User Requirement Specifications
Dry Heat Sterilizer

Equipment ID:	FG-DHS 01	600 mm(L) x 600(W) mm x 600(D) mm Or the nearest standard size

Revision index

Revision	Date	Reason for Revision
00	2012.06.01	First Draft for Client's Review
01	2012.11.16	As per the new URS format approved by HLL
02	2013.01.10	As per the comments from BCGVL/HLL

URS Annexure List

URS Annex No.	Detail
1.	Layout showing location of the DHS in the Formulation area
2.	List of Preferred Make for Components
3.	List of recommended spares

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	Equipment/System	Dry Heat Sterilizer			
	Identification	FG-DHS 01	**Document**	URS/FG-DHS 01	
	Effective Date	2013.03.04	**Revision**	02	

1.0 Approval Signature

This document is prepared by the Process and Validation and GMP compliance team of "NNE Pharmaplan India for the project "Revival of BCG Vaccine Laboratory" (**Project number:-110729**) of BCG Vaccine Laboratory, Guindy, Chennai under the authority of their Project Manager. Hence, this document before being effective shall be approved by the QA team and authorized by the appropriate Project Authority.

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Project Authority **BCG Vaccine Laboratory**		

2.0 Equipment description

Dry heat, as the name indicates for sterilisation of the articles hot air is used.DHS is used to sterilize the Aluminium seals.

S. No.	Description of the equipment	Purpose
1	Main Chamber	For keeping the items for Drying, sterilisation and Depyrogenation
2	The chamber carriage	For keeping the items
3	Air inlet filter module with pre filter and HEPA filter.	For filtering the air and supplying the filtered air to the circulation HEPA filter. Filtered air supply into the chamber and recirculation to maintain aseptic condition inside the chamber
4	Air exhaust Module with HEPA damper	For exhaust the air from the chamber to out side.
5	Exhaust HEPA filters	For avoiding the contamination of chamber from outside
6	Main circulation HEPA filters	For supplying the filtered air inside the chamber to create class-100 (Class-A)
7	Main blower	For circulation of the HEPA filtered air inside the chamber
8	Heating module	For achieving the set temperature of drying, sterilisation and Depyrogenation
9	Doors on both loading and unloading side.	To close the chamber and to have classification between sterile and non sterile side.
10	Bioshield	To seal the sterile and non-sterile areas.

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Note:

1.	This Technical Specification is the basis for an inquiry to a vendor and therefore the basis for the vendor's proposal.
2.	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. I n case of an deviation a comment must be inserted or enclosed as a separate annexure by referring to the respective URS specification number.
3.	The vendor must clearly comment each item of the Technical Specification. The comments must be in English language. If extra cost for necessary options become necessary the item must be clearly stated.
4.	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.
5.	The final version of this document including the vendor's comments will become basis of a potential purchase order or contract.
6.	The Technical Specification serves to define a summary of all vendor's requirements concerning scope of delivery and services.
7.	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.
8.	Special Instruction a. If no comments against any specification shall be considered as "NO" and b. If there is no reply / comments against the complete URS by the vendor then it shall be treated as unresponsive / technically non compliant and rejected.
9.	Refer document Installation Requirement Specification and Specific Instructions with URS; NPI_110729_IRS_BCG_01
10.	Refer Tender document with URS; NPI/110729/EQP/TD/05

	Specifications	Remarks
3.0	**Process Description**	
3.1	**Input & Charging method**	
3.1.1	SS316L loading carriage shall be provided for manual loading of the Aluminium seals for Depyrogenation	
3.1.2	SS 304 loading trolley shall be provided for easy loading of the SS loading carriage inside the chamber.	
3.1.3	A pair of SS316L railing shall be provided inside the chamber for smooth and easy loading of the carriage inside the chamber. The railing should be of fixed type with proper welding to facilitate cleaning.	
3.1.4	The carriage shall be designed with removable and adjustable type shelves for more flexibility. Suitable provision for inserting additional shelves, if required for loading the articles shall be provided.	
3.1.5	Articles such as Aluminium seals for Depyrogenation ,shall be loaded on to the carriage and the carriage is put inside the chamber on the railing provided inside the chamber.	
3.2	**Brief Process Steps**	
3.2.1	Loading of the Aluminium (The aluminium seals considered in the design are 13 mm flip off or tear off type. The seals shall comply the specification laid down in ISO standard 8362-6.) ***Note: Loading level shall be defined by the vendor.***	
3.2.2	Drying at 100 -110º C for Moisture removal	
3.2.3	Heating up with exhaust damper in closed condition till temperature reaches sterilization/depyrogenation set point	
3.2.4	Holding up for a set period at sterilization/Depyrogenation temperature(250 - 350º C)	
3.2.5	Cooling the article to ambient temperature with HEPA filtered air from cooling zone/ sterile area	
3.2.6	Unloading to sterile area	
3.3	**Output & Discharging method**	
3.3.1	Unloading of the carriage onto unloading trolley with the depyrogenated/ sterilized items from the chamber at the unloading side.	
3.3.2	Unloading of the Depyrogenated/sterilized items from the carriage in sterile side. ***Note: Unloading level height shall be defined by the vendor.***	

Specifications	Remarks
4.0 Productivity Requirement	
4.1 Desired/ suggested capacity	
FG-DHS 01(Formulation): **Inner chamber size :**600 mm(L) x 600 mm(W) x 600 mm (D) (Hinged door type) ***Note: Vendor shall also suggest the multiple sterilization cycles , if required***	
4.2 Standard batch size	
40,000 aluminium seals/batch(8 hrs batch time) ***Note:*** *The minimum total cycle time for the entire process should be mentioned by the vendor*	
4.3 Change Over Time	
Not Applicable	
4.4 Other Productivity Requirement	
4.4.1 The equipment shall be able to run for 24 hours.	
5.0 Containment	
Not Applicable	
6.0 GMP requirements	
6.1 Process control	
The Dry heat sterilizer should essentially have the necessary provision for adjustment / control of the following critical process parameters:	
6.1.1 Chamber temperature 0 to 300 deg C	
6.1.2 Moisture removal temperature	
6.1.3 Moisture removal time	
6.1.4 Depyrogenation temperature (250 ± 5 deg C)	
6.1.5 Depyrogenation hold time (45 min to 60 min)	
6.1.6 Sterilization Overshoot temperature more than 275 º C	
6.1.7 Sterilization stop temperature	
6.1.8 Sterilization reset temperature	
6.1.9 Process end temperature	

Specifications	Remarks
6.1.10 Cooling time (not more than 90 min)	
6.1.11 Cooling temperature (30 deg C to 45 deg C)	
6.1.12 Door opening temperature (45°C)	
6.1.13 Heat up time (not more than 60 min)	
6.1.14 Over pressure in chamber during depyrogenation cycle (Not more than 15 pa)	
6.1.15 The depyrogenation cycle should be controlled based on the slowest heating or lowest temperature indicating probe	
6.1.16 Chamber Probe Temperature uniformity from probe to probe should not vary more than 5º C during hold period.	
6.1.17 The temperature band for each probe should be within “Set temp ± 5º C” during hold period.	
6.1.18 Individual Probe temperature variation should be within ± 2º C during hold period	
6.1.19 Manual Operation must be possible apart from PLC based operation.	
6.1.20 After Process end, the Pressure Module and Exhaust Module continue to run until the equipment is reset (using Process End ACK through HMI) to prevent pressure build up and facilitate partial cooling of the load.	
6.2 Failure mode detection	
6.2.1 Equipment shall be capable to detect the following failure, notify the operator with alarm and shutdown the process:	
6.2.1.1 Low compressed air pressure (used for pneumatic operation)	
6.2.1.2 Temperature below low limit of depyrogenation temperature	
6.2.1.3 Temperature beyond the safe limit of chamber temperature	
6.2.1.4 Differential pressure of the chamber below low limit	
6.2.1.5 Loss of UPS power (optional)	
6.2.1.6 Activation of emergency stop switch	
6.2.2 Following condition need only notification to operator for procedural control:	
6.2.2.1 Low/high differential pressure across HEPA filter of supply, circulation and exhaust	
6.2.2.2 Malfunctioning of heater / blower	
6.2.2.3 End of cycle	
6.2.2.4 Door opening after the end of cycle	
6.2.2.5 Motor trips	

Specifications	Remarks
6.2.2.6 Pressure module motor trips	
6.2.2.7 Exhaust module motor trips	
6.2.2.8 Too long time for heat up	
6.2.2.9 Too long time for cooling	
6.2.2.10 Heater supply off	
6.2.2.11 Door pre-condition fail	
6.2.2.12 Compressed air pressure low	
6.2.3 **Following Interlocks to be provided**	
6.2.3.1 The door will not open during sterilization process.	
6.2.3.2 The process will not start unless both the doors are locked.	
6.2.3.3 Both doors will not open simultaneously.	
6.2.3.4 Heaters interlocked with circulation fan motor.	
6.2.3.5 The door shall not open with a high pressure inside the chamber.	
6.2.3.6 The door shall not open with a chamber temperature inside. (More than 60 degree centigrade approx)	
6.2.3.7 The door shall not open with a chamber temperature inside. (Not more than 45 °C approx)	
6.2.3.8 Blind temperature controller is provided to switch off the circuit in case the temperature overshoots.	
6.3 In – Process control	
Not Applicable	
6.4 Level of instrumentation	
Sufficient and suitable instrumentation for the process, safety and productivity control as indicated in the following table:	

Parameter	Purpose	Type of control and Instrumentation
Temperature at multipoint	Chamber temperature monitoring, controlling, displaying and recording	Temperature probe with transmitter and indicator
Temperature	To control temperature in manual mode.	Temperature Indicator Cum Controller

Specifications			Remarks
Temperature	To switch off the circuit/machine when temperature overshoots.	Blind Temperature Controller	
Time	Cycle time monitoring, controlling, displaying and recording	Timer	
Differential pressure	Differential pressure, across supply air HEPA, Exhaust HEPA filter and recirculation HEPA filter displaying.	Magnehelic Gauges	
Differential pressure	Chamber differential Pressure with respect to room for monitoring, displaying and recording	Magnehelic Gauge & Pressure transmitter with indicator	
Air pressure	Controlling and alarm	Air pressure switch	
Data logger and recorder	Recording and display of temperature and time	Data logger with digital display (DDMMYYYY/ HRS:MIN:SEC)	

6.5 Batch data display and record printing	
Refer IRS(Installation requirement Specification and Specific Instructions)	
6.6 GMP requirements (Others)	
6.6.1 Equipment design must realize zero contamination	
6.6.2 Minimum 2 validation ports for inserting at least 16 probes through each port during validation	
6.6.3 Data logging frequency should be min. 180 readings/ hold cycle and other than holding time 10sec.	
6.6.4 Suitable port for charging and measuring the aerosol challenge at upstream of each HEPA filter (supply air, exhaust air and circulation HEPA filter). There should have location for scanning the downstream by photometer for integrity testing.	
6.6.6 Space below the equipment shall be six inches for the accessibility of cleaning	
6.6.7 When the preventative maintenance requirements recommended by Vendor are followed, the machine shall have no more than one unscheduled repair per year	

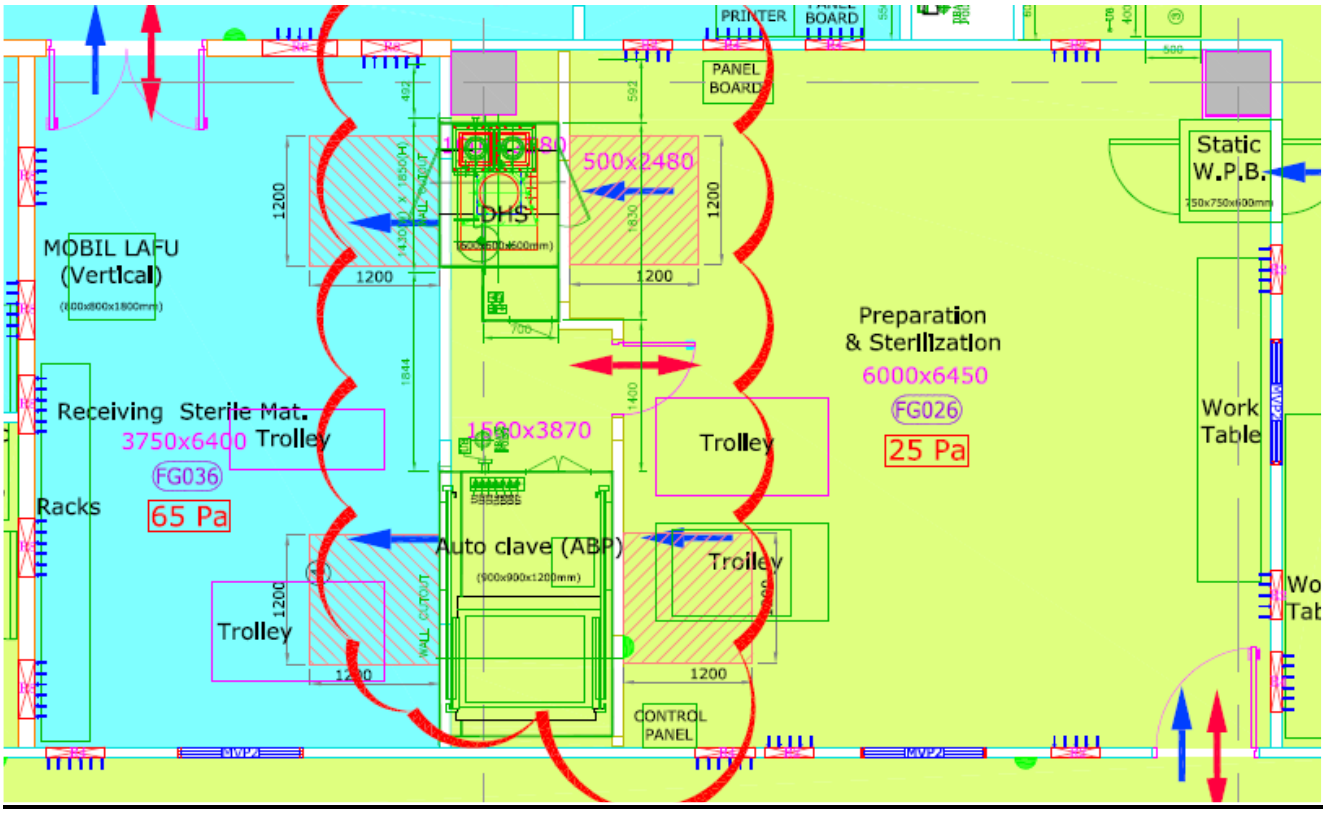
Specifications	Remarks
6.7 Specific requirements	
6.7.1 Hinged type door is preferred.	
6.7.2 Audio-Visual LED for door open/ close on both non-sterile and sterile side.	
6.7.3 The downstream connections of the supply and exhaust air HEPA filters with the duct should be easily removable (preferably without nuts/ bolts) for periodic HEPA filter replacement.	
6.7.4 The chamber trolleys should be provided with removable and adjustable shelves for more flexibility and suitable provision for inserting additional shelves, if required	
6.7.5 Depyrogenation cycle restarting from zero time if the temperature at any point of time goes beyond the defined temperature control band (255 ± 5.0°C).	
6.7.6 Automatic FH value calculation for each temperature monitoring port. (Optional)	
6.7.7 Forced cooling system such as cooling coil(to be quoted as optional).	
6.7.8 Fully automatic PLC/ PC based operation with option for manual operation	
6.7.9 Preferred make of PLC: Allen Bradley / Siemens.	
6.7.10 Computer system specification i.e. Hardware design specification (HDS) and software design specification (SDS)	
6.7.11 Software ladder logic/ operation and controls flow charts	
6.7.12 Temperature trend chart recording with printing software to be provided. Temperature probe installation diagram need to be approved by the client.	
6.7.13 Cables, top industrial plug, air tubes, etc required from the point (single utility point) to equipment are in scope of vendor.	
6.7.14 Equipment should be flushed with wall on both non-sterile and sterile side with bio seal.	
7.0 Constraints	
7.1 Equipment location and available space	
This equipment will be installed in the Formulation block of the BCG Vaccine Laboratory as follows. **Equipment Location:** **Floor:** Ground **Room:** Class'D'	

Specifications	Remarks
Room dimension: (L) 1.13m x (W) 2.58m **False ceiling height:** 3 m **Physical condition of the loading /Non-sterile side(FG026):Preparation & sterilization** 1. Room will be non-hazardous 2. Classification :Class 'D' 3. Differential pressure: '25' Pa 4. Room Temperature: 22±2ºC 5. Relative humidity: NMT 55% **Physical condition of the Unloading or Sterile side(FG036):Receiving sterile material** 1. Room will be non-hazardous 2. Classification :Class' B' 3. Differential pressure: '65' Pa 4. Room Temperature:22±2ºC 5. Relative humidity: NMT 55% **Note:** The equipment location is indicated in the layout enclosed as URS Annex-1.	
7.2 Utility	
a) Electricity:40 kW (Report Requirement) b) Compressed air @6 bar(g):_____CFM (Report Requirement) **Note:** Vendor to inform if there is any changes in the utilities required.	

8.0 Abbreviation

Abbreviation	Definition
BCGVL	BCG Vaccines Laboratory
GMP	Good Manufacturing Practices
HLL	HLL Lifecare Limited
NPI	NNE Pharmaplan India Ltd
ISO	International Standards Organization
DHS	Dry Heat Sterilizer
EUGMP	European Union Good Manufacturing Practices
UPS	Un-interrupted Power Supply
HEPA	High Efficiency Particulate Air
HTM	Health Technical Memorandum
PLC	Programmable Logic Controller
LED	Light Emitting Diode
NMT	Not More Than

URS Annexure 1: LAYOUT



URS Annexure 2: List of Preferred Make of components

SL.NO	DESCRIPTION	MAKE
A	**INSTRUMENTATION**	
1	PLC	Mitsubishi/Allen Bradley/ Siemens
2	Operator Interface/HMI	Mitsubishi/Allen Bradley/ Siemens
3	Temperature transmitter	Radix/ Yokogawa/ Emerson
4	Pressure transmitter	Dwyer/Sensocon/ Wika
5	Temperature indicator controller	Radix/ Wika/ Waaree instruments
6	Blind Temperature controller	Radix/ Nutronics/ Micronix Instruments
7	Printer	Epson/ HP/ Canon
8	DC source	Shavision/ Yokogawa/ Emerson
B	**MECHANICAL**	
9	Magnehelic gauges	Dwyer/Sensocon/ Waaree Instruments
10	Pre filter	Airtech/Fine airsys/ Millipore
11	Room temperature HEPA filter	Airtech/Fine airsys/ Dyna filters
12	Pressure switch	Orion/ Wika/ Emerson
C	**PNEUMATIC**	
13	Pneumatic door cylinder	Janatics/Rotex/ Parker
14	Solenoid valves for door cylinder	Janatics/ Festo/ Parker
15	Filter Regulator Lubricator	Janatics/ Festo/ Ingersoll
D	**ELECTRICAL**	
16	Control Panel	Allen Bradley/Siemens/ ABB
17	Limit switches	Bohmen/ Siemens/ Emerson
18	Heater	Common wealth
19	Electrical motor	Kirloskar/Crompton greaves Ltd./ABB
20	Switch gear and Relays	Siemens/ L&T/ Schneider
21	Miniature circuit breaker	Siemens/ Havells/ Legrand
22	Rotary switch	L&T/ Siemens/ Schneider

23	Indication lamps	Technik / Mimic/ Schneider

URS Annexure 3: List of recommended spares

SL.NO	DESCRIPTION	No. of quantity
1	Door gasket	1 No
2	Air heaters-1 kW	10 Nos
3	Door locking cylinders	2 Nos
4	Flasher cum buzzer	1 No
5	3 C/O Relay with base	2 Nos
6	O/L Relay 5 to 8 AMP 2 to 3.2 AMP 1.6 to 2.5 AMP	 1 No 1 No 1 No
7	Coil for Solenoid valves for doors	3 Nos
8	RTD sensors	6 Nos
9	Rotary switch	2 Nos
10	Push buttons	2 Nos
11	Indication bulb sets	3 Nos
12	Temperature transmitter	2 Nos