INSTALLATION QUALIFICATION PROTOCOL FOR HORIZONTAL LAMINAR FLOW UNIT

Pre - Execution Approval

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

INSTALLATION QUALIFICATION PROTOCOL FOR HORIZONTAL LAMINAR FLOW UNIT

1.0 Objective:

The purpose of installation qualification is as follows

- To provide documented evidence that the mentioned Horizontal Laminar Flow Unit is installed as per design.
- To ensure that the Horizontal Laminar Flow Unit installed confirms to purchase specifications and manufacturer literature, and to document the information that the Horizontal Laminar Flow Unit meets the specification.

2.0 Scope:

Scope is limited to the following

Equipment / System Name	**Horizontal Laminar Flow Unit**
ID Number	**……**
Location	**Sterility Testing Room**

3.0 Equipment / System Description:

KlenzFlo™ Horizontal Laminar Flow unit provides a contained environment to protect the product. It provide sterile and particle free conditions by continuous flushing of working area by supplying unidirectional horizontal airflow from the HEPA fitters situated besides the working area. This shall produce clean zone with air quality, which is equivalent or better than class 5 ISO 144644 - 1 / specifications.

The Horizontal Laminar Flow unit 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.

This equipment shall be used to maintain the aseptic condition of the product / accessories and for doing aseptic manipulations.

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4.0 Checklist for Preinstallation verification:

The purpose of the checklist is to confirm the availability of required documents for installation and to verify the availability of components and parts as per the approved purchase order in presence of the technical personnel of the vendor.

Preinstallation verification checklist is enclosed as Annexure - I.

5.0 Checklist for Installation verification:

Installation of Horizontal Laminar Flow Unit shall be verified for the compliance with the critical parameters mentioned in the Functional Design Specification.

The purpose of this checklist is to check and document the received material and installation at site with respect to drawings, details, and data sheets approved during DQ and GEP. GEP considers the basic engineering requirements for skilful maneuvering, means those methods and practices, which the administrator determines to be consistent with scientific and engineering principles.

Installation verification checklist is enclosed as Annexure - II.

6.0 Any Changes identified towards equipment design / lay out.

Refer Annexure - III.

7.0 Recommendations and Conclusions:

……
……
……
……
……

8.0 References:

Purchase order (already available with Design Qualification)

Packing list supplied by vendor (Not applicable).

List of spares (Not applicable).

Installation Qualification submitted by vendor.

Impact Assessment analysis.

9.0 Annexure

Annexure - I : Check list for Preinstallation Verification.

Annexure - II : Check list for Installation Verification.

Annexure - III : List of Changes / Deviation.

Annexure - IV : Installation Qualification Submitted by the vendor.

Annexure - V : Impact Assessment Analysis.

Annexure - VI : Summary Report of Installation Qualification

10.0 Abbreviations:

IQ : Installation Qualification

DQ : Design Qualification

Post execution approval:

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

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Annexure - I

Checklist for Preinstallation Verification

S.No.	Main Components Accessories / Documents	Code / Doc No.	Actual	Remarks
1.	Purchase Order No.	…..		
2.	Vendor's Name	……..		
3.	Instrument Make	…….		
4.	Instrument Model No.	Klenz Flo ™		
5.	Design qualification Reference	Design qualification submitted by the vendor		
6.	Factory Acceptance Test (FAT) Certificate	Should be provided		
7.	Instrument Manual	Instrument Manual submitted by the vendor		

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Annexure - II

Checklist for Installation Verification

S.No.	System Data	Acceptance Criteria	Actual	Remarks
A.	**Equipment /Instrument specific details**			
1.	Cabinet (MOC)	Should be SS 304		
2.	Bench (MOC)	Should be SS 304 with Provision of gas		
3.	HEPA filter Screen (MOC)	Should be SS 304		
4.	HEPA filters	Should be EU - 13, 1220 x 610 x 75 x 50 mm (Antimicrobial)		
5.	Pre filters	Should be EU - 6, 760 x 380 x 45 mm (Biocidal)		
6.	DOP Port	100 % DOP test port Should be provided		
7.	Electrical construction	a) Fluorescent light: 4'L ; 40-Watts ,U.V light: 3'L ; 36-Watts b) Independent controls for lighting, blowers & Sockets.		

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S.No.	System Data	Acceptance Criteria	Actual	Remarks
A.	**Equipment /Instrument specific details**			
8.	Front panel	1-piece polycarbonate front door with gas filled hinges100 % Should be provided		
9.	Side Panels	Toughened glass panels Should be provided		
10.	Relay / Switchgear	Should be provided		
11.	Indicators	➢ Power ON ➢ Blower ON ➢ Light switch Should be provided		
12.	Differential pressure gauge	Should be 0 to 25 mm WC		
13.	Special features	Soft touch key pad switch Should be provided		
		Analog Hour meter Should be provided		
		Adjustable floor aligner Should be provided		

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S.No.	System Data	Acceptance Criteria	Actual	Remarks
A.	**Equipment /Instrument specific details**			
14.	Motor	Should be 0.5 HP; 1440 RPM;		
15	Blower (Impeller)	Should be 185 x 85 mm		
16.	Overall Dimensions (W x D x H)	Should be 1302 x 910 x 1435 mm		
17.	Work Space Dimensions (W x D x H)	Should be 1187x 610 x 577 mm		
B.	**Location suitability**			
1.	Location	Should be place in Sterility Testing Room		
C.	**Utilities**			
1.	Electrical power supply	Should be 230 V; AC; 50 Hz		

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S.No.	System Data	Acceptance Criteria	Actual	Remarks
D.	**Safety**			
1.	Alarm	Audiovisual alarm for motor blower trip Should be provided		
E.	**MOC Certificates**	Should be provided		
F.	**Calibration Certificates**	Should be provided		
G.	**Testing Certificates**	Should be provided		
H.	**Drawing Details**	**Drawing No.**		
1.	Drawing of Horizontal Laminar Air Flow Unit	……..		

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Annexure - III

List of Changes / Deviations

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

Verified By:

Approved By:

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Annexure - VI

Summary Report of Installation Qualification

Checks	Observations (Yes / No)	Reviewed By Sign / Date
All test procedures executed and verified as per the protocol.		
All criteria set forth in the installation qualification were met.		
Deviation if any		

Summary:

_____

_____

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Summary Report Prepared By:

Date & Sign