

nne pharmaplan®	User Requirement Specifications				 <small>HLL BIOTECH LIMITED Subsidiary of HLL Lifecare Limited (A Government of India Enterprise)</small>
	Equipment/System	Stability Chamber			
	Identification #:	-	Document No:	URS/SBC-01	
	Effective Date:		Revision No:	00	

User Requirement Specifications Stability Chamber

Block Code	Block Name	Identification #	Capacity, L	Type	Qty [Nos]
M1	Sterility Media Preparation and Microbiology	M1-SBC-01	300	Reach-in	1

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REVIVAL OF DPT VACCINE MANUFACTURING FACILITY, PII, COONOOR

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URS Annexure List:

URS Annex No.	Detail
1	Layout showing location for the installation of the Stability Chambers

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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 “Revival of DPT Vaccines manufacturing Facility” (Project number:-110831) of Pasteur Institute of India, Coonoor under the authority of their Project Manager. Hence, this document before being effective shall be approved by the QA team of Pasteur Institute of India, and authorized by the appropriate Project Authority.

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1.0 EQUIPMENT DESCRIPTION

The stability chamber shall be used to store the stability samples of bulk and finished products.

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
- 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 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.

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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_110831_IRS_PII_01
XII.	Refer Tender document with URS; NPI/110831/EQP/TD/XX

Specifications	Remarks
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2.0 PROCESS DESCRIPTION

2.1 Input & Charging method

The samples will be stored inside the racks of stability chambers manually and the desired parameters will be set using operator panel.

2.2 Brief Process Steps

This equipment will be used to maintain the desired parameters like temperature, relative humidity etc. precisely to store the vials.

2.3 Output & Discharging method

The vials stored in the trays in different shelves will be removed manually.

3.0 PRODUCTIVITY REQUIREMENT

3.1 Desired/ suggested capacity

The capacities and operating temperatures of equipment is as follows

Sl. No.	Equipment ID	Capacity L	Operating Temperature °C	Operating RH range
1	M1-SBC-01	300	37 ± 1°C	60 ± 5% RH

3.2 Standard batch size

Not Applicable

3.3 Change Over Time

Not Applicable

3.4 Other Productivity Requirement

Continuous 24x7 operation & system shall be able to run on 0% load for longer period

4.0 CONTAINMENT

Not applicable

5.0 GMP REQUIREMENTS

5.1 Process control

Equipment should be monitored using temperature and relative humidity controller using

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HMI / PLC provided with inbuilt battery.
 Equipment should have provision of remote monitoring.

5.2 In –Process control

Not applicable

5.3 Level of instrumentation

Not Applicable

5.4 Batch data display and record printing

Basic / standard data acquisition to be done in HMI / PLC. This should be mainly to collect and store the data using external device.

5.5 Technical Specification

6.5.1	Model	cGMP
6.5.2	Internal dimensions (W X D X H) mm	Vendor to specify
6.5.3	Shelves (W X D) mm	Vendor to specify
6.5.4	Height between the shelves (mm)	Adjustable shelves
6.5.5	Temperature Uniformity	±1 °C
6.5.6	Temperature Readability	0.1 °C
6.5.7	Temperature precision (setting resolution)	± 0.2 °C
6.5.8	Relative Humidity	As mentioned section 4.1
6.5.9	Number of door opening in a day	Minimum 1 in a day
6.5.10	Temperature recovery time	vendor to specify
6.5.11	RH recovery time	vendor to specify
6.5.12	Accuracy of relative humidity	±2.0% RH
6.5.13	Humidity uniformity	±3.0% RH
6.5.14	Total quantity	1 No.
6.5.15	Compressor type	CFC free and Hermitically sealed type

5.6 Material of Construction

6.6.1	Body Construction	Inner panel	SS 304 sheets, Surface finish – 240grit
		Outer panel	Epoxy, Powder Coated GI sheets or pre-fabricated modular panel type
		Insulation	High grade mineral glass wool/ PUF insulated
6.6.2	Gaskets, seals, O-rings	Food Grade/ nontoxic material Use of Asbestos is prohibited	
6.6.3	Glass window	Double glazed 5mm thick safety glass with desiccant material for moisture trapping between the panels.	

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6.6.4	Door	Inner Door	Thick safety glass (only for Q1-STC-03 & Q1-STC-04)
		Outside Door	Powder Coated GI along with small glass window with silicone rubber gasket
		Lock and door access control/security system to be considered	
		DP gauge to be provided.	
6.6.5	Heating unit	SS 304 and it shall be Fin Type.	
6.6.6	Copper refrigerant tubes	Properly insulated with tube type nitrile rubber and black tape for fastening.	
6.6.7	Sealing	FDA approved clear silicon sealant	
6.6.8	Coving	Anodized aluminum (wall to wall, wall to ceiling, wall to floor)	
6.6.9	Insulation	Heavy walled CFC Free	
6.6.10	Fans	Low noise axial fans of SS 304 construction	
6.6.11	Racks	SS 304	
6.6.12	All welds shall be ground finish		
6.6.13	MOC of the chamber should be easily cleanable and compatible with suitable cleaning agents.		

5.7 Specific Equipment requirement

6.7.1	Chamber should have smooth covered corners for easy cleaning.	
6.7.2	Standby cooling and humidity systems with auto switch over shall be provided.	
6.7.3	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, etc.	
6.7.4	Arrangement of alternative power supply (UPS) to control and monitoring system	
6.7.5	Doors shall be electro magnetically operated (Spring loaded, self closing door with 90° angle stay open feature should be provided with holder).	
6.7.6	Light control shall be provided and interlocked with door as well	
6.7.7	Display: LCD/ LED (7"-10" VGA colored screen or better) with touch keypad shall be provided at front panel	
6.7.8	Key lock for Parameter change Protection to be provided	
6.7.9	Temperature and RH sensors shall be provided. Vendor shall specify the numbers	
6.7.10	Temperature controlling must be based on set point.	
6.7.11	Interface port RS 232 to transfer data to be provided.	
6.7.12	One inkless Chart recorder / graphic recorder and printing for traceability of alarms (TBD)	
6.7.13	A complete batch record indicating the following important parameters, but not limited to these: a) Date, Time b) All failures and alarms including condensing unit (outdoor) alarm.	
6.7.14	Internal clock to be maintained to retrieve data at setpoint interval i.e.; 24 hrs.	
6.7.15	Condensing unit • Non CFC refrigerant. Vendor shall specify the make of the cooling system	

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	<ul style="list-style-type: none"> • Compressor shall be coupled with evaporation coil and condenser Note: Technical Specification, type of refrigerant to be provided by vendor	
6.7.16	Alarms for parameters like high temperature, low temperature, high humidity, low humidity shall be provided. Audio (hooter), visual (indication lamp), Mail alerts & SMS alert shall be considered.	
6.7.17	Audio alarms have to be in the range of 2.3 — 2.9 kHz in order to avoid interference and confusion with evacuation alarms.	
6.7.18	Alarm if door is open for more than specified minutes (time to be specified during the validation)	
6.7.19	Heating System: <ul style="list-style-type: none"> • Heating unit: SSR shall be used to control the temperature • FIN type • No. of heater shall be provided by the vendor • Provision for forced air circulation to be provided Note: Technical Specification shall be mentioned by the vendor	
6.7.20	VFD ((Variable Frequency drive) shall be provided to control fan speed.	
6.7.21	Special note: Stability chamber shall have provision to connect monitoring device with printer - Vendor scope (Cable length between stability chamber to monitoring device with printer should be minimum of approx. 15 m) Computer & printer shall be considered as required.	
6.7.22	Control lights and other display elements shall not be influenced by voltage failure.	
6.7.23	Empty load validation to be done for 72 hours with minimum 16 probe data logger.	
6.7.24	Equipment shall have redundancy for refrigeration & compressor system.	
6.7.25	Vendor to provide the details of the drain requirement.	
6.7.26	Door auto closure to be considered	
6.7.27	Door are hinged type and should be opened outside.	
6.7.27	Software shall be capable of providing MKT calculation, Printing of trends, Graphical view, Alarm logs and Manual/Automatic back up shall be provided	
6.7.28	Validation: Temperature mapping and moisture mapping to be done during commissioning.	

5.8 Regulatory guidelines / standards

6.8.1	US FDA 21 CFR Part 11	
6.8.2	US FDA and UK MHRA	

5.9 Safety requirements

6.9.1	Emergency stop function on accessible area.	
6.9.2	Noise level below 75 decibel at a distance of 1 meter from the equipment.	
6.9.3	All electrical wiring shall be concealed and with proper earthing	
6.9.4	No sharp edges/Corners, crevices, pin holes in the process wetted parts of the equipment.	
6.9.5	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	

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	a safe condition.	
6.9.6	Warning stickers – Fluorescent Sticker	
6.9.7	Emergency hooter shall be provided inside the chamber	

5.10 Documents

6.10.1	DQ Specification (GA drawing, Equipment data sheets, instrument calibration certificate, certificates for bought out instruments)	
6.10.2	IQ specification	
6.10.3	OQ specification	
6.10.4	PQ specification	
6.10.5	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.	
6.10.6	Operation and maintenance manuals for the bought out items (as applicable).	
6.10.7	Vendor should provide list of change parts (if applicable) with ordering information	
6.10.8	MOC certificates for all product contact surfaces.	
6.10.9	All equipment warranty should be valid for one year from the date of completion.	
6.10.10	Trouble shooting manual to be provided	

6.0 CONSTRAINTS

6.1 Equipment location and available space

<p>This equipment will be installed in the Sterility Media Preparation and Microbiology block of PIIC, COONOOR.</p> <p>Equipment Location: M1-SBC 01 Block: Sterility Media Preparation and Microbiology Room No.: M1G037 Floor: Ground floor Room Dimensions (L x W),mm: 2925 x 2810 False ceiling height: 3000 mm</p> <p>The equipment location is indicated in the relevant block of the layout enclosed as URS Annex-1. The equipment must be positioned as per the generic layout provided below.</p> <p>Physical condition of the rooms: Sterility Lab -1:</p> <ol style="list-style-type: none"> 1. Room will be non-hazardous 2. Class: B area 3. Differential Pressure: 65 Pascal 4. Temperature maintained: 22±2 °C 5. Relative Humidity: NMT 55 % 	
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6.2 Utility

a) Electricity: Single Phase (220 V) & 3 phase (420 - 440 V) (Report Requirement)
 b) Compressed air 6 bar (Report Requirement)

7.0 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

8.0 REVISION INDEX

Revision	Date	Reason for revision
00	2015-10-20	First Draft for Client's Review

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URS Annexure 1: LAYOUT POSITION
For M1-SBC 01

