User Requirement Specifications
Mobile LAF

URS Annexure List:

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

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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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nne pharmaplan	User Requirement Specifications				HBL
	Equipment/System	Mobile LAF			
	Identification #:	-	Document No:	URS/MLF 01	
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2.0 EQUIPMENT DESCRIPTION

The mobile LAF is used for aseptic manipulation and for transfer of sterile materials.

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
- 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 mobile LAF is used for aseptic manipulation and for transfer of sterile materials.	
3.2	**Brief Process Steps**	
3.2.1	U V lamp and blower in the LAF should be switched on for prior to using the LAF.	
3.2.2	UV lamp should be switched off but the blower should be kept on till the end of the process.	
3.2.3	The front sash should be opened, the product / accessories to be placed inside.	
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. should be removed from the LAF through the door.	
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 spill tray should be provided underneath 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	

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. Also it should give alarm.	
6.2.2.3	Change of HEPA filter alarm/ indication	
6.2.2.4	Alarm in case of differential pressure across HEPA filter out of limit	
6.2.2.5	Alarm shall be triggered if the front door is raised more than safe clear opening during operation	
6.2.2.6	Alarm in case of Low Battery	

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 based controller to show the current filter status.
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
UV light with Hour meter	UV radiation	with digital hour meter On/Off automation(Timer) for exposure time with Manual Switch
Battery	To monitor the battery Health	Digital Voltmeter with Controller.

6.5	**Batch data display and record printing**		
	Not applicable		
6.6	**Technical Specification**		
6.6.1	Model	cGMP	
6.6.2	External dimension (W X D XH ,mm)	vendor to specify	
6.6.3	Internal dimension (W X D XH ,mm)	Refer section 4.1	
6.6.4	Type & Capacity	a) Uni-directional positive type b) Double Stage filtration c) Horizontal / vertical air flow d) Front and back sides shall be covered and side should be openable type (for loading and unloading material)	
6.6.5	Pre- Filter	EU EN779Class G3Efficiency 95% down to 5 µ	
6.6.6	HEPA Filter	EU EN 1822 Class H14 / ISO 29463 Class 45H Efficiency >>99.995% down to 0.3 µ	
6.6.7	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	
6.6.8	Air flow rate	0.45 ±20 % m/s	
6.6.9	Electrical Requirement	Power Consumption: ***Vendor to specify, 220-230 V, 50 Hz Single phase*** ***Battery backup with inverter for minimum of 2 hours.***	
6.6.10	Total quantity	As per 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	Working Table	SS 316L	
6.7.5	Side Panels	UV protected safety glass	
6.7.6	Back Panels	SS 304	
6.7.7	MOC Fan	Aluminum or SS 304	
6.7.8	Safety Glass	UV protected safety glass	
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	LAF shall comply with ISO Class 5 (Grade A as per EU CGMP)	
6.8.2	Direct Drive centrifugal blowers for vibration free operations	
6.8.3	2 no.- Magnehelic gauge to be provided to monitor the differential pressure across the HEPA filter	
6.8.4	Soft touch controls for blower and light	
6.8.5	It shall be provided with sliding door from top to bottom	
6.8.6	LAF shall be provided with tear drop light fitting suitable to provide minimum 1000 lux level	
6.8.7	Battery backup with inverter for at-least 2 hours along with chargeable point. So that LAF can work on battery as well as direct electrical supply	
6.8.8	Pre-filters should be easily detachable for periodic cleaning.	
6.8.9	Fully automatic AC / DC changeover system.	
6.8.10	Lighting through diffusers with switch control and it shall have one three-pin plug outside panel.	
6.8.11	Sleeving for accommodating the pre filters.	
6.8.12	Side access panel for final filters and blowers.	
6.8.13	LED display for motor operation.	
6.8.14	Battery shall be kept closed with self-roll cable wire min 6 meter length to be provided in proper and secure enclosure	
6.9	**Regulatory guidelines / standards**	
6.9.1	ISO 14644	
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.	
6.10.5	In the event of equipment malfunction or loss of utilities, the unit must contain all necessary protection devices to ensure that the equipment and the product remain in a safe condition.	
6.11	**Other requirement**	
6.11.1	Antistatic lockable Castor wheels shall be provided	

6.11.2	Cleaning shall be done manually	
6.11.3	All bolts, nuts shall be of dome type of SS304 material	
6.11.4	Vendor to give code numbers for each component	
6.11.5	There shall be no crevices, so as to avoid dust accumulation	
6.11.6	In general the equipment has to be designed in a way to get easy and quick access to all necessary maintenance points e. 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 specific disinfectants	
6.11.9	The heat given off by the unit must be stated (inside the room).	
6.11.10	Failure mode detection	
6.11.11	A. Equipment shall be capable to detect the following failure, notify the operator with alarm and shutdown the process:	
	a) Blower motor overload	
	b) LAF blower is stop	
	C) Chocking of HEPA	
6.10.15	B. Following condition need only notification to operator for procedural control:	
	a) Differential pressure across the HEPA filter not within the limit	
6.10.17	The following test to be conducted at site during qualification	
	a. Air velocity test	
	b. Filter Integrity Test	
	c. Flow Visualization Test (videography)	
	d. Non-viable Particle Count	
	e. Recovery Test	
	f. Lux 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	

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 Ltd
HMI	Human Machine Interface
IOQ	Installation operation and qualification
IQ	Installation Qualification
ISO	International Standards Organization
LAF	Laminar Air Flow
MLF	Mobile Laminar Air Flow
MOC	Material Of Construction
NPI	NNE Pharmaplan India LTD
OQ	Operational Qualification
PAO	Poly alpha olefin
PQ	Performance Qualification
QA	Quality Assurance
RH	Relative Humidity
SS	Stainless steel
TBD	To be discussed
HEPA	High Efficiency Particulate Air
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						HIBL HLL BIOTECH LIMITED
	Document Name:	URS Annexure-1:Mobile LAF List					
	Document number:	NPI_120310_EQP_URS_MLF_01					
	Date / Revision:	17-06-2015 / 01					
Sl. No	**Room Number**	**Room Name**	**Equipment code**	**Description**	**Quantity**	**Room Height, mm**	**Remark**
BACTERIAL FORMULATION BLOCK							
1	F2G011	Sterile Buffer	F2-MLF 01	Vertical Air Flow (1500 x 620 x900 mm)	1	3000	
2	F2G028	Blending	F2-MLF 02	Horizontal Air Flow (1500 x 620 x900 mm)	1	4000	
VIRAL VACCINE FORMULATION BLOCK - RABIES							
3	F1G043	Vial Filling	F1-MLF 01	Vertical Air Flow (1500 x 620 x900 mm)	1	3000	
4	F1G043	Vial Filling	F1-MLF 02	Vertical Air Flow (1200 x 620 x900 mm)	1	3000	
VIRAL VACCINE FORMULATION BLOCK - MEASLES							
5	F1G086	Vial Filling	F1-MLF 03	Vertical Air Flow (1500 x 620 x900 mm)	1	3000	
RABIES BULK BLOCK							
6	B4G057	Purification	B4-MLF 01	Vertical Air Flow (1500 x 620 x900 mm)	1	3000	