



**INSTALLATION QUALIFICATION PROTOCOL FOR HORIZONTAL LAMINAR FLOW UNIT**

**Pre - Execution Approval**

	<b>Name</b>	<b>Designation</b>	<b>Signature</b>	<b>Date</b>
Prepared By				
Reviewed By				
Reviewed By				
Reviewed By				
Approved By				



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**1.0 Objective:**

- To establish documented evidence which will provide a High degree of assurance and reliability about the performance of the Horizontal Laminar Flow unit.
- To determine that the Horizontal 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**

<b>Equipment / System Name</b>	<b>Horizontal Laminar Flow Unit</b>
<b>ID Number</b>	.....
<b>Location</b>	<b>Sterility Testing Room</b>

**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



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**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

**Post execution approval:**

	<b>Name</b>	<b>Designation</b>	<b>Signature</b>	<b>Date</b>
Compiled By				
Reviewed By				
Reviewed By				
Reviewed By				
Approved By				



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**Annexure - I**  
**Checklist for Performance Verification**

S.No.	Test		Acceptance Criteria	Actual Result	Remarks	Verification Done by
1.	HEPA Filter Integrity (% Penetration)		0.001 % penetration			
2.	Average Air Velocity (fpm)	At supply	90 ± 10 %			
	Average Air Velocity (fpm)	At exhaust	Not applicable			
3.	Pressure Drop (mm of WC)	Across Supply HEPA Filter	10 to 20 mm of WC			
	Pressure Drop (mm of WC)	Within Work area	Not applicable			
4.	Particle Count (Cum. # of particles / cu.m of air) (If applicable)	> 0.5 µm	3520	1. _____		
				2. _____		
				3. _____		
		> 5.0 µm	29	1. _____		
				2. _____		
				3. _____		



PHARMA DEVILS

MICROBIOLOGY DEPARTMENT

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S.No.	Test	Acceptance Criteria	Actual Result	Remarks	Verification Done by
5.	Passive Air Sampling (Settle Plate Exposure) (Grade A)	1 (cfu/4 hrs)	1 <sup>st</sup> Day _____		
			2 <sup>nd</sup> Day _____		
			3 <sup>rd</sup> Day _____ _____		
6.	Active Air Sampling (Grade A)	1 (cfu/m <sup>3</sup> )	1 <sup>st</sup> Day _____		
			2 <sup>nd</sup> Day _____		
			3 <sup>rd</sup> Day _____		

**Note:**

**Remarks:** Performance Verification of Horizontal Laminar Flow Unit - Complies / Does not comply.



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**Annexure - II**

**List of Changes / Deviations**

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

**Verified By:**

**Approved By:**