User Requirement Specifications
Walk-In Incubator

Block Code	Block Name	Identification #	Temperature °C	Qty. [Nos.]
M1	Sterility Media Preparation and Microbiology	M1-WIN-01	35 ± 2.5	1
M1	Sterility Media Preparation and Microbiology	M1-WIN-02	22 ± 2.5	1
M1	Sterility Media Preparation and Microbiology	M1-WIN-03	35 ± 2.5	1
M1	Sterility Media Preparation and Microbiology	M1-WIN-04	22 ± 2.5	1

nne pharmaplan	User Requirement Specifications				HBL HLL BIOTECH LIMITED
	Equipment/System	Walk In Incubator			
	Identification #:	-	**Document No:**	URS/WIN-01	
	Effective Date:		**Revision No:**	00	

URS Annexure List:

URS Annex No.	Detail
1	Layout showing location for the installation of the Walk In Incubator

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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 walk in incubator shall be used for storage of samples under controlled conditions. Incubator maintains optimal temperature.

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.

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
2.0 PROCESS DESCRIPTION	
2.1 Input & Charging method	
The Samples will be stored inside the racks of Incubators manually and desired parameters will be set using operator panel.	
2.2 Brief Process Steps	
All inputs required for walk in Incubators will be fed through.	
2.3 Output & Discharging method	
The stored samples will be taken out 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 (External dimensions available) (L x W x H),mm	Temperature range, °C
1	M1-WIN-01	Capable of holding 1500 No's of 225 ml bottles for a period of 14 days (Bottle size : 15 cm H x 6 cm B x 4 cm Dia)	32.5 ± 2.5
2	M1-WIN-02	Capable of holding 1500 No's of 125 ml bottles for a period of 14 days (Bottle size : 13.5 cm H x 5.5 cm B x 3.5 cm Dia)	22.5 ± 2.5
3	M1-WIN-03	Capable of holding 1500 No's of 225 ml bottles for a period of 14 days (Bottle size : 15 cm H x 6 cm B x 4 cm Dia)	32.5 ± 2.5
4	M1-WIN-04	Capable of holding 1500 No's of 125 ml bottles for a period of 14 days (Bottle size : 13.5 cm H x 5.5 cm B x 3.5 cm Dia)	22.5 ± 2.5

Note: Actual measurements to be taken by vendor at site before proceeding to manufacture of equipment

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 controlled using PLC/HMI provided with inbuilt battery.		
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. 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 dimension, (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	
6.5.5	Temperature Uniformity	±1 ºC	
6.5.6	Temperature Readability	0.1 ºC	
6.5.7	Temperature precision (setting resolution)	± 0.2 ºC	
6.5.8	Temperature accuracy	± 0.5 ºC	
6.5.9	Number of time door opening in a day	Minimum 8 to 10 times in a day	
6.5.10	Temperature recovery time	vendor to specify	
6.5.11	Total quantity	4 No.	
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.	
6.6.4	Door	Inner Door	Thick safety glass
		Outside Door	Powder Coated GI along with small glass window
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		

5.7 Specific Equipment requirement

6.7.1	Chamber shall have smooth coved corners for easy cleaning	
6.7.2	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.	
6.7.3	Arrangement of alternative power supply (UPS) to control and monitoring system	
6.7.4	Doors shall be electro magnetically operated (Spring loaded, self-closing door with 90º angle stay open feature should be provided with holder).	
6.7.5	Light control shall be provided and interlocked with door as well	
6.7.6	Display: LCD/ LED (7”-10” VGA colored screen or better) with touch keypad shall be provided at front panel	
6.7.7	Key lock for Parameter change Protection to be provided	
6.7.8	PT 100 type of temperature sensor shall be provided. Minimum + 1 sensors at cold spots to be considered.	
6.7.9	Temperature controlling must be based on set point.	
6.7.10	Interface port RS 232 to transfer data to be provided.	
6.7.11	One inkless Chart recorder / graphic recorder and printing for traceability of alarms	
6.7.12	A complete batch record indicating the following important parameters, but not limited to these: a) Date, Time b) All failures and alarms	
6.7.13	Internal clock to be maintained to retrieve data at set point interval i.e.; 24 hrs.	
6.7.14	Condensing unit • Non CFC refrigerant. Vendor shall specify the make of the cooling system • Compressor shall be coupled with evaporation coil and condenser Note: Technical Specification to be provided by vendor	

6.7.15	Alarms for parameters like high temperature, low temperature shall be provided. Audio (hooter), visual (indication lamp), Mail alerts & SMS alert shall be considered.	
6.7.16	Heating System: • Heating unit: SSR shall be used to control the temperature • FIN type • No. of heater shall be provided by the vendor Note: Technical Specification shall be mentioned by the vendor	
6.7.17	VFD ((Variable Frequency drive) shall be provided to control fan speed.	
6.7.18	**Special note:** All walk in incubator shall have provision to connect monitoring device(common) with printer (common) **- Vendor scope** (Cable length between walk in incubator to common monitoring device with printer (common) should be minimum of approx. 15m)	
6.7.19	Control lights and other display elements shall not be influenced by voltage failure.	
6.7.20	Audio alarms have to be in the range of 2.3 — 2.9 kHz in order to avoid interference and confusion with evacuation alarms.	
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 1m distance from 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 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 sheet, Instrument calibration certificate, Certificate for bought out items.)	
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	Spare and/ or change parts list with ordering information.	
6.10.8	MOC certificates for all product contact surfaces.	

6.10.9	Comprehensive 2 year warranty from the date of completion.	
6.10.10	Trouble shooting manual to be provided.	

6.0 CONSTRAINTS

6.1 Equipment location and available space

This equipment will be installed in the **Quality Control block** of **Integrated Vaccines Complex**, Chengalpattu.

Equipment Location: M1-WIN 01

Block: Sterility Media Preparation and Microbiology

Room No.: **M1G021**

Floor: **Ground floor**

Room Dimensions (L x W),mm: **2210 x 1525**

False ceiling height: **2400 mm**

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.

Physical condition of the rooms:

Walk in Incubator:

1. Room will be non-hazardous
2. Class: Unclassified
3. Differential Pressure: Not applicable
4. Temperature maintained: NA
5. Relative Humidity: NA

Equipment Location: M1-WIN 02

Block: Sterility Media Preparation and Microbiology

Room No.: **M1G020**

Floor: **Ground floor**

Room Dimensions (L x W),mm: **2210 x 1525**

False ceiling height: **2400 mm**

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.

Physical condition of the rooms:

Walk in Incubator:

1. Room will be non-hazardous
2. Class: Unclassified
3. Differential Pressure: Not applicable
4. Temperature maintained: NA
5. Relative Humidity: NA

Equipment Location: M1-WIN 03

Block: Sterility Media Preparation and Microbiology

Room No.: **M1G031**

Floor: **Ground floor**

Room Dimensions (L x W),mm: **3020 x 1850**

False ceiling height: **2400 mm**

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.

Physical condition of the rooms:

Walk in Incubator:

6. Room will be non-hazardous
7. Class: Unclassified
8. Differential Pressure: Not applicable
9. Temperature maintained: NA
10. Relative Humidity: NA

Equipment Location: M1-WIN 04

Block: Sterility Media Preparation and Microbiology

Room No.: **M1G032**

Floor: **Ground floor**

Room Dimensions (L x W), **mm** : **3020 x 1850**

False ceiling height: **2400 mm**

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.

Physical condition of the rooms:

Walk in Incubator:

1. Room will be non-hazardous
2. Class: Unclassified
3. Differential Pressure: NA
4. Temperature maintained: NA
5. Relative Humidity: NA

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

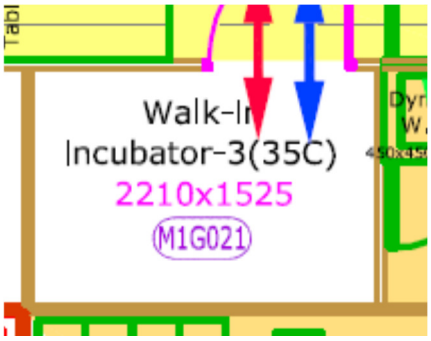
HMI	Human Machine Interface
IQ	Installation Qualification
ISO	International Standards Organization
MOC	Material Of Construction
NA	Not Applicable
NPI	NNE Pharmaplan India LTD
OQ	Operational Qualification
PQ	Performance Qualification
QA	Quality Assurance
RH	Relative Humidity
SS	Stainless steel
TBD	To be discussed
UPS	Uninterrupted Power Supply
URS	User Requirement Specifications
WIN	Walk-In Incubator

8.0 REVISION INDEX

Revision	Date	Reason for revision
00	23-04-2015	First Draft for Client's Review

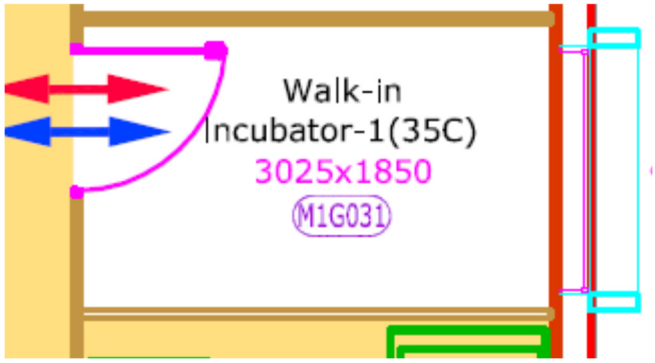
URS Annexure 1: LAYOUT POSITION

For M1-WIN 01 (35 ± 2.5 ℃)
Room Name: Walk in Incubator



For M1-WIN 02 (22 ± 2.5 ℃)
Room Name: Walk in Incubator

For M1-WIN 03 (35 ± 2.5 ℃)
Room Name: Walk in Incubator



For M1-WIN 04 (22 ± 2.5 ℃)
Room Name: Walk in Incubator