

HLL Biotech Pharmaplan	User Requirement Specifications			 <small>HLL BIOTECH LIMITED                  Subsidiary of HLL Health Care                  &amp; Government of India Hospital</small>	
	Equipment/System	Air Shower			
	Identification #:	-	Document No:		URS/ASH 01
	Effective Date:		Revision No:		01

## User Requirement Specifications Air Shower

Block Code	Block Name	Identification #	Minimum internal dimensions (W x D x H), m	Qty [Nos]
G1	Animal House	G1-ASH-01 G1-ASH-02	(1.5 x 1.5 x 2.1)	2

**HLL BIOTECH LIMITED, CHENNAI**

**INTEGRATED VACCINES COMPLEX, CHENGALPATTU**

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**URS Annexure List:**

URS Annex No.	Detail
1	Layout / Schematic showing room locations of Air Shower in the layout

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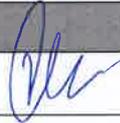
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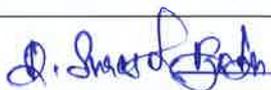
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**1.0 APPROVAL SIGNATURE**

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.

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**2.0 EQUIPMENT DESCRIPTION**

Air showers are self-contained chambers installed at entrances from general areas to controlled areas. They help in minimizing the particulate matter entering or exiting the clean space. The personnel entering or exiting the controlled environment are scrubbed by high velocity HEPA filtered air jets with velocities of minimum 22 m/s. The air inside the air shower is drawn from the base within the unit, filtered and recirculated.

**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

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XII.	Refer Tender document with URS; NPI-120310-EQP-S1-TD-14
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Specifications		Remarks
<b>3.0</b>	<b>PROCESS DESCRIPTION</b>	
<b>3.1</b>	<b>Input &amp; Charging method</b>	
	Not Applicable	
<b>3.2</b>	<b>Brief Process Steps</b>	
	The personnel entering or exiting the controlled environment are scrubbed by high velocity HEPA filtered air jets with velocities of minimum 22 m/s.	
<b>3.3</b>	<b>Output &amp; Discharging method</b>	
	Not Applicable	
<b>4.0</b>	<b>PRODUCTIVITY REQUIREMENT</b>	
<b>4.1</b>	<b>Desired / suggested capacity</b>	
	Required dimensions of equipment are defined in URS annexure-1 <b>No of persons per cycle</b> : 2-3 persons per cycle <b>Cycle Time</b> : -Settable up to 120 Seconds	
<b>4.2</b>	<b>Standard batch size</b>	
	Not Applicable	
<b>4.3</b>	<b>Change Over Time</b>	
	Not Applicable	
<b>4.4</b>	<b>Other Productivity Requirement</b>	
	Not Applicable	
<b>5.0</b>	<b>CONTAINMENT</b>	
	Not applicable	
<b>6.0</b>	<b>GMP REQUIREMENTS</b>	
<b>6.1</b>	<b>Process control</b>	
	The entire control of the air shower shall be with a microprocessor control system. The LCD display shall display shower duration and countdown and reports cycle progress and operational status. A 24 hour clock shall display local time.	
<b>6.2</b>	<b>In –Process control</b>	
	Not applicable	
<b>6.3</b>	<b>Level of instrumentation</b>	
	Sufficient and suitable instrumentation for the process, safety and productivity control as indicated in the following table:	

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<b>Specifications</b>			<b>Remarks</b>
<b>Type of control</b>	<b>Purpose</b>	<b>Instrumentation</b>	
Door Interlocks	To keep the doors in Close Position until the Cycle finish.	Both Doors shall be Interlocked.	
Blower ON/OFF	To start /Stop the Blower as per the Cycle timing.	It shall be interlocked with Doors.	
Light ON/OFF	To Start/Stop the Light	It shall be interlocked with Doors.	

**6.4 Batch data display and record printing**

Not applicable

**6.5 Technical Specification**

6.5.1	Model	cGMP	
6.5.2	Entry /Exit Direction	L- Type	
6.5.3	External dimension(W X D XH ,mm)	Refer URS annexure-1	
6.5.4	Internal dimension(W X D XH ,mm)	Vendor to specify .(Approval to be taken from Client)	
6.5.5	Filter type	HEPA filter type H-13 Efficiency >>99.99% down to 0.3 μ	
6.5.6	Air Cleanliness	ISO Class 5	
6.5.7	Light source	CFL lights with milky diffusers ensure even and uniform lighting throughout the chamber	
6.5.8	Noise Level	< 60 dB	
6.5.9	Interlock	Light & Blower shall be interlocked with electromagnetic type door interlocking system.	
		Entry and exit Door interlock to be provided	
6.5.10	IP Rating of blower	IP54	
6.5.11	Electrical Requirement	To be compatibility to the standard Indian Power supply sockets	
6.5.12	Quantity	Refer URS annexure-1	

**6.6 Material of Construction**

6.6.1	Exterior sheet	Electro galvanized steel sheets of minimum 1.5 mm thickness with an abrasion resistant oven baked epoxy powder coated finish
6.6.2	Interior Sheet	Cabinet made of IS 304 Grade stainless steel construction with matt finish(SS 304 smoothed to 240 grit can also be considered)
6.6.3	Door Assembly	Heavy duty durable aluminum framed, constructed with glass windows (minimum 5 mm thick toughened glass) permitting

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<b>Specifications</b>	<b>Remarks</b>
	visibility shall be provided along with hydraulic door closer and lockset

<b>6.7 Specific Equipment requirement</b>		
6.7.1	Air shower shall be a two way type i.e.; personnel may enter or exit the controlled areas through the air shower. In both directions the air shower shall be activated.	
6.7.2	The doors to be provided with door closures to withstand the internal chamber pressure	
6.7.3	The shower shall utilize a fresh air pre-filter made from Non-Woven Synthetic with HDPE mesh and Al expanded mesh on air leaving side; conforms to EU 4 Grade, with efficiency of 90% down to 10 micron.	
6.7.4	The pre filters shall be cleaned by compressed air & also washable and a final filter of mini pleat HEPA filter type made from water resistant, fire retardant, imported micro fine glass fiber media; conforms to EU - 14 Grade, with an efficiency rating better than 99.99% for 0.3 μ.	
6.7.5	The filters shall be designed to accommodate higher airflow volume.	
6.7.6	The air shall be pumped through minimum 6 nozzles (made of stainless steel) from each sides of the chamber and 2 Nozzles from Top and the return shall be collected from the bottom through return air grills (preferably stainless steel). The minimum air changes per hour shall be not less than 350/hr.	
6.7.7	Statically and dynamically balanced permanently lubricated motor blower combination shall be utilized for suction of return air (& as a booster, designed for supply of sufficient capacity and static pressure to take care of airflow requirement for entire life of HEPA can be utilized) alternatively a blower motor assembly with variable frequency drives can be utilized	
6.7.8	Magnehelic gauges shall be utilized for measuring the pressure drop across the HEPA filter.	
6.7.9	Indicator lamps for the locked or unlocked status of the shower shall be provided along with the emergency buttons mounted on both external faces of the air shower. Emergency ON – OFF Rotary switch with indicator shall be provided inside the chamber also.	
6.7.10	CFL lights with diffusers shall be provided with light fittings (44w/m2) and on/off switches for light.	
6.7.11	All the validation test including airflow checking, filter integrity testing, nonviable particle count test (ISO Class 9) and recovery test to be done and documented as per the ISO 14644-3 guidelines.	
6.7.12	The auto reset feature shall be provided for unlocks doors incase personnel open the air shower door but do not actually enter, thus preventing accidental lock outs.	
6.7.13	In case of a power failure, all doors should unlock automatically	

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Specifications		Remarks
<b>6.8 Regulatory guidelines / standards</b>		
6.8.1	ISO 14644	
6.8.2	EN-1822 (H13), Europe	
6.8.3	IEST-RP-CC001.3, USA	
6.8.4	IEST-RP-CC0007, USA	
6.8.5	IEST-RP-CC-002.2, USA	
6.8.6	IEST-RP-CC-034.1, USA	
6.8.7	IEC:61010-1	
<b>6.9 Safety requirements</b>		
6.9.1	All welds shall be ground finish	
6.9.2	Sharp edges to be prevented at accessible areas	
6.9.3	Safety and performance of the air shower should comply in accordance with international standards	
6.9.4	All electrical components shall be UL listed or UL Recognized.	
<b>6.10 Other requirement</b>		
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.	
6.10.8	Training for proper operation and maintenance to be included.	
<b>6.11 Documents</b>		
6.11.1	DQ document	
6.11.2	IQ & OQ Protocol.	
6.11.3	Operation and maintenance manuals.	
6.11.4	As built & electrical wiring drawings	
6.11.5	Test Certificates for HEPA, Pre Filters, Motor & blower, MOC of unit, Magnehelic gauge calibration, Hour meter	
6.11.6	GA and elevation drawings	
6.11.7	Vendor should provide warranty Letter for Minimum 1 year, from the date of supply	
6.11.8	Vendor should provide list of standard spare parts with ordering information.	
6.11.9	Vendor should provide list of change parts (if applicable) with ordering information	

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<b>Specifications</b>		<b>Remarks</b>
<b>7.0 CONSTRAINTS</b>		
<b>7.1 Equipment location and available space</b>		
<p>This equipment will be installed in the <b>Animal House block of Integrated Vaccines Complex, Chengalpattu.</b></p> <p>The equipment location is indicated in the relevant block of the layout enclosed as <b>URS Annex-1</b>. The equipment must be positioned as per the generic layout provided below.</p> <p><b>Physical condition of the rooms:</b></p> <ol style="list-style-type: none"> <li>Class: Grade CNC</li> <li>Differential Pressure: NA</li> <li>Temperature maintained: Not more than 25 °C</li> <li>Relative Humidity: Not more than 60%</li> </ol>		
<b>7.2 Utility</b>		
a) Electricity: Single Phase (220 V) & 3 phase (420 - 440 V) (Report Requirement)		
<b>8.0 ABBREVIATION</b>		

<b>Abbreviation</b>	<b>Definition</b>
CNC	Controlled Not Classified
DQ	Design Qualification
GMP	Good Manufacturing Practice
HBL	HLL Biotech Ltd
IQ	Installation Qualification
ISO	International Standards Organization
MOC	Material Of Construction
NPI	NNE Pharmaplan India LTD
OQ	Operational Qualification
NLT	Not Lower Than
QA	Quality Assurance
SS	Stainless steel
UPS	Uninterrupted Power Supply
URS	User Requirement Specifications
HEPA	High efficiency particulate air

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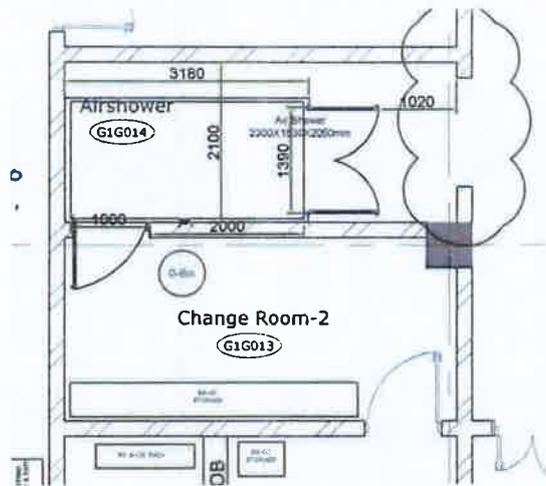
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**9.0 REVISION INDEX**

Revision	Date	Reason for revision
00	04-07-2015	First Draft for Client's Review
01	15-07-2015	Updated as per comments received by HBL on 15-07-2015

**URS Annexure 1: LAYOUT POSITION**



**Sample Schematic of Air Shower**

