User Requirement Specifications
Sampling / Dispensing Booth

URS Annexure List:

URS Annex No.	Detail
1	Layout showing location for the installation of the Sampling / Dispensing booths

Table of Contents

nne pharmaplan	User Requirement Specifications				HBL
	Equipment/System	Sampling/ Dispensing booth			
	Identification #:	-	Document No:	URS/DSB-01	
	Effective Date:		Revision No:	01	

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			
Ms. Niharika Ruhela	Engineer - Process	for. Megha	
Checked by			
Mr. Yogesha M J	Process Engineer	yogesha-m j	
Approved by			
Mr. Vikas Katial	GM & Head-COC Vaccines		

HLL Biotech Limited			
Name	**Designation**	**Signature**	**Date**
Reviewed by			
User department (Warehouse) K.R. RADHAKRISHNAN	DY. MANAGER (Planning)		
Project / Engineering Department HARSHAD DABHI	Dy. MANAGER (HVAC)	H.B. Dabhi	
Approved By			
Head of User Department (Warehouse) Dr. K. RAMAN	DVP		
Head of User Department (QA) R. Suresh Babu	DGM	R. Suresh Babu	
Authorized by			
Project Authority	CEO		

2.0 EQUIPMENT DESCRIPTION

The Dispensing Booth shall be used in dispensing, and sampling of raw 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, ASME
- 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 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 vendors' 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	
Not Applicable	
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	
VFD based control systems shall be provided	
6.2 In –Process control	
Not applicable	
6.3 Level of instrumentation	
Not Applicable	
6.4 Batch data display and record printing	
Not Applicable	

6.5	**Technical Specification**		
6.5.1	Model	cGMP Dispensing booth	
6.5.2	Overall Area (cu. Mm)	Vendor to Specify	
6.5.3	Working Area (cu. mm)	Refer Annexure-1	
6.5.4	Type	Reverse Laminar Air Flow type	
6.5.5	Design	Grade A (Class ISO - 5, as per ISO 14644-1)	
6.5.6	Machine compliance	EU GMP	
6.5.7	Pre Filter	Washable type pleated pre filter, efficiency vendor to specify	
		EU- 4 rating, size: vendor to specify	
		EU- 7 rating size: vendor to specify	
6.5.8	Filter rating	EU-4 90% down to 10µm	
		EU-7 95% down to 3µm	
		EU-14 99.997% down to 0.3 µm	
6.5.9	Minipleat HEPA Filter	0.3µm (EU - 14 rating) with frame box	
6.5.10	Exhaust HEPA Filter	0.3µm (EU - 14 rating) with suitable size (Not with a common frame with SS Grill)	
6.5.11	Air flow rate	0.45 m/s ± 20%	
6.5.12	Operating Pressure	vendor to specify	
6.5.13	Electrical Requirement	220 – 230 V AC, 1ph, 50 Hz	
6.5.14	Quantity	Refer Annexure-1	
6.5.15	Dimension	vendor to specify (booth size, HEPA filter frame size etc)	
6.6	**Material of Construction**		
6.6.1	Body Construction	SS 304, min 240 grit (puffed side panel wall)	
6.6.2	Gaskets, seals, O-rings	Food Grade/ nontoxic material Use of Asbestos is prohibited	
6.6.3	Coving	SS 304	
6.6.4	Working Table	SS 304, min 240 grit (puffed side panel wall)	
6.6.5	MOC Fan	Aluminum/ SS	
6.6.6	All welds shall be grounded and smoothened		
6.7	**Specific Equipment requirement**		
6.7.1	Motor Blower shall be statically and dynamically balanced for less vibration and noise level.		
6.7.2	The dead working table with perforation (Capsule Perforation) shall be SS type with zero vibration.		
6.7.3	3 no. Magnehelic gauge shall be provided (for intermediate-filter, HEPA filter, exhaust filter) exterior to the working area for pressure measurement (pressure drop).		

6.7.4	Dedicated electrical panel for booth (In built).	
6.7.5	2 no. Electrical switch/ sockets shall be provided with SS cladding flushed with dispensing booth walls.	
6.7.6	Soft Touch controller for motor and light	
6.7.7	PVC curtains shall be provided at the front of booth to maintain the air flow pattern. Length of the curtains shall be till 200-300mm above the gorund floor	
6.7.8	Booth shall be provided with fluorescent lamp suitable to provide minimum 450 lux level.	
6.7.9	Audio visual alarm system :a) audio/visual alarm for motor, b) clean down timer with indication, c)audio alarm system for pressure drop across the filter.	
6.7.10	Dead zone of ceiling area shall be considered as minimum as possible to get maximum laminar flow.	
6.7.11	POA test port to be provided	
6.7.12	The following test to be conducted at site during qualification 1. air velocity test 2. Filter Integrity Test 3. Flow Visualization Test (videography) 4. Non-viable Particle Count 5. Recovery Test 6. Lux Level 7. Sound Level	
6.7.13	Preferred make for Motor Blower Assembly: Crompton Greaves/ ABB/ GE/ Siemens/EBM-PAPST/Nicotra	
6.7.14	Safe Zone shall be defined by the vendor to perform operations.	
6.7.15	Cleaning shall be done manually.	
6.7.16	Vendor to submit detailed fabrication drawing for approval before fabrication. Detailed HEPA Filter fixing Arrangement shall be get approved before fabrication.	
6.7.17	Vendor to provide wall to wall coving for the equipment as well as floor to equipment coving at site	
6.7.18	Air changes per hour shall be consider to maintain ISO Class 5 as per ISO 14644 environment.	
6.7.19	Approved makes for filters: a) Camfil farr b) Freudenberg c) AAF	
6.8	**Regulatory guidelines / standards**	
6.8.1	ISO 14644 – 1 (For Cleanliness Class)	
6.8.2	ISO 14644 – 3 (For HEPA filter integrity testing & Velocity testing)	
6.8.3	EU-GMP-Guideline Part 1, Annexes 1, 11 & 15	
6.8.4	Schedule M of Indian Drugs and Cosmetics Act	

6.8.5	Code of Federal Regulations (CFR) 21, Part 210: cGMP in Manufacturing, Processing, Packing and Holding of Drugs	
6.9	**Safety requirements**	
	Following facilities must be provided to protect personnel and equipment:	
6.9.1	Emergency stop function on accessible area.	
6.9.2	No sharp edges/Corners, crevices, pin holes in the process wetted parts of the equipment.	
6.9.3	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.	
6.9.4	The heat given off by the unit must be stated.	
6.9.5	Arrangement of alternative power supply (UPS) to control and monitoring system and blower	
6.9.6	Noise level below 65 decible.	
6.10	**Documents**	
6.10.1	Vendor to submit detailed fabrication drawing for approval before fabrication.	
6.10.2	Post ordering and prefabrication stage of the equipment	
6.10.3	Functional design specification	
6.10.4	Equipment descriptions	
6.10.5	Equipment operation steps	
6.10.6	List of failure indications and interlocks (as applicable)	
6.10.7	Critical list of major component, devices and instruments with their specific functions, specs and data sheets.	
6.10.8	GA/ Schematic diagram of the equipment	
6.10.9	DQ specification as per client approved format	
6.10.10	IOQ specification as per client approved format	
6.10.11	Vendor shall provide the FAT protocol at least 1 month in advance of the date of FAT, for the approval by the user.	
6.10.12	System shall be inspected and tested (FAT) at the Vendor's site in the presence of user's representative before delivery.	
6.10.13	Vendor shall provide the following documents in the delivery package in minimum 2 sets. The delivery package shall reach the site of user at least 15 days before the delivery equipments for the engineering check of the documents.	
6.10.14	Shipping checklist.	
6.10.15	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.	
6.10.16	Operation and maintenance manuals for the bought out items (as applicable).	
6.10.17	Drawings: Electrical, instrumentation, final GA drawing etc.	

6.10.18	Spare and/ or change parts list with ordering information.	
6.10.19	MOC certificates	
6.10.20	Calibration certificates of critical instruments with respect to the traceable national reference standard instrument and their calibration procedure.	
6.10.21	Comprehensive warranty for 1 year after the date of installation.	
6.10.22	Types of Lubricant and Lubrication instructions. Food grade certificates.	
6.10.23	The Vendor shall provide start-up services through successful completion of the site acceptance test. The site acceptance test will be a repeat of the factory integration test performed at the Vendor's facility.	

7.0 CONSTRAINTS

7.1 Equipment location and available space

Refer URS Annexure-1 for the locations of the equipment

7.2 Utility

Electricity: 230V AC, 1ph, 50 Hz

8.0 ABBREVIATION

Abbreviation	Definition
cGMP	current GMP
DQ	Design Qualification
FAT	Factory Acceptance Test
GA	General Arrangement
GMP	Good Manufacturing Practice
HBL	HLL Biotech Ltd
IOQ	Installation & Operation Qualification
ISO	International Organization for Standardization
MOC	Material Of Construction
NPI	NNE Pharmaplan India LTD
PAO	Poly Alpha Olefin
QA	Quality Assurance
SAT	Site Acceptance test
SS	Stainless steel

9.0 REVISION INDEX

nne pharmaplan	User Requirement Specifications				IIBL
	Equipment/System	Sampling/ Dispensing booth			
	Identification #:	-	Document No:	URS/DSB-01	
	Effective Date:		Revision No:	01	

Revision	Date	Reason for revision
00	24-02-2015	First Draft for Client's Review
01	22-06-2015	Changes as per Clients comments

HLL BIOTECH LIMITED,							
nne pharmaplan	INTEGRATED VACCINES COMPLEX, CHENGALPATTU						HBL HLL BIOTECH LIMITED
	Document Name:	URS Annexure-1: Sampling / Dispensing Booth					
	Document number:	NPI_120310_EQP_URS_DSB_01					
	Date / Revision:	22-06-2015 / 01					
Sl. No	Room Number	Room Name	Equipment code	External Dimensions in mm	Quantity	Room height, mm	Remark
WAREHOUSE BLOCK							
1	W1G033	Dispensing Room - 1	W1-DSB 01	(1400 x 1900 x 2400) mm (W x D x H)	1	3000	
2	W1G034	Dispensing Room - 2	W1-DSB 02	(1400 x 1900 x 2400) mm (W x D x H)	1	3000	
3	W1G031	Sampling Room	W1-DSB 03	(1400 x 1900 x 2400) mm (W x D x H)	1	3000	