes / Deviation.

Annexure - III : Performance Qualification Report.

8.0 Abbreviations:

SOP : Standard Operating Procedure

INSTALLATION QUALIFICATION PROTOCOL FOR VERTICAL LAMINAR AIR FLOW

Post execution approval:

	Name	Designation	Signature	Date
Compiled By				
Reviewed By				
Reviewed By				
Reviewed By				
Approved By				

INSTALLATION QUALIFICATION PROTOCOL FOR VERTICAL LAMINAR AIR FLOW

Annexure - I
Checklist for Performance Verification

S.No.	Test		Acceptance Criteria	Actual Result	Remarks	Verification Done by
1.	HEPA Filter Integrity (% Penetration)	Ist Location	0. 001 % penetration			
		2nd Location				
		3rd Location				
		4th Location				
2a.	Average Air Velocity (fpm) (At supply)	Ist Location	90 ± 10 %			
		2nd Location				
		3rd Location				
		4th Location				
2b.	Average Air Velocity (fpm) (At exhaust)	Ist Location	Not applicable			
		2nd Location				
		3rd Location				
		4th Location				

INSTALLATION QUALIFICATION PROTOCOL FOR VERTICAL LAMINAR AIR FLOW

S.No.	Test		Acceptance Criteria	Actual Result	Remarks	Verification Done by
3a.	Pressure Drop (mm of WC) (Across Supply HEPA Filter)	Ist	10 to 20 mm of WC			
		2nd				
		3rd				
		4th				
3b.	Pressure Drop (mm of WC) (Within Work area)	Ist	Not applicable			
		2nd				
		3rd				
		4th				
4a.	Particle Count (Cum. # of particles / cu.m of air) (If applicable) **(Ist Location)**	> 0.5 µm	3520	1. _____		
				2. _____		
				3. _____		
		> 5.0 µm	29	1. _____		
				2. _____		
				3. _____		

INSTALLATION QUALIFICATION PROTOCOL FOR VERTICAL LAMINAR AIR FLOW

S.No.	Test		Acceptance Criteria	Actual Result	Remarks	Verification Done by
4b.	Particle Count (Cum. # of particles / cu.m of air) (If applicable) **(2nd Location)**	> 0.5 µm	3520	1. _____		
				2. _____		
				3. _____		
		> 5.0 µm	29	1. _____		
				2. _____		
				3. _____		
4c.	Particle Count (Cum. # of particles / cu.m of air) (If applicable) **(3rd Location)**	> 0.5 µm	3520	1. _____		
				2. _____		
				3. _____		
		> 5.0 µm	29	1. _____		
				2. _____		
				3. _____		
4d.	Particle Count (Cum. # of particles / cu.m of air) (If applicable) **(4th Location)**	> 0.5 µm	3520	1. _____		
				2. _____		
				3. _____		

INSTALLATION QUALIFICATION PROTOCOL FOR VERTICAL LAMINAR AIR FLOW

S.No.	Test		Acceptance Criteria	Actual Result	Remarks	Verification Done by
4d.	Particle Count (Cum. # of particles / cu.m of air) (If applicable) **(4th Location)**	> 5.0 µm	29	1. _____		
				2. _____		
				3. _____		
5.	Passive Air Sampling (Settle Plate Exposure) (Grade A)		1 (cfu/4 hrs)	1st Day _____		
				2nd Day _____		
				3rd Day _____		
6.	Active Air Sampling (Grade A)		1 (cfu/m^3)	1st Day _____		
				2nd Day _____		
				3rd Day _____		

Note:

Remarks: Performance Verification of Dynamic Pass Box - Complies / Does not comply.

INSTALLATION QUALIFICATION PROTOCOL FOR VERTICAL LAMINAR AIR FLOW

Annexure - II

List of Changes / Deviations

S.No.	Description of Change / Deviations	Justification based on impact analysis

Verified By:

Approved By: