User Requirement Specifications
Laminar Air Flow Unit

URS Annexure List:

URS Annex No.	Detail
1	Excel sheet showing room location, quantity and dimension details of LAF unit

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1.0 APPROVAL SIGNATURE

This document is prepared by the Process, Validation and GMP Compliance team of "NNE Pharmaplan India" for the project "Integrated Vaccine Complex, Chengalpattu, Chennai" (**project number:** 120310) of HLL BIOTECH LIMITED (Chennai) under the authority of their Project Manager. Hence, this document before being effective shall be reviewed by the QA team of HBL, approved by Team lead and authorized by the appropriate Project authority.

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2.0 EQUIPMENT DESCRIPTION

A LAFU is used to Carry out aseptic operations.

All points of the IRS except the below mentioned would be applicable for the equipment

- 4.1.11
- FDA Guidance for industry- Documentation for sterilization Process Validation
- ASME, ANSI / NSF 49-2008, EN12469
- ISO 8362
- 5.2.7, 5.2.8

Note:

I.	This Technical Specification is the basis for an inquiry to a vendor and therefore the basis for the vendor's proposal.
II.	The vendor is asked to state in "REMARKS" column with "yes" if the described requirement will be completely fulfilled and with "no" in case the requirement will not or cannot be fulfilled with the proposed equipment. In case of any deviation a comment must be inserted or enclosed as a separate annexure by referring to the respective URS specification number.
III.	The vendor must clearly comment each item of the Technical Specification. The comments must be in English language. If extra cost for necessary options becomes necessary the item must be clearly stated.
IV.	In case that the requirement includes a question or request or an information from the vendor, the answer / information should be stated in the "REMARKS" column.
V.	The final version of this document including the vendor's comments will become basis of a potential purchase order or contract.
VI.	The Technical Specification serves to define a summary of all vendor's requirements concerning scope of delivery and services.
VII.	The vendor is responsible for technically unobjectionable function of the equipment. This TS is not intended to dictate a technical design to the vendor. If agreed upon with the vendor, the vendor can apply his practically proven design.
VIII.	Special Instruction a. If no comments against any specification should be considered as "NO" and b. If there is no reply / comments against the complete URS by the vendor then it should be treated as unresponsive / technically non-compliant and rejected.
IX.	All the instruments and controls mentioned in the URS(s) are expected to be standard supply and part of your standard equipment model. In case of any deviation or redundancy or additional scope of supply is noticed, vendor is required to obtain clarification from HBL

	before submitting the quotes.
X.	The makes requested are standard international makes. In case of any deviation, vendor to seek clarification from HBL before submitting the offers.
XI.	Refer document Installation Requirement Specification and Specific Instructions with URS; NPI-120310-IRS-S1-01
XII.	Refer Tender document with URS; NPI-120310-EQP-S1-TD-14

Specifications	Remarks
3.0 PROCESS DESCRIPTION	
3.1 Input & Charging method	
The LAFU is used to Carry out aseptic operations.	
3.2 Brief Process Steps	
3.2.1 U V lamp and blower in the LAF will be switched on prior to using the LAFU.	
3.2.2 When the UV lamp is switched-off the blower should be in "ON" mode till the completion of process activity.	
3.2.3 The front sash will be opened by sliding movement to place the product / accessories inside the LAFU.	
3.2.4 LAF's use vertical / horizontal laminar airflow to create a barrier to product & Environment.	
3.3 Output & Discharging method	
The product / accessories etc. will be removed from the LAFU through the adjustable sash opening after completion of process activity	
4.0 PRODUCTIVITY REQUIREMENT	
4.1 Desired/ suggested capacity	
The capacities and operating temperatures of equipment is defined in URS annexure-1	
4.2 Standard batch size	
Not Applicable	
4.3 Change Over Time	
Not Applicable	
4.4 Other Productivity Requirement	
Not Applicable	
5.0 CONTAINMENT	
A SS spill containment tray with same MOC as the LAFU work bench should be provided below the work bench.	
6.0 GMP REQUIREMENTS	
6.1 Process control	
Equipment should be controlled using HMI provided with inbuilt battery.	
6.2 Failure mode detection	
6.2.1 Equipment shall be capable to detect the following failure, notify the operator with alarm and shutdown the process:	
6.2.1.1 Blower motor overload	

Specifications	Remarks
6.2.2 Following condition (not limited to the mentioned below) need only notification to operator for procedural control	
6.2.2.1 Audible and visual alarm for low air flow	
6.2.2.2 The UV lamp shall be interlocked with blower, sash, fluorescent lamp and UV lamp can be switched on only when the front sash is completely closed, and UV lamp should be automatically switched off when the sash is raised.	
6.2.2.3 Change of HEPA filter alarm/ indication	
6.2.2.4 Alarm in case of differential pressure across HEPA filter is out of limit	
6.2.2.5 Alarm shall be triggered if the front door is raised more than safe clear opening during Operation	
6.3 In –Process control	
Not applicable	
6.4 Level of instrumentation	

Sufficient and suitable instrumentation for the process, safety and productivity control as indicated in the following table:

Type of control	Purpose	Instrumentation
Differential Pressure	Monitor the pressure drop of the HEPA (H-14) filter w.r.t the ambient pressure	Microprocessor control to provide current filter condition
Air velocity	To measure the laminarity of air	Air velocity sensing device with continuous digital display on the LED
Speed controller	To maintain the stable motor voltage and airflow despite building voltage fluctuations	Microprocessor based speed controller
Movement of Sash opening (Manual /Motorized)	For the Manual / motorized upward and downward movement of Front sash.	Microprocessor based Movement of sash.
UV Lamp with Hour meter	UV radiation	with digital hour meter On/Off automation(Timer) for exposure time with Manual Switch

6.5 Batch data display and record printing			
Not applicable			
6.6 Technical Specification			
6.6.1	Model	cGMP compliant Class 100 (ISO 5) Laminar Flow Unit	
6.6.2	External dimension(W X D XH ,mm)	Vendor to specify	

	Specifications		Remarks
6.6.3	Internal dimension (W X D XH ,mm)	Refer URS annexure-1	
6.6.4	Positioning of the LAFU work bench from floor level	Minimum 750mm	
6.6.5	Type & Capacity	Vertical Laminar Air Flow type a)Unidirectional Laminar Air Flow type b)Double Stage filtration	
6.6.6	Pre- Filter	EU EN779Class G3Efficiency 95% down to 5 µ	
6.6.7	HEPA Filter	EU EN 1822 Class H14 / ISO 29463 Class 45H Efficiency >>99.995% down to 0.3 µ	
6.6.8	UV light	a) UV light emitting lamp with Hour meter The minimum operate able life of UV Lamp should be 8000 hr & light emitted shall be short-wave UV radiation with a peak at 253.7 nm (UV-C) for germicidal action. The hour meter should be able to be manually re-set. b) UV light with digital Hour Meter	
6.6.9	Air flow rate	0.45 ± 20 % m/s	
6.6.10	Electrical Requirement	Power Consumption: ***Vendor to specify Battery*** 220-230 V, 50 Hz , Single phase	
6.6.11	Total quantity	Refer URS annexure-1	
6.7	**Material of Construction**		
6.7.1	Body Construction	SS 304, min 240 grit	
6.7.2	Support Stand	SS 304, min 240 grit	
6.7.3	Coving	SS in built	
6.7.4	Internal Work bench	SS 316 L , Surface finish <1.2 Ra	
6.7.5	Panel facing towards the operator	UV protected safety glass to be provided	
6.7.6	Side and Back Panels	SS 304	
6.7.7	MOC Fan	Aluminium or SS 304	
6.7.8	Safety Glass	Should provide protection to the operator from product splash and UV light	
6.7.9	Wheels	Non shedding Teflon/PU with lockable castor wheels	
6.7.10	All welds shall be ground finish		
6.8	**Specific Equipment requirement**		
6.8.1	LAFU shall comply ISO Class 5 (Grade A as per WHO)		
6.8.2	Angled arm support made of SS316 L before work bench shall be provide for the		

	Specifications	Remarks
	ease of the operator	
6.8.3	Automatic controlled front glass sash adjustment shall be provided with safe clear opening	
6.8.4	Blower System shall be balanced for vibration free operation and noise level.	
6.8.5	The dead working table shall be SS 316 L with minimal vibration. One piece formed stainless steel work surface	
6.8.6	2 no.- Magnehelic gauge to be provided to monitor the differential pressure across the HEPA filter	
6.8.7	2no. Electrical switch/ sockets shall be provided within the LAFU with SS cladding flushed with cabinet walls.	
6.8.8	Soft touch controls for blower, light, outlet and UV shall be provided along color coded indicator (different for each application)	
6.8.9	The UV lamp shall be interlocked with blower, sash, fluorescent lamp and UV lamp can be switched on only when the front sash is completely closed, otherwise it should give alarm	
6.8.10	Pre-filters should be ergonomically positioned for periodic cleaning.	
6.8.11	LAFU shall be provided with fluorescent lamp suitable to provide minimum 1000 lux level. The fluorescent/UV lamp should be positioned in a manner that it is not in in direct visual contact of the operator	
6.8.12	Sleeving for accommodating the pre filters should be provided	
6.8.13	Mechanical adjustment of the level of LAFU should be provided	
6.8.14	LED display for motor operation.	
6.8.15	Entire Work Bench should not have Perforation. Preferred area for perforation is on the outside periphery of workbench.	
6.9	**Regulatory guidelines / standards**	
6.9.1	ISO 14644 – 1 (For Cleanliness Class)	
6.9.2	DIN EN 1822 and ISO 29463 (Filter Class)	
6.9.3	DIN EN779 (2012) for Filter Efficiency	
6.9.4	IEST-RP-CC002.2 (Cabinet performance)	
6.9.5	IEST-RP-CC001.3, CC007.1, CC034.1 (Filtration)	
6.9.6	IEC 61010-1 (Electrical safety)	
6.10	**Safety requirements**	
6.10.1	Following facilities must be provided to protect personnel and equipment:	
6.10.2	Emergency stop function on accessible area.	
6.10.3	Noise level below 65 decibel.	
6.10.4	Appropriate closure of all the rotating parts.	
6.11	**Other requirement**	
6.11.1	Support stand shall be adjustable with manual lift.	

	Specifications	Remarks
6.11.2	Cleaning shall be done manually	
6.11.3	All bolts, nuts shall be of dome type made of SS304.	
6.11.4	Vendor to give code numbers for each component	
6.11.5	There shall be no crevices, so as to avoid particle accumulation	
6.11.6	In general the equipment has to be designed in a way to get easy and quick access for cleaning and maintenance of all necessary partse. g. motors, filters, etc.	
6.11.7	The design shall be maintenance friendly for the ease of replacement of filters	
6.11.8	All parts of the machine exposed in A/B area must be resistant to standard disinfectants or vendor shall provide the name of compatible disinfectants	
6.11.10	Failure mode detection	
6.11.11	Equipment shall be capable to detect the following failure, notify the operator with alarm and shutdown the process:	
	a) Blower motor overload.	
	b) LAFU blower is stopped.	
	C) Chocking of HEPA	
6.11.12	Following condition need only notification to operator for procedural control:	
	a) Differential pressure across the HEPA filter not within the limit	
6.11.13	The following test to be conducted at site during qualification	
	a. Air velocity test	
	b. Filter Integrity Test	
	c. Flow Visualization by smoke pattern (videography)	
	d. Total Non-viable Particle Count	
	e. Recovery Test	
	f. Lux Level and UV light intensity	
	g. Sound Level	
6.12	**Documents**	
6.12.1	DQ Documentation as per the user approved format.	
6.12.2	IQ-OQ- PQ Documentation as per the user approved format.	
6.12.3	Operation and maintenance manuals; preventive maintenance instruction & schedule for equipment major component as well as the operating system. Control system operation manual. Cleaning procedures to be provided.	
6.12.4	Spare and/ or change parts list with ordering information.	
6.12.5	MOC certificates for all product ,contact surfaces ,components etc.	
6.12.6	Comprehensive 1 year warranty from the date of installation	
7.0	**CONSTRAINTS**	
7.1	**Equipment location and available space**	
	Refer URS Annexure-1 for the locations of the equipment	

Specifications	Remarks
7.2 Utility	
a) Electricity: Single Phase (220 V)	

8.0 ABBREVIATION

Abbreviation	Definition
CFC	Chlorofluorocarbon
CFR	Code of Federal Regulations
DQ	Design Qualification
FDA	Food and Drug Administration
GMP	Good Manufacturing Practice
HBL	HLL Biotech Limited
HMI	Human Machine Interface
IQ	Installation Qualification
ISO	International Standards Organization
LAFU	Laminar Air Flow Unit
MOC	Material Of Construction
NPI	NNE Pharmaplan India Limited
OQ	Operational Qualification
PAO	Poly Alpha Olefin
PQ	Performance Qualification
QA	Quality Assurance
RH	Relative Humidity
SS	Stainless steel
TBD	To be discussed
UPS	Uninterrupted Power Supply
URS	User Requirement Specifications

9.0 REVISION INDEX

Revision	Date	Reason for revision
00	28-02-2015	First Draft for Client's Review
01	17-06-2015	Updated as per client comments

HLL BIOTECH LIMITED,							
nne pharmaplan	INTEGRATED VACCINES COMPLEX, CHENGALPATTU Document Name: URS Annexure-1: LAFU List Document number: NPI_120310_EQP_URS_LAF_01 Date / Revision: 17-06-2015 / 01						IIBL
Sl. No	Room Number	Room Name	Equipment code	Dimensions in mm	Quantity	Room height, mm	Remark
QC BLOCK							
1	Q1S043	Water test lab	Q1-LAF 01	Vertical type, Internal Dimension Internal Dimension 1.55(L) x 0.62(W) x0.65 (H) , Maximum Height of the unit shall be 1.8 mtr.	1	2400	
2	Q1S065	Sterility test lab (Bacterial)	Q1-LAF 02	Vertical type, Internal Dimension 1.85(L) x 0.62(W) x0.65 (H) , Maximum Height of the unit shall be 2.1 mtr.	1	2400	
3	Q1S067	Sterility test lab (viral)	Q1-LAF 03		1	2400	
4	Q1S052	Sterlised Media Store	Q1-LAF 04	Vertical type, Internal Dimension 1.25(L) x 0.62(W) x0.65 (H) , Maximum Height of the unit shall be 1.8 mtr.	1	2400	
VIRAL VACCINES FORMULATION BLOCK							
5	F1G036	Blending / Formulation Room	F1-LAF 01	Internal Dimension 1.55(L) x 0.65(W) x0.65 (H) , Maximum Height of the unit shall be 1.8 mtr.	1	4000	
6	F1G030	Disinfection Preparation	F1-LAF 02	Internal Dimension 1.55(L) x 0.65(W) x0.65 (H) , Maximum Height of the unit shall be max 1.8 mtr.	1	3000	
7	F1G028	Buffer Preparation	F1-LAF 03	Internal Dimension 1.55(L) x 0.65(W) x0.65 (H) , Maximum Height of the unit shall be 1.8 mtr.	1	3500	
8	F1G072	Preparation & Sterilization Material Loading	F1-LAF 04	Internal Dimension 1.85(L) x 0.62(W) x0.65 (H) , Maximum Height of the unit shall be 2.1 mtr.	1	3000	
9	F1G081	Blending and Formulation Room	F1-LAF 05	Internal Dimension 1.55(L) x 0.62(W) x0.65 (H) , Maximum Height of the unit shall be 1.8 mtr.	1	4000	
RABIES BULK BLOCK							
10	B4G027	Filtration Room	B4-LAF 01 B4-LAF 02	Internal Dimension 1.55(L) x 0.65(W) x0.65 (H) , Maximum Height of the unit shall be 1.8 mtr.	2	2700	
11	B4G029	Disinfectant Preparation	B4-LAF 02	Internal Dimension 1.55(L) x 0.65(W) x0.65 (H) , Maximum Height of the unit shall be 1.8 mtr.	1	2700	
Hepatits-B (MBB)BLOCK							
12	B1G036	Sterile Filtration Room	B1-LAF 01	Internal Dimension 2.0(L) x1.0(W) x0.65 (H) , Maximum Height of the unit shall be 1.8 mtr.	1	3000	
13	B1G019	Media Preparation Room	B1-LAF 02	Internal Dimension 1.55(L) x 0.65(W) x0.65 (H) , Maximum Height of the unit shall be 1.8 mtr.	1	3000	
HIB(MBB)BLOCK							
14	B1G036	Sterile Filtration Room	B1-LAF 03	Internal Dimension 2.0(L) x1.0(W) x0.65 (H) , Maximum Height of the unit shall be 1.8 mtr.	1	3000	
WAREHOUSE BLOCK							
15	W1G033	Dispensing room-1	W1-LAF 01	Internal Dimension 1.55(L) x 0.65(W) x0.65 (H) , Maximum Height of the unit shall be 1.8 mtr.	1	3000	
16	W1G034	Dispensing room-2	W1-LAF 02	Internal Dimension 1.55(L) x 0.65(W) x0.65 (H) , Maximum Height of the unit shall be 1.8 mtr.	1	3000	
17	W1G031	Sampling room	W1-LAF 03	Internal Dimension 1.55(L) x 0.65(W) x0.65 (H) , Maximum Height of the unit shall be 1.8 mtr.	1	3000	