DESIGN QUALIFICATION PROTOCOL FOR VERTICAL LAMINAR FLOW UNIT

Pre - Execution Approval

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

DESIGN QUALIFICATION PROTOCOL FOR VERTICAL LAMINAR FLOW UNIT

1.0 Objective:

The purpose of Design Qualification of the Horizontal Laminar Flow Unit is to ensure that all the critical aspects including safety, effective cleaning, maintenance, utility requirement, working space, have been considered while designing the equipment and they are properly documented.

2.0 Scope:

Scope is limited to the following

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

3.0 Equipment / System Description:

KlenzFlo™ Vertical Laminar flow clean air workstation provides a contained environment to protect the product. It provide clean zone and particle free conditions by unidirectional down ward airflow from the HEPA filters situated above the working area. This shall produce clean zone with air quality, which is equivalent or better than class 5 ISO 144644 - 1 / specifications.

The Vertical Laminar flow clean air workstation is required to provide local class 5 (ISO 144644 - 1) grade environment for aseptic processing. The equipment should be designed for continuous run and shall not experience any major breakdown because of workmanship. The equipment is intended to be in operation in all the three shift 7 days a week.

The Vertical Laminar flow clean air workstation shall be used for maintaining class 5 (ISO 14644 - 1) environment during unloading of sterilized equipments, accessories, materials, etc.

4.0 Checklist for Design Verification:

Design of Horizontal Laminar Flow unit shall be verified for the compliance with the critical parameters mentioned in the URS/ executed tender.

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Parameters	User requirement / Technical Specification	Vendor Design / Specification	Remarks
Construction			
Material of construction	SS 304	SS 304	
Curtain	Not Mentioned	Antistatic PVC curtain	
HEPA filter Screen	SS 304	SS 304	
HEPA filters	Not Mentioned	EU - 13, 610x915x75 mm (Antimicrobial)	
Pre filters	Not Mentioned	EU – 6, 765x298x45 mm (Biocidal)	
	Not Mentioned	EU – 6, 728x298x45 mm (Biocidal)	
	Not Mentioned	EU – 6, 840x298x45 mm (Biocidal)	
DOP Port	Should be provided	100 % DOP test port	
Electrical construction	a) 300 lux along with one number of 5/15 amp, each switch socket (combined) b) Independent controls for lighting, blowers & sockets.	a) Fluorescent light: 4'L ; 40-Watts b) Independent controls for lighting, blowers & Sockets.	

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Parameters	User requirement / Technical Specification	Vendor Design / Specification	Remarks
Acceptable Tolerance for Control Parameter			
Air velocity	Between 0.50 m/sec to 0.45 m/sec	0.45 ± 0.05 m/sec	
Noise (Decibels)	Less than 65	Not Mentioned	
Differential pressure	Should be between 7 to 12 mm WC	Not Mentioned	
Particle count	As per ISO 14644 - 1	Complies	
Type of Control System			
Relay / Switchgear	Should be provided	Provided	
Indicators	➢ Power ON ➢ Blower ON ➢ Light switch	Provided	
Differential pressure gauge	0 to 25 mm WC	0 to 25 mm WC	
Accuracy of gauge	± 3 %	± 3 %	
Electrical power supply	440 - 3 phase 50 Hz / 220 1 phase 50 Hz	230 V; AC; 50 Hz	

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Parameters	User requirement / Technical Specification	Vendor Design / Specification	Remarks
Special features	Not Mentioned	Soft touch key pad switch	
Safety			
Alarm	Audiovisual alarm for motor blower trip	Audiovisual alarm for motor blower trip	
MCB	Make Hager / Merlin gerlin / Legrand	Provided	
Motor	Not Mentioned	0.5 HP; 1440 RPM;	
Blower (Impeller)	Not Mentioned	210 x 85 mm	
Overall Dimensions (WxDxH)	72 x 36 inches (2743 x 914 mm)	1065 x 2746 x 610 mm	

5.0 Any Changes identified towards equipment design / lay out.

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6.0 Recommendations and Conclusions:

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7.0 References:

User requirement specification.

Copy of purchase order.

Risk assessment.

Document submitted by the supplier / vendor

8.0 Documents Attached

Document Title	Annexure No.
List of changes / deviation	I
User requirement specification.	II
Copy of purchase order	III
Risk assessment	IV
Document submitted by the supplier / vendor	V

9.0 Abbreviations:

URS	: User requirement specification
SS	: Stainless Steel
mm	: millimeter
WC	: water content
%	: Percentage
m/sec	: Meter per second

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Annexure - I

List of changes / Deviations

S.No.	Description of Change / Deviations	Justification

Verified By:

Approved By:

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Post execution approval:

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