



nne pharmaplan®	User Requirement Specifications				
	Equipment/System	Dry Heat Sterilizer			
	Identification	D-DHS-01	Document	URS/D/DHS- 01	
	Effective Date	2013-06-24	Revision	03	

User Requirement Specifications

Dry Heat Sterilizer

Process Code	Area	Equipment code	Qty(Nos)	Capacity
D	Diphtheria	D-DHS 01	1	600 mm x 600 mm x 600 mm (W X D x H)

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URS Annexure List

URS Annex No.	Detail
1	Layout showing location of the DHS in the Diphtheria block
2	List of Preferred Make for Components

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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 DPT Vaccine 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 and authorized by the appropriate Project Authority.

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2.0 EQUIPMENT DESCRIPTION

Dry heat, as the name indicates for sterilization of the articles, hot air is used. In the Diphtheria block (B1) the DHS is used for the sterilization of 10 L flasks- 4 Nos per charge. Multiple sterilization cycle need to be considered for other articles.

The equipment should consist of following parts in order to run operation smoothly.


S. No.	Description	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 damper	For exhaust the air from the chamber to outside.
5	Exhaust HEPA filters	For avoiding the contamination of chamber from outside contamination
6	Heat resistance HEPA filter	To sustain the higher Depyrogenation temperature
7	Main circulation HEPA filters	For supplying the filtered air inside the chamber to create class-100 (Class-A)
8	Main blower	For circulation of the HEPA filtered air inside the chamber
9	Heating module	For achieving the set temperature of drying, sterilisation and depyrogenation
10	Doors on both loading and unloading side.	To close the chamber and to have classification between sterile and non sterile side.
11	Bio shield	To seal the sterile and non-sterile areas

Note: The following points which are there in the IRS (Installation Requirement Specifications) are NOT APPLICABLE for this equipment:

- **Sec 5.1 Table 2**
SI.NO 2
SI.NO 5 CE Conformity
- SI.NO 7 ANSI/NSF 49-2008, ISO 14664, ISO 8362
- SI.NO 8 ISO 14664
- SI.NO 9 ISO 8362
- Sec 5.4.1 All metallic product contact / critical surfaces should be constructed of SS316 L grade with internal mirror finish (< 0.5µm Ra for filling line and < 0.8µm Ra for lyophiliser) and external surface matte finish (< 1.2µm Ra)

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For surface finish values refer the point 9 under Sec 2.0.2 Table 2 mentioned in the URS


- Sec 5.6

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. In case of any 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 becomes necessary the item must be clearly stated.
4.	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.
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.	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 HLL before submitting the quotes.
10.	The makes requested are standard international makes. In case of any deviation, vendor to seek clarification from HLL before submitting the offers.
11.	Refer document Installation Requirement Specification and Specific Instructions with URS; NPI_110831_IRS_PII_01
12.	Refer Tender document with URS; NPI/110831/EQP/TD/05

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Specifications	Remarks
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3.0 PROCESS DESCRIPTION

3.1 Input and charging method

3.1.1	SS316L loading carriage shall be provided for manual loading of the articles 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 and carriage floor trolley MOC shall be of SS304. Suitable provision for inserting additional shelves, if required for loading the articles shall be provided.	
3.1.5	Articles such as SS items and other articles 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 articles manually Note: Loading level shall be defined by the vendor	
3.2.2	Drying at 100 -110 deg 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 - 300 °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 shall be defined by the vendor	

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4.0 PRODUCTIVITY REQUIREMENT

4.1 Desired/ suggested capacity

Internal chamber size: 600 mm x 600 mm x 600 mm (W x D x H)

4.2 Standard batch size

10 L flasks- 4 Nos(Dia-300 mm; height-400 mm) are to be sterilized in one charge.

Note: Multiple sterilization cycles to be considered for other following articles:

- 1 L flask- 4 Nos(W-5", L-8")
- Test tubes-200 Nos(Dia- 1", L-6")
- 10 ml Pipettes-100 Nos(L-15 cm)

4.3 Change Over Time (if applicable)

Not applicable

4.4 Other Productivity Requirement

4.4.1 The equipment shall be able to run for 24 hours/batch process requirement

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 Multipoint temperature probe(minimum 5 nos) for measuring chamber temperature, the range should be 0°C to 300°C

6.1.2 Moisture removal temperature

6.1.3 Moisture removal time

6.1.4 Depyrogenation temperature (Temperature set point \pm 5 deg C)

6.1.5 The control of hold temperature should be as per the following concept: **Thyristor** based temperature control required for depyrogenation hold time. While designing the heater bank the voltage bank to be considered as 415 \pm 20 V.


6.1.6 Sterilization overshoot temperature not more than 275 ° C

6.1.7 Sterilization stop temperature

6.1.8 Sterilization reset temperature

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6.1.9 Process end temperature	
6.1.10 Cooling time (not more than 90 min), another 30 min extra in case of glass wares	
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 Depyrogeneration cycle (Not more than 15 pa)	
6.1.15 The Depyrogeneration 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 5° C during hold period.	
6.1.17 The temperature band for each probe should be within “Set temp ± 5° C” during hold period.	
6.1.18 Individual Probe temperature variation should be within ± 2° 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 Depyrogeneration 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	
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	
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	
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Specifications	Remarks
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 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
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

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Specifications				Remarks
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 Installation Specification Requirement

Batch report should not be in strip chart recording ie. online printing is desired with minimum storage of 10 cycles. After the cycle completion the batch report and as well as trend print out should be in different colours.

6.6 GMP requirements (Others)


6.6.1	Equipment design must realize zero contamination.	
6.6.2	Minimum 2 validation port 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 (DOP 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 HEPA integrity testing.	
6.6.5	Space below the equipment shall be six inches for the accessibility of cleaning	

6.7 Specific requirements

6.7.1	Hinged type door	
6.7.2	Audio-Visual LED for door open/ close on both non-sterile and sterile side	
6.7.3	Exhaust blower capacity should be designed to blow out an exhaust air up to 15 m distance from the equipment exhaust point of DHS. Ducting for exhaust air from the exhaust blower outlet to the outside atmosphere will not be in the vendor scope. 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	

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6.7.5 Depyrogenation cycle restarting from zero time if the temperature at any point of time goes beyond the defined temperature control band ($255 \pm 5.0^{\circ}\text{C}$).	
6.7.6 Automatic FH value calculation for each temperature monitoring port.	
6.7.7 Fully automatic PLC/ PC based operation with option for manual operation	
6.7.8 Computer system specification i.e. Hardware design specification (HDS) and software design specification (SDS)	
6.7.9 Software ladder logic/ operation and controls flow charts	
6.7.10 Batch report should not be in strip chart recording ie, online printing is desired with minimum storage of 10 cycles. After the cycle completion the batch report and as well as trend print out should be in different colours. Printers (colour) should be placed inside the control cabinet.	
6.7.11 Performance criteria for Endotoxin test: The Depyrogenation cycle is valid if the Endotoxin test confirms the >3 log reduction in Endotoxin in the Depyrogenated samples. It must be conducted during FAT and SAT.	
6.7.12 All utility points will be provided nearer to the equipment. Hooking up of the equipments to the nearest utility points will be in the vendor's scope.	
6.7.13 Equipment should be flushed with water on both non-sterile and sterile side with bio seal.	
6.7.14 Supplier to connect the equipment drain point to the nearest floor drain located in the equipment technical area (within 3 m)	

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7.0 CONSTRAINTS

7.1 Equipment location and available space

This equipment will be installed in the **Revival DPT vaccine manufacturing facility, at PII ,Coonoor** as follows:

Floor: Ground floor Diphtheria block, (B1G079A)

Room size: 2 m X 6.5 m

Room height: 5.5 m

False ceiling height: 3 m

Loading side: Wash + Preparation and sterilization (B1G077)

1. Room will be Non hazardous
2. Class- EU Class D (ISO 7)
3. Pressure differential : 5 Pa
4. Temperature maintained : 22°C ±2°C
5. Relative humidity :NMT 55% RH

Unloading side: Unloading/sterile store (B1G080)

6. Room will be Non hazardous
7. Class-: EU Class C (ISO 7)
8. Pressure differential : 35 Pa
9. Temperature maintained :22°C ±2°C
10. Relative humidity :NMT 55 % RH


The equipment location is indicated in the layout enclosed as **URS Annex-1**.

7.2 Available Utility

- a) Electricity: 40 kW Report Requirement)
- b) Compressed air@6 bar(g) _____(Report Requirement)

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8.0 ABBREVIATION


Abbreviation	Definition
GMP	Good Manufacturing Practices
PIIC	Pasteur Institute of India, Coonoor
HLL	HLL Life care 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

REVISION INDEX

Revision	Date	Reason for Revision
00	2012-09-12	First Draft for client's review
01	2012-10-23	Format has been changed by HLL
02	2013-06-04	As per the MOM dated 09.04.2013 and 10.04.2013 with HLL/PIIC
03	2013-06-24	As per the comments from HLL by email dtd:2013-06-17

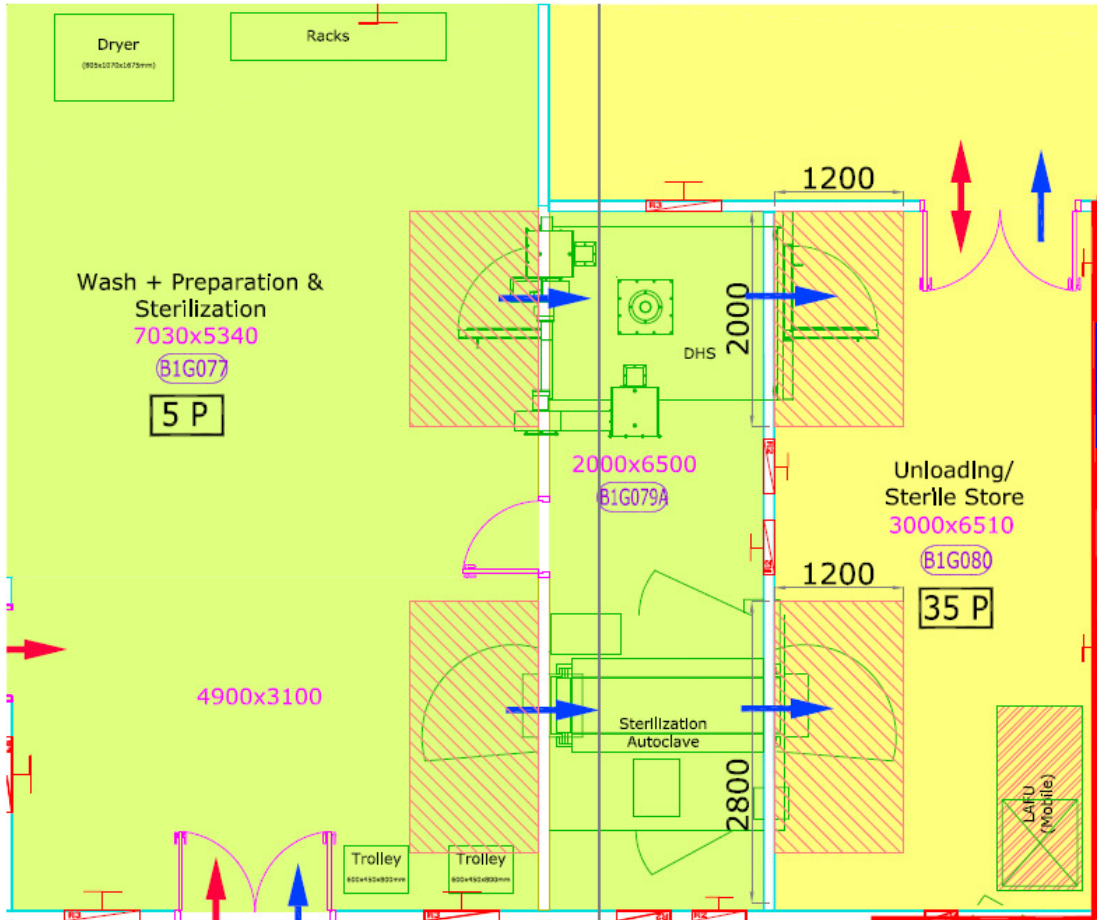
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URS Annexure 1: LAYOUT OF DIPHTHERIA BLOCK

Room No: B1G079A; (Dimension: 2 m x 6.5 m)



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URS Annexure 2: List of Preferred Make of components

SL.NO	DESCRIPTION	MAKE
A	INSTRUMENTATION	
1	PLC	Allen Bradley/ Siemens
2	Operator Interface/HMI	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 airsyst/ Millipore
11	Room temperature HEPA filter	Airtech/Fine airsyst/ 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	Limit switches	Bohmen/ Siemens/ Emerson
17	Heater	Common wealth
18	Electrical motor	Kirloskar/Crompton greaves Ltd./ABB
19	Switch gear and Relays	Siemens/ L&T/ Schneider
20	Miniature circuit breaker	Siemens/ Havells/ Legrand
21	Rotary switch	L&T/ Siemens/ Schneider
22	Indication lamps	Technik / Mimic/ Schneider