User Requirement Specifications
Biosafety Cabinet (Class II Type A2)

Table of Contents

1. APPROVAL SIGNATURE 4
2. EQUIPMENT DESCRIPTION 6

REMARKS 6

3. PROCESS DESCRIPTION 8
   - 3.1 INPUT & CHARGING METHOD 8
   - 3.2 BRIEF PROCESS STEPS 8
   - 3.3 OUTPUT & DISCHARGING METHOD 8
4. PRODUCTIVITY REQUIREMENT 8
   - 4.1 DESIRED/ SUGGESTED CAPACITY 8
   - 4.2 STANDARD BATCH SIZE 8
   - 4.3 CHANGE OVER TIME 8
   - 4.4 OTHER PRODUCTIVITY REQUIREMENT 8
5. CONTAINMENT 8
6. GMP REQUIREMENTS 9
   - 6.1 PROCESS CONTROL 9
   - 6.2 FAILURE MODE DETECTION 9
   - 6.3 IN –PROCESS CONTROL 9
   - 6.4 LEVEL OF INSTRUMENTATION 10
   - 6.5 BATCH DATA DISPLAY AND RECORD PRINTING 10
   - 6.6 TECHNICAL SPECIFICATION 10
   - 6.7 MATERIAL OF CONSTRUCTION 11
   - 6.8 GMP REQUIREMENTS (OTHERS) 11
   - 6.9 SPECIFIC REQUIREMENTS 12
   - 6.10 FAILURE MODE DETECTION 13
   - 6.11 REGULATORY GUIDELINES/STANDARDS: 13
   - 6.12 DOCUMENTS 14
7. CONSTRAINTS 14
   - 7.1 EQUIPMENT LOCATION AND AVAILABLE SPACE 14
   - 7.2 AVAILABLE UTILITY 14
8. ABBREVIATION 15
9. REVISION INDEX 15

URS Annexure List:

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

HLL BIOTECH LIMITED, CHENNAI

INTEGRATED VACCINES COMPLEX, CHENGALPATTU

nne pharmaplan	User Requirement Specifications			
	Equipment/System	Biosafety Cabinet (Class II Type A2)		
	Identification #		Document No.	URS/BSC-01
	Effective Date		Revision#	03

1. APPROVAL SIGNATURE

This document is prepared by the Process, Validation and GMP Compliance team of "NNE Pharmaplan India" for the project "Integrated Vaccines 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 HBL user/s and project/ engineering team, approved by team lead of user department and QA and authorized by the appropriate Project Authority.

NNE Pharmaplan India Limited			
Name	**Designation**	**Signature**	**Date**
Prepared by			
Mr. Kiran Kumar M S	Engineer - Process	Kiran	
Checked by			
Mr. Yogesha M J	Process Engineer	yogesha-m j	
Approved by			
Mr. Vikas Katial	GM – Projects (SME) & Head COC		

HLL Biotech Limited			
Name	**Designation**	**Signature**	**Date**
Reviewed by			
User Department (Quality Control Block)	MANAGER		
User Department (Rabies Bulk block)	Dy. MANAGER - VIRAL VACCINE		
User Department (Animal House Block)	Deputy Manager		
User Department (MBB Block - Hib)	Sr. MANAGER		
User Department (MBB Block – Hep B)	Assistant Manager		
User Department (BCG Bulk and Formulation)	Deputy Manager		
Project / Engineering Department	DY. MANAGER (HVAC)		
Approved By			
Head of User Department (Quality Control Block)	Dy.M		

HLL BIOTECH LIMITED, CHENNAI

INTEGRATED VACCINES COMPLEX, CHENGALPATTU

nne pharmaplan	User Requirement Specifications			HBL HLL BIOTECH LIMITED
	Equipment/System	Biosafety Cabinet (Class II Type A2)		
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Dr. Nilakshi Veerasundaran			
Dr. K. A. Arul Anand	Manager	K. A. Arul Anand	
M.V. SUBRAHMANYAM	Head Vaccines Development	M.V. Subrahmanyam	
G. NARASIMHA REDDY	Sr. Manager	G. Narasimha Reddy	
RENJITH. M. C BCG	Manager		
A. Suresh Babu	DGM	A. Suresh Babu	
Authorized by			
Appropriate Project Authority	CEO		

2. EQUIPMENT DESCRIPTION	REMARKS
A Biosafety Cabinet (BSC) is an enclosed, ventilated laboratory workspace and provides the primary barrier protection for Personnel & Product from Biological Material. BSC protects the operator and environment from aerosols or droplets produced during aseptic procedures Following type of cabinet shall be considered: **Class II type A2**: 70% air from the positive plenum is re-circulated within the cabinet through ULPA (U15) filter and 30% is discharged to the environment through the U15 exhaust filter. Velocity of airflow to the work zone creates an aseptic environment for product protection. This cabinet will be used for aseptic operations like culturing, harvesting etc. • Installation of BSC's must allow access to both supply and exhaust filters for annual certification testing and filter changes: • Top of cabinet must be far enough below the ceiling (at least 18" except QC block) to allow field testing of exhaust flow according to NSF49. The Supplier should provide calibration protocols and guidelines for preparing SOPs for recalibration.	

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. I n case of an 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 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 shall be considered as "NO" and b. If there is no reply / comments against the complete URS by the vendor then it shall 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
XIII.	**All points of the IRS except the below mentioned would be applicable for the equipment** 4.1.11 5.1- Table 2, point 3 FDA guidance for industry for sterilization equipment. ASME ISO 8362 5.2.7, 5.2.8

Specifications	Remarks
3. PROCESS DESCRIPTION	
3.1 Input & Charging method	
3.1.1 The product / accessories etc. will be placed inside the BSC through the front panel with Sliding sash.	
3.2 Brief Process Steps	
3.2.1 BSC's are designed to provide aseptic work environment and provide protection ULPA for product & personnel.	
3.2.2 UV lamp and blower in the biosafety cabinet should be switched on before the process and the blower should be kept on till the end of the process.	
3.2.3 The front sash will be opened by sliding movement to place the product / accessories inside the BSC	
3.2.4 BSC's use vertical laminar airflow to create a aseptic barrier between product & cleanroom	
3.2.5 The unit should have a unique design and strategically located ULPA filters made of non-woven superior grade pleated media.	
3.3 Output & Discharging method	
3.3.1 The product / accessories etc. should be removed from the BSC through the adjustable front sash opening after completion of the procedure	
4. PRODUCTIVITY REQUIREMENT	
4.1 Desired/ suggested capacity	
The capacities 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. CONTAINMENT	
A SS spill containment tray with same MOC as the BSC work bench should be provided below the work bench with a SS Tap.	

6. GMP REQUIREMENTS

6.1 Process control

6.1.1 Differential Pressure	
6.1.2 Air Velocity	
6.1.3 Speed Control of motor	

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, and should give alarm.	
6.2.2.3 Change of ULPA filters alarm/ indication.	
6.2.2.4 Alarm in case of differential pressure across ULPA 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	

6.3 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 ULPA (U15) filter w.r.t the ambient pressure.	Microprocessor control (It should display the Current Filter Condition).
Air velocity	To measure the velocity of Air and to maintain the positive and negative plenum of the cabinet.	Air velocity sensing device with continuous digital display on the LED
Motor speed controller	To maintain the stable motor voltage and airflow despite building voltage fluctuations.	Microprocessor based speed controller
UV Lamp with Digital Hour meter	UV radiation. On/Off automation with Timer for exposure time Manual Switch.	UV light with Hour meter

6.5 Batch data display and record printing

Not Applicable

6.6 Technical Specification

6.6.1	Model	cGMP compliant Class 100 (ISO 5) Biosafety Cabinet	
6.6.2	Internal dimensions (W X D XH ,mm)	As per URS annexure-1	
6.6.3	External dimensions (W X D XH ,mm)	Vendor to specify	
6.6.4	Fixed positioning of the BSC work bench from floor level	Minimum 750mm	
6.6.5	ULPA (U15) (Ultra Low Penetration Air filter	Efficiency of 99.9995% at MPPS .0.3 Micron	
6.6.6	Pre-filter	EU EN779Class G3Efficiency 95% down to 5 µ	
6.6.7	Air flow rate	0.45 ±20 % m/s	
6.6.8	UV light	UV light emitting lamp with Hour meter The minimum operate able life of UV Lamp should be 5000 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.	

6.6.9	Noise level	<65 db	
6.6.10	Operating RH	20 to 80%	
6.6.11	Operating temperature, °C	10 to 50	
6.6.12	Illumination	1000 LUX	
6.6.13	Electrical Requirement	Power Consumption: ***Vendor to specify, 220-230 V, 50 Hz Single phase***	
6.6.14	Total quantity	As per URS annexure-1	

6.7 Material of Construction

6.7.1	Cabinet 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	Interior Working Table	SS 316L ,< 1.2 Ra	
6.7.5	MOC Fan	Aluminum or SS	
6.7.6	Safety Glass	Should provide protection to the operator from product splash and UV light	
6.7.7	All welds shall be ground finish		

6.8 GMP requirements (Others)

6.8.1 Moving parts between the technical and the clean areas are not permitted. Necessary shafts and moving parts have to be tightly sealed.	
6.8.2 Illumination • Unit to be provided with adequate illumination at the work table by means of fluorescent light panel concealed at the upper portion of the unit. • The illumination at the work table is to be minimum 1000 Lux	
6.8.3 Ultraviolet Light i. Optimal wattage of UV light to be incorporated for sanitization of the chamber area ii. The UV lamp installed shall be mounted out of the operator's line of sight and the radiation output should not be less than 40 microwatts per square centimeter at a wavelength of 253.7 nanometers (nm). iii. UV light with Hour Meter (UV Life : Minimum 5000 Hours)	
6.8.4 All metallic non product contact surface finish should be not more than 1.2 Ra	
6.8.5 The equipment shall be tested and validated with the following test: i. Microbial testing with specific microorganisms according to the NSF49 guidelines. This includes: personnel protection test, product protection test, cross contamination test ii. Inflow and outflow velocity test iii. Air flow pattern visualization test	

iv. Light/ noise/ vibration test And other GMP compliance test (or other contamination test) for BSC performance and safety. Vendor shall provide certificates (NSF49) and perform test and validate the equipment after the installation.	
6.8.6 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	
6.9 Specific requirements	
6.9.1 In general the equipment has to be designed in a way to get easy and quick access to all necessary maintenance points e. g. Filters, Motors, etc.	
6.9.2 All switches should be ergonomically located for operator convenience.	
6.9.3 All setting should be user adjustable with password.	
6.9.4 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	
6.9.5 BSC shall be provided with fluorescent lamp suitable to provide minimum 1000 lux level. The fluorescent lamp should be positioned in a manner that it is not in in direct visual contact of the operator	
6.9.6 Soft touch controls for blower, light, outlet and UV shall be provided along color coded indicator (different for each application)	
6.9.7 The Vendor shall ensure maintenance parts availability for a minimum of 36 months from commissioning.	
6.9.8 ULPA (U15) should be provided : • ISO Class 5 needs to be maintained inside the BSC during operation	
6.9.9 Laminated safety glass front sash • Optimum resistance to and filtering of germicidal UV radiation and standard surface disinfectants. • Higher optical quality and less reflection and glare off of glass surface. • High tolerance to heat and cleaning agents. • The interlayer should dampen the sound significantly • Tilted front panel for operator ease.	
6.9.10 Airflow velocity sensor shall be provided to overcome the filter choking and to maintain the inward flow velocity of 0.45m/s ± 20%.	
6.9.11 Automatic speed control of motor (VFD) shall be provided to overcome the filter choking and to maintain the inward flow velocity of 0.45 m/s ± 20%.	

6.9.12 Two electrical sockets, (single outlets on 230 volt models), located one Inside on each side and covered with stainless steel covers.	
6.9.13 The interior work area is formed from a single piece of stainless-steel with large radius for easy cleaning	
6.9.14 Integrated sash Proximity sensors which contacts sense proper sash position, serve as an interlock for the UV lamp, and activate an alarm if the sash is improper positioned.	
6.9.15 POA test port to be provided.	
6.9.16 Sanitation cycle (germicidal UV radiation) shall be taken care of after resuming power.	
6.9.17 All MOCs shall be made of durable type and have to be resistant against surface cleaning and wiping disinfecting using common detergents, disinfectants (chlorine free) and 70% Ethanol / IPA.	
6.9.18 The SS316 work tray shall be integrated with the front air grille, for joint-free construction.	
6.9.19 The main body and support stand to be SS304, min 240 grit. The support stand to be provided with castor wheels with lockers made of PU castor/Teflon.	
6.9.20 All side panels shall be SS 304 with min. 240 grit	
6.9.21 The inner Surface of the bio safety cabinets to be SS 316 L with single sheet.	
6.9.22 Blower: a) Blower shall be permanently lubricated b) Motor blower assembly MOC; Aluminum/SS304	
6.9.23 Preferred make for Motor Blower assembly: EBM-PAPST / Nicotra / Kruger / Zeil-Abegg./ABB/Crompton	
6.9.24 Internal and external dampers and sealant should be cGMP compliant	
6.9.25 Following condition need only notification to operator for procedural control:	
6.9.26 Differential pressure across the ULPA filter not within the limit	
6.10 Failure mode detection	
6.10.1 Inward & Outward Velocity not within the limit.	
6.10.2 Equipment shall be capable to detect the following failure, notify the operator with alarm and shutdown the process:	
6.10.3 Blower motor overload and BSC Blower is stopped.	
6.11 Regulatory Guidelines/Standards:	
• ISO 14644 – 1 (For Cleanliness Class)	
• NSF49 (Biosafety Cabinet)	
• DIN EN779 (2012) for Filter Efficiency	
• IEST-RP-CC002.2 (Cabinet performance)	

- IEST-RP-CC001.3, CC007.1, CC034.1 and EN 1822 (H14) (Filtration)
- IEC 61010-1 (Electrical safety)

6.12 Documents

- DQ Documentation as per the User approved format.
- IOQ & PQ Documentation as per the user approved format.
- 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.
- Spare and/ or change parts list with ordering information.
- MOC certificates for all product contact surfaces.
- Comprehensive 1 year warranty from the date of Installation.

7. CONSTRAINTS

7.1 Equipment location and available space

This equipment will be installed in the **Integrated Vaccines Complex**, Chengalpattu. Refer URS Annexure-1 for locations of equipment in the respective buildings.

7.2 Available Utility

a) Electricity: _____(Report Requirement)

8. ABBREVIATION

Abbreviation	Definition
BSC	Biosafety Safety Cabinet
MOC	Material of Construction
GMP	Good Manufacturing Practice
ULPA	Ultra Low Penetration Air filter
ISO	International Organization of Standardization
LED	Light Emitting Diode
MPPS	Most Penetrating Particle Size
NPI	NNE Pharmaplan India
NSF/ ANSI	National Safety Foundation/ American National Standard Institute
PAO	Poly alpha olefin
QA	Quality Assurance
SOP	Standard Operating Procedures
SS	Stainless steel
UV	Ultra Violet

9. REVISION INDEX

Revision	Date	Reason for revision
00	14-03-2014	First Draft for Client's Review
01	12-11-2014	Updated as per client inputs dated 11-11-2014.
02	23-06-2015	Updated as per client inputs dated 04-06-2015.
03	13-07-2015	Updated as per comments received by HBL dated 08-07-2015

HLL BIOTECH LIMITED,							
nne pharmaplan	INTEGRATED VACCINES COMPLEX, CHENGALPATTU						HBL HLL BIOTECH LIMITED
	Document Name:	URS Annexure-1: BSC (A2 type) List					
	Document number:	NPI_120310_EQP_URS_BSC_01					
	Date / Revision:	13-07-2015 / 03					
Sl. No	Room Number	Room Name	Equipment code	Inner Dimensions in mm	Quantity	Room height, mm	Remark
RABIES BULK BLOCK							
1	B4G036	Cell Culture	B4-BSC-01	Internal Dimension 1.270 mm (L) x 0.65 mm (W) x0.65 mm (H) , Maximum Height of the unit shall be 1.8 mtr.	1	2700	
2	B4G038	Cell Lab - 1	B4-BSC-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	
3	B4G046	Virus Propagation	B4-BSC-03	Internal Dimension 1.55(L) x 0.65(W) x0.65 (H) , Maximum Height of the unit shall be 1.8 mtr.	1	2700	
4	B4G046	Virus Propagation	B4-BSC-04	Internal Dimension 1.270(L) x 0.65(W) x0.65 (H) , Maximum Height of the unit shall be 1.8 mtr.	1	2700	
5	B4G048	Virus Seed Lab	B4-BSC-05	Internal Dimension 1.55(L) x 0.65(W) x0.65 (H) , Maximum Height of the unit shall be 1.8 mtr.	1	2700	
6	B4G057	Purification	B4-BSC-06	Internal Dimension 1.55(L) x 0.65(W) x0.65 (H) , Maximum Height of the unit shall be 1.8 mtr.	1	3000	
7	B4G057	Purification	B4-BSC-07	Internal Dimension 1.55(L) x 0.65(W) x0.65 (H) , Maximum Height of the unit shall be 1.8 mtr.	1	3000	
8	B4G060	Clarification	B4-BSC-08	Internal Dimension 1.55(L) x 0.65(W) x0.65 (H) , Maximum Height of the unit shall be 1.8 mtr.	1	2700	
QUALITY CONTROL BLOCK							
9	Q1S037	Rabies/JE BSC + Titration + Advent	Q1-BSC-01	Internal Dimension 1.55(L) x 0.62(W) x0.65 (H) , Maximum Height of the unit shall be 1.8 mtr.	1	2400	
10	Q1S038	Rabies BSC + Titration + Advent	Q1-BSC-02	Internal Dimension 1.55(L) x 0.62(W) x0.65 (H) , Maximum Height of the unit shall be 1.8 mtr.	1	2400	
11	Q1S039	Measles BSC + Titration + Advent	Q1-BSC-03	Internal Dimension 1.55(L) x 0.62(W) x0.65 (H) , Maximum Height of the unit shall be 1.8 mtr.	1	2400	
12	Q1S071	BSC Rabies/JE	Q1-BSC-04	Internal Dimension 1.55(L) x 0.62(W) x0.65 (H) , Maximum Height of the unit shall be 1.8 mtr.	1	2400	
13	Q1S072	BSC Measles	Q1-BSC-05	Internal Dimension 1.55(L) x 0.62(W) x0.65 (H) , Maximum Height of the unit shall be 1.8 mtr.	1	2400	

Sl. No	Room Number	Room Name	Equipment code	Inner Dimensions in mm	Quantity	Room height, mm	Remark
14	Q1S045	Microbiology Lab	Q1-BSC-06	Internal Dimension 1.85(L) x 0.62(W) x0.65 (H) , Maximum Height of the unit shall be 2.1 mtr.	1	2400	
ANIMAL HOUSE BLOCK							
15	G1G056	Sample Preparation (Main Testing Area)	G1-BSC-01	Internal Dimension 1.55(L) x 0.62(W) x0.65 (H) , Maximum Height of the unit shall be 1.8 mtr.	1	3000	
16	G1G048	Post Mortem Room - Testing	G1-BSC-02	Internal Dimension 1.55(L) x 0.62(W) x0.65 (H) , Maximum Height of the unit shall be 1.8 mtr.	1	3000	
17	G1G094	Post Mortem Room - Breeding	G1-BSC-03	Internal Dimension 1.55(L) x 0.62(W) x0.65 (H) , Maximum Height of the unit shall be 1.8 mtr.	1	3000	
MULTIPLE BACTERIAL BULK BLOCK							
18	BIG006	Seed Lab	B1-BSC-01	Internal Dimension 1.55(L) x 0.62(W) x0.65 (H) , Maximum Height of the unit shall be 1.8 mtr.	1	3000	
19	BIG109	Seed Lab	B1-BSC-02	Internal Dimension 1.55(L) x 0.62(W) x0.65 (H) , Maximum Height of the unit shall be 1.8 mtr.	1	3000	
BCG BULK AND FORMULATION BLOCK							
20	F4G021	Harvest & Purification	F4-BSC-01	Internal Dimension 1.55(L) x 0.62(W) x0.65 (H) , Maximum Height of the unit shall be 1.8 mtr.	1	3000	
21	F4G028	Seed Room	F4-BSC-02	Internal Dimension 1.55(L) x 0.62(W) x0.65 (H) , Maximum Height of the unit shall be 1.8 mtr.	1	3000	