

HLL BIOTECH LIMITED Solutions & Services Group Department of Health & Safety	User Requirement Specifications		
	Equipment/System	Fume Hood	
	Identification #:	-	Document No: URS/FMH 01
	Effective Date:		Revision No: 01

User Requirement Specifications Fume Hood

HLL BIOTECH LIMITED, CHENNAI

INTEGRATED VACCINES COMPLEX, CHENGALPATTU

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URS Annexure List:

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

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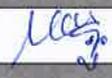
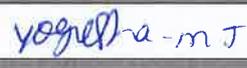
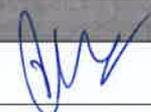
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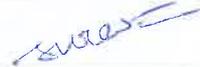
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1.0 APPROVAL SIGNATURE

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.

NNE Pharmaplan India Limited			
Name	Designation	Signature	Date
Prepared by			
Mr. Manohar M S	Process Engineer		
Checked by			
Mr. Yogesha M J	Process Engineer		
Approved by			
Mr. Vikas Katial	GM – Project (SME) & Head COC Vaccines		

HLL Biotech Limited			
Name	Designation	Signature	Date
Reviewed by			
SANJEEV KUMAR R (Quality control)	MANAGER		
SURESH (User Department MBB-Hib)	SO. MANAGER		
HARSHAD DABHI Project / Engineering Department	DY. MANAGER (HVAC)	H.B. Dabhi	
Approved By			
Head of User Department (Quality Control)	DM		
Head of User Department (MBB-Hib)	Head Vaccines Development	M.V. Subrahmanyam	
Head of User Department (QA)	DM		
Authorized by			
Project Authority	CEO		

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2.0 EQUIPMENT DESCRIPTION

The fume hood is used to protect personnel from hazardous chemical fumes.

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

- 4.1.11, 4.1.13, 4.1.17
- FDA Guidance for industry- Documentation for sterilization Process Validation
- 21 CFR Part 11
- ISO 8362
- ANSI/NSF 49-2008
- 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

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	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

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HLL BIOTECH LIMITED CHENGALPATTU CHENNAI 600044 TEL: 044-26100000 FAX: 044-26100001 E-MAIL: hll@hllbiotech.com	User Requirement Specifications				
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Specifications		Remarks									
3.0	PROCESS DESCRIPTION										
3.1	Input & Charging method										
	The fume hood is used to protect personnel from hazardous chemical fumes.										
3.2	Brief Process Steps										
	Not Applicable										
3.3	Output & Discharging method										
	Not Applicable										
4.0	PRODUCTIVITY REQUIREMENT										
4.1	Desired/ suggested capacity										
	Internal dimensions of equipment are 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										
	Not applicable										
6.0	GMP REQUIREMENTS										
6.1	Process control										
	Equipment should be controlled using microcontroller										
6.2	In -Process control										
	Not applicable										
6.3	Level of instrumentation										
Sufficient and suitable instrumentation for the process, safety and productivity control as indicated in the following table:											
<table border="1"> <thead> <tr> <th>Type of control</th> <th>Purpose</th> <th>Instrumentation</th> </tr> </thead> <tbody> <tr> <td>Air velocity</td> <td>To measure the velocity of air</td> <td>Air velocity sensing device with continuous digital display on the LED</td> </tr> <tr> <td>Speed controller</td> <td>To maintain the stable motor voltage and airflow despite building voltage fluctuations</td> <td>Micro based speed controller</td> </tr> </tbody> </table>			Type of control	Purpose	Instrumentation	Air velocity	To measure the velocity 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	Micro based speed controller
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Specifications	Remarks
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6.4 Batch data display and record printing	
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Not applicable	
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6.5 Technical Specification	
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6.5.1	Model	cGMP	
6.5.2	External dimension(W X D XH ,mm)	Vendor to specify	
6.5.3	Internal dimension(W X D XH ,mm)	Refer URS annexure-1	
6.5.4	Maximum Sash Opening	740 mm or As approved by client	
6.5.5	Duct Collar	Vendor to specify	
6.5.6	Face Velocity	0.41 m/s	
6.5.7	Static pressure rate	Vendor to specify	
6.5.8	Electrical Requirement	To be compatibility to the standard Indian Power supply sockets UPS connection for exhaust blower and control system to be provided	
6.5.9	Quantity	Refer URS annexure-1.	

6.6 Material of Construction	
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6.6.1	Hood exterior	Epoxy Coated Electro polished Steel	
6.6.2	Hood interior	SS 304 powder coated	
6.6.3	Hood lining	Epoxy coated steel	
6.6.4	Base cabinet	SS 304	
6.6.5	Safety glass	7/32" thick laminated safety glass	
6.6.6	Front sash /Door	Toughened Glass	
6.6.7	Back Panels	SS 304	
6.6.8	All welds shall be ground finish		

6.7 Specific Equipment requirement	
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6.7.1	Internal access panels on side walls facilitate access to plumbing connections for service.	
6.7.2	Removable front panel shall be provided for easy access to lighting and electrical.	
6.7.3	Baffles should be able to remove to allow cleaning inside the hood.	
6.7.4	Rear baffle arrangements shall be provided for internally adjustable baffles.	
6.7.5	Blower System shall be balanced for vibration free operation and noise level.	
6.7.6	Vertical sashes should be provided for full face opening.	
6.7.7	It should have sink fixtures and fittings.	
6.7.8	It Should be provided with airtight, gasket-sealed door to prevent leakages.	
6.7.9	Soft touch controls for blower, light and outlet.	

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Specifications		Remarks
6.7.10	Sash shall be easily operated manually.	
6.7.11	Base cabinet should have rear access panel, soft close door, adjustable shelf, base cabinet height leveler, base cabinet filler panel, MCB/ELCB set and ventilation provision.	
6.7.12	Flush airfoil sill should be provided for comfortable usage.	
6.7.13	Front panel shall be Slanted/Vertical	
6.7.14	It shall be provided with fluorescent lamp suitable to provide minimum 450 lux level	
6.7.15	Side viewing panels shall be provided	
6.7.16	Hood should consist of sash with sash handle and horizontal sash, worktop, service panel, control panel FAZ or AC, service modules in the fume hood side wall, upper sash window, removable front filler panel, extra manifold and baffle with scaffold points.	
6.7.17	Exhaust blower shall be connected to UPS power	
6.7.18	Provision shall be provided to have utilities like cooling water, WFI, Air, chilled water, purified water inside the hood	
6.8 Regulatory guidelines / standards		
6.8.1	ASHRAE 110-1995	
6.8.2	EN 1417	
6.9 Safety requirements		
6.9.1	Noise level should be below 65 decibel at a distance of 1m from the equipment	
6.9.2	Chamber shall be insulated properly to maintain inner environment	
6.9.3	Scrubber to be considered for equipment B1-FMH 01 (refer URS annexure-1 for details of equipment location)	
6.10 Other requirement		
6.10.1	Cleaning shall be done manually	
6.10.2	All bolts, nuts shall be of dome type of SS304 material	
6.10.3	Vendor to give code numbers for each component	
6.10.4	There shall be no crevices, so as to avoid dust accumulation	
6.10.5	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.	
6.10.6	The design shall be maintenance friendly for the ease of replacement of filters	
6.10.7	Vendor to submit detailed fabrication drawing for approval before fabrication.	
6.11 Documents		
6.11.1	IOQ Protocol.	
6.11.2	Operation and maintenance manuals.	
6.11.3	Vendor should provide warranty Letter for Minimum 1 year, from the date of installation	
6.11.4	Vendor should provide list of standard spare parts with ordering information.	
6.11.5	Vendor should provide list of change parts (if applicable) with ordering information	

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Specifications		Remarks
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) & 3 phase (420 - 440 V) (Report Requirement) b) Compressed air 6 bar (Report Requirement) c) Cooling water (Report Requirement) d) Chilled water (Report Requirement) e) Purified water (Report Requirement) f) WFI (Report Requirement)	
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
IQ	Installation Qualification
ISO	International Standards Organization
MOC	Material Of Construction
NPI	NNE Pharmaplan India LTD
OQ	Operational Qualification
PQ	Performance Qualification
QA	Quality Assurance
RH	Relative Humidity
SS	Stainless steel
TBD	To be discussed
UPS	Uninterrupted Power Supply
URS	User Requirement Specifications
FMH	Fume Hood

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9.0 REVISION INDEX

Revision	Date	Reason for revision
00	28-02-2015	First Draft for Client's Review
01	23-06-2015	Updated as per client comments dated 15.06.2015

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HLL BIOTECH LIMITED, INTEGRATED VACCINES COMPLEX, CHENGALPATTU								
Document Name: URS Annexure-1: Fume Hood URS								
Document number: NPI-120310-EQP-URS-FMH 01								
Date / Revision: 23-06-2015 / 01								
SI. No	Room Number	Room Name	Equipment name	Equipment ID	Description	Quantity	Room height, mm	Remark
QC BLOCK								
1	Q1S022	Chemical Lab / Bio Chemistry	Fume Hood	Q1-FMH 01	Internal Dimension 1.2(L) x 0.6(W) x 1.6(H)	1	2400	
2				Q1-FMH 02		1	2400	
3				Q1-FMH 03		1	2400	
Hib(MBB) BLOCK								
5	BIG133	Conjugation Purification Room	Walk in Fume Hood (To be used for Cynogen Bromide)	B1-FMH 01	Internal Dimension 1.3 m (L) x 0.67 m(W) x 1.6 m (H) , Maximum Height of the unit shall be 2.2 m	1	3000	
6	BIG136	Polysaccharide Purification Room	Walk in Fume Hood (To be used for Pure Ethanol)	B1-FMH 02	Internal Dimension 1.3 m (L) x 0.67 m(W) x 1.6 m (H) , Maximum Height of the unit shall be 2.2 m	1	3000	



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	Document Name:	URS Annexure-2: Fume Hood Scrubber		
	Document number:	NPI-120310-EQP-URS-FMH 01		
	Date / Revision:	27-07-2015 / 01		
1	General			
2	Service	Scrubber		
3	Construction type	Spray scrubber + packed tower		
4	Quantity	1		
5	Process Conditions			
6	Gas		Cyanogen Bromide	
7	Type of Scrubber		Spray nozzles followed by packed column	
8	Gas flow Rate	Nm ³ /hr	Vendor to Specify	
9	Gas inlet temperature	Deg. C	Max 60	
10	Gas inlet pressure	mBar	Vendor to Specify	
11	Spray Scrubber			
12	Scrubbing Liquid		Soft Water	
13	Flow rate	m ³ /hr	Vendor to Specify	
14	Pressure	Bar (g)	Vendor to Specify	
15	Suction / Discharge / Motive Size	NB	Vendor to Specify	
16	Packed Tower			
17	Scrubbing Liquid		Re circulated water	
18	Tower		Cylindrical, flanged	
19	Packing		Pall Rings / Rashing ring / vendor to specify	
20	Size		vendor to specify	
21	Tower (Diameter / Height)	mm	vendor to specify	
22	Packing Height	mm	vendor to specify	
23	Tower Thickness	mm	vendor to specify	
24	Pressure Drop Across the Tower	mm WC	vendor to specify	
25	MOC		Corrossion and chemical resistant	
26	Packed Tower shell		PP-FRP with binding agent as Super Vinyl Ester	
27	Packing		PP	
28	Tower Internal (Packings, Mist.Eliminator, Spary cone nozzle, Support Plate etc)		PP-FRP with binding agent as Super Vinyl Ester	
29	Storage cum Circulation Tank For Dilution Fluid			
30	Height	mm	vendor to specify (to be designed to fit in the technical area having the clear height of 3.5 m)	
31	Diameter	mm	vendor to specify	
32	Volumetric Capacity	Lit	vendor to specify	
33	Material of Construction		PP-FRP with binding agent as Super Vinyl Ester	
34	Thickness of tank	mm	vendor to specify	
35	Glass tube level indicator	1 No.	Required (Consider Isolation Valve & Drain Valve)	
36	Provision for sampling		required	
37	Nozzle for pH / conductivity meter in pump suction line	1	required	
38	Note: Support Arrangement (FRP lining) To Be Considered To Hold spray nozzles & Packed Coloumn.			
39	General			
40	Filter in the recirculation line	-	Required (manually cleanable)	
41	Diameter of main header (for water inlet)	mm	vendor to specify	
42	Gaskets		Soft Teflon, Neoprene	
43	FRP Piping connection between fume hood and scrubber	-	Required	
44	Interlock between fume hood and scrubber	-	Required	
45				
46	Recirculation Pump			
47	Type of pump		Back Pull Type, Centrifugal Pump	
48	Make		Antico	
49	Model		Vendor to specify	
50	Quantity	No.	One	
51	Capacity	m ³ /hr	Vendor to Specify based on fume hood capacity	
52	MOC		Corrossion and chemical resistant	
53	Casing		SS304 With PP Coating	
54	Impeller		SS304 With PP Coating	

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55	Shaft		EN 19	
56	Shaft sleeve		SS304 With PP Coating	
57	Type of seal		Teflon Bellow Seal with Ceramic base	
58	Seal make		Flowserve/EPIL	
59	Blower			
60	Make		ABB/Kruger/Crompton Greaves	
61	Model		Vendor to specify	
62	Quantity	No	One	
63	Capacity	m3/hr	Vendor to Specify	
64	Pressure	mmWC	Vendor to Specify	
65	MOC		FRP	
66	Impeller		FRP Lining	
67	Absorb Power	KW	Vendor to Specify	
68	Note: Pressure Selection Of The Blower Should Be Equilibrium With Exust Pressure Of Packed Coloum			
69	Other accessories required			
70	PVC moisture eliminator		required	
71	Control panel		required	
72	inter connecting piping		required	
73	Documents Required			
74	Pump test certificates			
75	Pump performance curves			
76	Pump operating and installation manual			
77	Spares list and contact Nos. to be provided			
78	Mechanical seal drawing			
79	Blower and Motor test certificates			
80	Blower performance curves			
81	Blower operating and installation manual			
82	General Requirements and Notes			
83	Performance guarantee			
84	Pressure drop across the scrubber			
85	Running trails for the scrubbing efficieny as per PCB norms.			
86	Vendor to consider the spares required for Installation and chemicals for trials.			
87	Vendor to quote per R.Mtr basis for all sizes of ducts and cables with thickness proposed Including supports, fittings & Valves.			
88	Cable Specification: 3 core x 1.5 Sq.mm. armoured copper conductor (2XWY), Make: Polycab, RPG			
89	FRP Duct Specification: FRP ducting using 3mm thick PPGL sheets with 2 mm thick FRP lining using polyester resin including flanges & bends.			