

HLL pharmaplan	User Requirement Specifications			 <small>HLL BIOTECH LIMITED Ministry of Hi, Marine Biotech Government of Tamil Nadu</small>	
	Equipment/System	Dynamic Garment Cubicle			
	Identification #:	-	Document No:		URS/DGC 01
	Effective Date:		Revision No:		01

User Requirement Specifications

Dynamic Garment Cubicle

HLL BIOTECH LIMITED, CHENNAI

INTEGRATED VACCINES COMPLEX, CHENGALPATTU

nne pharmaplan	User Requirement Specifications			 <small>HLL BIOTECH LIMITED A Division of H. Ltd. in India 10, Government of India Street</small>	
	Equipment/System	Dynamic Garment Cubicle			
	Identification #:	-	Document No:		URS/DGC 01
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URS Annexure List:

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

HLL BIOTECH LIMITED, CHENNAI

INTEGRATED VACCINES COMPLEX, CHENGALPATTU

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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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HLL BIOTECH LIMITED, CHENNAI

INTEGRATED VACCINES COMPLEX, CHENGALPATTU

HLL BIOTECH LIMITED Chennai, Tamil Nadu 600 028	User Requirement Specifications		
	Equipment/System	Dynamic Garment Cubicle	
	Identification #:	-	Document No: URS/DGC 01
	Effective Date:		Revision No: 01

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Project Authority	CEO		

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HLL BIOTECH LIMITED, CHENNAI

INTEGRATED VACCINES COMPLEX, CHENGALPATTU

HLL BIOTECH LIMITED CHENNAI	User Requirement Specifications			 HLL BIOTECH LIMITED CHENNAI	
	Equipment/System	Dynamic Garment Cubicle			
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2.0 EQUIPMENT DESCRIPTION

Dynamic garment cubicles are used for storing the clean room garments in a visible and organized manner and to avoid the particulate contamination.

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

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Specifications	Remarks
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3.0 PROCESS DESCRIPTION

3.1 Input & Charging method

Cleanroom garments will be kept inside the dynamic garment cubicle manually.

3.2 Brief Process Steps

Not Applicable

3.3 Output & Discharging method

Not Applicable

4.0 PRODUCTIVITY REQUIREMENT

4.1 Desired/ suggested capacity

Required 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 microprocessor controller.

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:

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	Microprocessor 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	Cabinet type	Re-circulatory		
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		
6.5.5	Door type	240 grit with internally coved joints & with double leaf, double glazed view panel door		
6.5.6	Filter type	Minipleat HEPA filter type H-14		
6.5.7	Air Velocity	0.45 ± 20% m/s		
6.5.8	Light source	Fully flushed/Fully protected CFL and UV (protection with SS cage)		
6.5.9	Interlock	Light shall be interlocked (electromagnetic type) door		
6.5.10	Noise Level	< 65 dB		
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				
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6.6.1	Exterior sheet	SS 304, 18 gauge		
6.6.2	Door Handle	SS 304, 240 grit smoothed		
6.6.3	Hinges	SS 304, 240 grit smoothed		
6.6.4	Shelves	SS 304, 16 gauge, 240 grit smoothed		

6.7 Specific Equipment requirement				
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6.7.1	Magnetic latches shall be provided for keeping the doors closed.			
6.7.2	The Dynamic garment cubicles shall be floor mounted and legs to be provided with non-shedding nylon bush at the bottom.			
6.7.3	Dynamic garment cubicles shall not be flushed with the floor and shall have a minimum clearance of 150 mm for cleaning			
6.7.4	The Dynamic garment cubicles shall provide an ISO Class 5 air cleanliness.			
6.7.5	Permanently lubricated type blower shall be provided.			
6.7.6	The unit shall be provided with alarm for alerting the personnel's of an open/unattended door & blower failure, Low/High Air velocity.			
6.7.7	Visual indication for UV lamps, emergency push button, manual blower switch, separate manual switches for UV and CFL lights, SS304 smoothed to 240 grit grills for air suction etc shall be provided.			

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6.7.8	The equipment shall be provided with minimum two Shelves / Hanging Rod for storing garments, hair covers and socks.	
6.7.9	The Shelves/ Hanging Rod shall be provided with necessary stiffeners. Hanging Rod shall be provided with hangers.	
6.7.10	Top portion of the equipment shall be provided with a slope to assist in easier clean ability.	
6.7.11	By default the UV light inside the cubicle to be switched on when doors are closed which will be done by the user on activation of the manual switch.	
6.7.12	An interlock shall be incorporated by the vendor such that UV light shall switch off and CFL light switch on if the door of the cubicle is opened.	
6.7.13	Internal SS round pencil coving	
6.7.14	The following to be provided by vendor with the dynamic garment cubicles	
a.	Magnehelic gauges across HEPA (0-750 Pa) & Pre-Filter (0-300 Pa)	
b.	Door with UV absorbing double glazed view panel (minimum 5 mm thick ,UV absorbing toughened glass)	
c.	UV light with Hour meter. The minimum life of light 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 manually re-set.	
d.	Normal CFL (Lux level: min.500 Lux)	
e.	Pre filter : EU4 Grade (SS 304 frame with Non Woven Polyester media) with initial pressure drop of not more than 60 Pa and final pressure drop of not more than 120 Pa.	
f.	Final Minipleat HEPA filter : Separator less type H14 Grade (Aluminum anodized frame with micro fiber glass media) with initial pressure drop of not more than 250 Pa and final pressure drop of not more than 500 Pa.	
g.	Blower and motor assembly: Permanently lubricated type blower with S.S. Blower frame with external rotor with integrated electronics and the complete unit statically and dynamically balanced in two planes. The motor shall be with IP 54 protection and with maintenance-free ball bearings and permanent lubrication.	
h.	POA upstream port (and injection port if applicable)for HEPA filter	

6.8 Regulatory guidelines / standards

6.8.1	ISO 14644 – 1 (For Cleanliness Class)	
6.8.2	DIN EN779 (2012) for Filter Efficiency	
6.8.3	DIN EN 1822 and ISO 29463 (Filter Class)	
6.8.4	IEST-RP-CC002.2 (Cabinet performance)	
6.8.5	IEST-RP-CC001.3, CC007.1, CC034.1 (Filtration)	
6.8.6	IEC 61010-1 (Electrical safety)	

6.9 Safety requirements

6.9.1	All welds shall be ground finish	
6.9.2	Sharp edges to be prevented at accessible areas	

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	

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Specifications	Remarks
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6.10.3	Vendor to give code numbers for each component	
6.10.4	There shall be no crevices.	
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 ergonomic 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.	
6.10.9	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	

6.11 Documents

6.11.1	DQ document as per approved format	
6.11.2	IQ & OQ Protocol as per approved format	
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, UV light, Hour meter etc.	
6.11.6	GA and elevation drawings	
6.11.7	Vendor should provide warranty Letter for Minimum 1 year, from the date of Installation.	
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	

7.0 CONSTRAINTS

7.1 Equipment location and available space

Refer URS Annexure-1 for the locations of the equipment	
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7.2 Utility

a) Electricity: Single Phase (220 V)	
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8.0 ABBREVIATION

Abbreviation	Definition
DQ	Design Qualification
GMP	Good Manufacturing Practice
HBL	HLL Biotech Ltd
HEPA	High Efficiency Particulate Air
IQ	Installation Qualification
ISO	International Standards Organization
MOC	Material of Construction
NPI	NNE Pharmaplan India Ltd
OQ	Operational Qualification
PQ	Performance Qualification
PAO	Poly Alpha Olefin
QA	Quality Assurance
SS	Stainless steel
TBD	To be discussed
UPS	Uninterrupted Power Supply
URS	User Requirement Specifications
DGC	Dynamic Garment Cubicle

9.0 REVISION INDEX

Revision	Date	Reason for revision
00	03-07-2015	First Draft for Client's Review
01	15-07-2015	Updated As per comments received by HBL dated 14-07-2015

HLL BIOTECH LIMITED, INTEGRATED VACCINES COMPLEX, CHENGALPATTU							
HLL pharmaplan®	Document Name: URS Annexure-1: Dynamic Garment Cubicles List						
	Document number: NPI_120310_EQP_URS_DGC_01						
	Date / Revision: 15-07-2015 / 01						
Sl. No	Room Number	Room Name	Equipment Code	Description	Quantity	Room Height, mm	Remark
BACTERIAL VACCINES FORMULATION BLOCK							
1	F2G041	PAL-2 (Vial Washing)	F2-DGC 01	Approx. size : 720x865x2300mm	1	3000	
2	F2G016	PAL-3, Female(Grade C)	F2-DGC 02	Approx. size : 720x865x2300mm	1	3000	
3	F2G020	PAL-3, Male (Grade C)	F2-DGC 03	Approx. size : 720x865x2300mm	1	3000	
4	F2G033	PAL - 2 (Class B)	F2-DGC 04	Approx. size : 720x865x2300mm	1	3000	
VIRAL VACCINES FORMULATION BLOCK							
5	F1G032	PAL-2 (Class B)	F1-DGC 01	Approx. size : 720x865x2300mm	1	3000	
6	F1G078	PAL-2 (Class B)	F1-DGC 02, 03	Approx. size : 720x865x2300mm	2	3000	
HIB(MBB) BLOCK							
7	BIG104	PAL-1 (UpStream Entry)	B1-DGC 01	Approx. size : 900x400x1800mm	1	3000	
8	BIG115	PAL-2 (Media Prep. Entry)	B1-DGC 02	Approx. size : 900x400x1800mm	1	3000	
9	BIG130	PAL (Male Entry)	B1-DGC 03	Approx. size : 720x865x2300mm	1	3000	
10	BIG138	PAL (Female Entry)	B1-DGC 04	Approx. size : 720x865x2300mm	1	3000	
11	BIG140	PAL (Sterile Fill. Entry)	B1-DGC 05	Approx. size : 720x865x2300mm	1	3000	
HEPATITS-B(MBB) BLOCK							
12	BIG004	PAL-1 (UpStream Entry)	B1-DGC 06	Approx. size : 900x400x1800mm	1	3000	
13	BIG016	PAL-2 (Media Prep. Entry)	B1-DGC 07	Approx. size : 900x400x1800mm	1	3000	
14	BIG029	PAL (Male Entry)	B1-DGC 08	Approx. size : 720x865x2300mm	1	3000	
15	BIG031	PAL (Female Entry)	B1-DGC 09	Approx. size : 720x865x2300mm	1	3000	
16	BIG034	PAL (Sterile Fill. Entry)	B1-DGC 10	Approx. size : 900x400x1800mm	1	3000	
RABIES BULK BLOCK							
17	B4G043	Cell Culture /Entry	B4-DGC 01	Approx. size : 720x865x2300mm	1	2700	
18	B4G045	Virus Propagation/Entry	B4-DGC 02	Approx. size : 720x865x2300mm	1	2700	
19	B4G061	Purification/Entry	B4-DGC 03	Approx. size : 720x865x2300mm	1	2700	
20	B4G056	Inactivation /Entry	B4-DGC 04	Approx. size : 720x865x2300mm	1	2700	
21	B4G027A	Filtration Room/Entry	B4-DGC 05	Approx. size : 720x865x2300mm	1	2700	
BCG BLOCK							
22	F4G006	PAL (Grade C Entry)	F4-DGC 01	Approx. size : 720x865x2300mm	1	3000	
23	F4G053	PAL (Grade C Entry)	F4-DGC 02	Approx. size : 720x865x2300mm	1	3000	
24	F4G016	PAL (Grade B Entry)	F4-DGC 03	Approx. size : 720x865x2300mm	1	3000	
QC BLOCK							
25	Q1S033	Change room	Q1-DGC 01	Approx. size : 720x865x2300mm	1	2400	
26	Q1S060	Change room	Q1-DGC 02	Approx. size : 720x865x2300mm	1	2400	
27	Q1S061	Change room	Q1-DGC 03	Approx. size : 720x865x2300mm	1	2400	
WAREHOUSE							
28	W1G029	Change room	W1-DGC 01	Approx. size : 720x865x2300mm	1	3000	

HLL BIOTECH LIMITED, INTEGRATED VACCINES COMPLEX, CHENGALPATTU							
nne pharma plan	Document Name: URS Annexure-1: Dynamic Garment Cubicles List						
	Document number: NPI_120310_EQP_URS_DGC_01						
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6	F1G076	PAL-2 (Class B)	F1-DGC 02, 03	Approx size : 720x865x2300mm	2	3000	
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10	BIG138	PAL (Female Entry)	B1-DGC 04	Approx size : 720x865x2300mm	1	3000	
11	BIG140	PAL (Sterile Fill Entry)	B1-DGC 05	Approx size : 720x865x2300mm	1	3000	
HEPATITS-B(MBB) BLOCK							
12	BIG004	PAL-1 (UpStream Entry)	B1-DGC 06	Approx size : 900x400x1800mm	1	3000	
13	BIG016	PAL-2 (Media Prep Entry)	B1-DGC 07	Approx size : 900x400x1800mm	1	3000	
14	BIG029	PAL (Male Entry)	B1-DGC 08	Approx size : 720x865x2300mm	1	3000	
15	BIG031	PAL (Female Entry)	B1-DGC 09	Approx size : 720x865x2300mm	1	3000	
16	BIG034	PAL (Sterile Fill Entry)	B1-DGC 10	Approx size : 900x400x1800mm	1	3000	
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21	B4G027A	Filtration Room/Entry	B4-DGC 05	Approx size : 720x865x2300mm	1	2700	
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24	F4G016	PAL (Grade B Entry)	F4-DGC 03	Approx size : 720x865x2300mm	1	3000	
QC BLOCK							
25	Q1S033	Change room	Q1-DGC 01	Approx size : 720x865x2300mm	1	2400	
26	Q1S060	Change room	Q1-DGC 02	Approx size : 720x865x2300mm	1	2400	
27	Q1S061	Change room	Q1-DGC 03	Approx size : 720x865x2300mm	1	2400	
WAREHOUSE							
28	W1G029	Change room	W1-DGC 01	Approx size : 720x865x2300mm	1	3000	