

HLL LIFECARE LIMITED, CHENNAI

REVIVAL OF DPT VACCINE MANUFACTURING FACILITY, PII, COONOOR

nne pharmaplan®

User Requirement Specifications

Equipment/System	Sterilization - Autoclave		
Identification	Q-SAT 02	Document	URS/Q-SAT 02
Effective Date	2013-06-24	Revision	03



User Requirement Specifications Sterilization - Autoclave

Process Code	Area	Equipment code	Qty(Nos)	Capacity
Q	Sterility Media, Microbiology, QC	Q-SAT02	1	600 x 600 x 600 mm (W x H x D in mm)

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URS Annexure List

URS Annex No.	Detail
1.	Layouts showing location of the Sterilisation Autoclave (Q-SAT 02) in media preparation and sterilisation area
2.	List of Preferred Make of 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 OVERVIEW

Autoclave shall be used to sterilize media being used for sterility tests.

S.No.	Identification no.	Area Specification	Process	Chamber inner Dimension (W x H x D in mm)
1.	Q-SAT 02	Media preparation and sterilization	Used for sterilizing air monitoring like petri plates, glass bottles, media, rubber closures used for closing glass bottles and micro-pipette tips for sterility tests per shift	600 x 600 x 600 mm

Autoclave for sterilization shall have following main features:

- Operation programs for liquid, solid and porous goods

Package Unit (PU) including the following:

- Sterilizer chamber
- Supporting structure
- Integrated vacuum system
- filters for Process air and for exhaust air
- Piping (valves, safety devices, filters, steam traps, pipes, fittings, etc.)
- Sanitary type pressure reducing valve in Pure steam inlet (for regulating the pure steam inlet pressure to the autoclave chamber as the header pressure is more than 3.0 kg/cm²) Pressure reducing valve in plant steam line
- Pressure reducing valve in plant and pure steam line
- All mating flanges/fittings, gaskets, bolts and screws for utility supplies, returns and drain
- Instrumentation
- The unit shall be direct steam heated as well as jacket steam heated and designed for full vacuum.
- Control System with printer for batch report and color trend printing
- Bio shield to seal the sterile and non-sterile areas

Design, function and control of the units **has to be GMP compliant**

All points of the IRS except the below mentioned would be applicable for the equipment


➤ , 4.1.11, 4.1.13, 4.1.17

➤ **Sec 5.1 Table 2**

- SI.NO 5 CE Conformity,
- SI.NO 7 ANSI/NSF 49-2008,
- SI.NO 8 ISO 14664
- SI.NO 9 ISO 8362

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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. In 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 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


Specifications

Remarks

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3.0 PROCESS DESCRIPTION

3.1 Input & Charging method

3.1.1	The sterilizer shall be suitable for sterilization of various items such as: Air monitoring like petri plates, glass bottles, media, rubber closures used for closing glass bottles and micro-pipette tips for sterility tests per shift.	
3.1.2	Articles for sterilization will be loaded manually in the autoclave so that all articles can come in contact of the sterilizing steam using movable carriage or any other better option.	
3.1.3	SS316 L loading carriage with a pair of SS316 L railing (provided inside the chamber) for smooth and easy loading. The railing should be fixed type properly welded	
3.1.4	The chamber carriage should be provided with removable shelves for more flexibility and carriage floor trolley MOC shall be of SS304	
3.1.5	The chamber floor shall be on the same plane with the floor of the trolley, so that the loading carriage can directly be moved into the chamber. Loading level shall be defined by the vendor.	
3.1.6	Loading environment: <ul style="list-style-type: none"> Q-SAT 01 loading will be from room of Class C (ISO 7). 	

3.2 Brief Process Steps

Sterilization shall have following steps <ol style="list-style-type: none"> 1. Loading 2. Initial Vacuum Pulsation 3. Heating (Steaming) 4. Hold period (Sterilization) 5. Post vacuum 6. Drying 7. Unloading 	
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3.3 Output & Discharging method

3.3.1	All sterilized articles will be unloaded from the loading side Class C	
3.3.2	Carriage will be taken out and articles will be unloaded from the carriage.	
3.3.3	All condensates and liquids shall lead to common drain.	

4.0 PRODUCTIVITY REQUIREMENT

4.1 Desired/ suggested capacity


Q-SAT 01: Dimension of chamber of autoclave: (W X H X D): 600mm x 600mm x 600 mm Chamber total volume: Vendor to Specify	
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4.2 Standard batch size

Not applicable	
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4.3 Change Over Time

Not applicable

4.4 Other Productivity Requirement

Total sterilization cycle must not exceed 2 hours.

5.0 CONTAINMENT

Not Applicable

6.0 GMP REQUIREMENTS

6.1 Process control

6.1.1 The equipment must operate and control the following process cycle:


- Vacuum leak test cycle (As per HTM 2010)
- Bowie Dick cycle (17 min at 121 °C and 3.5 min at 135 °C)
- Standard sterilization cycle (loading → steaming → hold period → slow/fast exhaust (for fluid cycle, the exhaust will be slow)
- Liquid cycle
- Sterilization of the vent filter
- High-pressure high vacuum sterilization cycle (loading → steam/vacuum pulsing → heat up → hold period → exhaust → vacuum drying → vacuum bleeding by sterile air.

6.1.2 For the above processes following are the critical process parameters which must be controlled by the equipment

- Pre vacuum
- Pre pressure
- No. of Pre pulses
- Heat up
- Heat up hold
- heat up control band
- Small valve set point
- Sterilization hold temperature
- Sterilization hold time

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• Temperature control band	
• Overshoot temperature	
• Sterilization stop temperature	
• Sterilization reset temperature	
• Post vacuum start pressure	
• Post vacuum	
• Post vacuum hold time	
• Post pressure	
• No of post pulses	
• Exhaust on	
• Exhaust off	
• Process end pressure	
• Chamber pressure high	
• Too long time for pre vacuum	
• Too long time for heat up	

6.2 Failure mode detection

6.2.1	The Autoclave shall be capable to detect the following failure, notify the operator with alarm and shutdown the process:	
6.2.1.1	If chamber vacuum leak test is failed	
6.2.1.2	If the chamber temperature overshoots	
6.2.1.3	If chamber temperature falls below specified level & the timer stops counting	
6.2.1.4	If chamber temperature falls further below specified level & the timer resets previously counted time	
6.2.1.5	If chamber pressure is greater than the set value	
6.2.1.6	Too long time for heat up	
6.2.1.7	Too long time for pre vacuum	
6.2.1.8	Too long time for post vacuum	
6.2.1.9	If vacuum pump trips	
6.2.1.10	Door pre condition fails	

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6.2.1.11 Failure in utility supply

- a) Compressed air pressure low
- b) Plant steam pressure low
- c) Pure steam pressure low
- d) Softened water pressure low

6.2.1.12 Failure in data communication

6.2.1.13 Vendor shall propose detail list of alarms and interlocks in Functional specifications. The alarms and interlocks list shall be finalized with the final user during discussion of detail engineering design of the equipment

6.2.1.14 Emergency stop activated

6.2.1.15 Power failure

6.2.1.16 Following condition need only notification to operator for procedural control

- a) UPS power low
- b) End of cycle
- c) Door opening after end of cycle

6.3 In –Process control

Manual diaphragm valves are provided as sampling valves for pure steam & chamber condensate sampling.
All necessary ports for steam quality testing as per EN 285 shall be incorporated.

6.4 Level of instrumentation

Sufficient and suitable instrumentation for the process, safety and productivity control as indicated in the following table:

Type of control	Purpose/ Observation	Operation range	Desired Least Count	Extent of Instrumentation			
				Indication	Alarm	Control	Recording
Temperature @ (multipoint), min 5 Nos	Chamber temperature	0°C to + 150°C	0.1°C	Y	Y	N	Y
Temperature	Chamber condensate drain	0°C to + 150°C	0.1°C	Y	Y	Y	Y
Temperature	Jacket temperature	0°C to + 150°C	0.1°C	Y	Y	Y	Y
Temperature	Air leak	0°C to + 150°C	0.1°C	Y	Y	Y	Y
Time	Sterilization time	On real time basis	1 Sec	Y	Y	Y	Y

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Pressure	Chamber pressure and vacuum	Full vacuum to 2000 mbar	1.0 mbar	Y	Y	Y	Y
Pressure	Jacket pressure	0 to 5.0 bar	0.1 bar	Y	Y	Y	N
Pressure	Pressure across the sterilizing grade vacuum break filter	0 to 2000 mbar	1.0 mbar	Y	N	N	N
Pressure	Main compressed air line for pneumatic control	0 to 10.0 bar	0.1bar	Y	Y	N	N
Pressure regulating valve along with Pressure gauge	Main Pure steam line for regulating the pressure	0 to 10.0 bar	0.1bar	Y	Y	Y	N
Pressure regulating valve along with Pressure gauge	Main plant steam line for regulating the pressure	0 to 10.0 bar	0.1bar	Y	Y	Y	N
Pressure	To give pressure input to PLC and HMI	0 to 5.0 bar	0.1 bar	Y	Y	Y	Y
Temperature	To convert temperature input to 4-20 mA	0°C to + 150 °C	0.1 °C	Y	Y	Y	Y
Temperature	For manual operation in case of PLC failure and indication of chamber temperature	0°C to + 150 °C	0.1 °C	Y	Y	Y	-

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6.5 Batch data display and record printing

Refer Installation requirement Specification

6.6 GMP requirements (Others)

6.6.1 Validation port:

- The validation ports with tri-clamp connections and with special leak tight ferrules for insertion of 16 flexible temperature sensor
- There must be two sanitary ports complete with sanitary blank, for validation thermocouples. The port shall be located on side of chamber in an easily accessible location (Size: 2" OD)
- The sanitary port shall have validation connections for thermocouples (Size: 2" OD).
- There shall be a Tri clamp at the drain near the filter housing (downstream) (Size: 1" OD).
- There shall be a sanitary Tri-clamp type port in the drain piping, immediately adjacent to the drain temperature monitor, for installation of validation monitoring probe(Size: 1" OD)

6.6.2 Automatic F0 value calculation for each temperature monitoring location.

6.6.3 Standard door interlocking function during sterilization cycle and at the end.

- During the running cycle the door shall not open
- The door shall not open with over pressure inside the chamber.

6.6.4 Temperature trend chart recording and printing software to be provided with minimum storage of 10 cycles.

6.6.5 Vacuum pump to be provided with the system.

6.6.6 Vacuum bleed filter: hydrophobic with arrangements for in place sterilization and provision for in-place integrity test.

6.6.7 Provision for air leak probe as per HTM 2010

6.6.8 Jacket to be provided with steam trap.

6.6.9 Sampling valve in the steam inlet line for collection of steam sample.

6.6.10 Sampling valve in the condensate drain line for collection of condensate sample.


6.6.11 For easy & safety operation vendor shall provide the condenser in the steam sample valve outlet

6.6.12 Vendor to give code numbers for each component

6.6.13 Equipment, valves, and instrumentation shall be uniquely identified in accordance with a standard numbering and location system. The system will be agreed between Vendor and Client at the time of order.

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6.6.14 SS panel to be flushed appropriately to the wall /ceiling/floor/LAF accordingly to avoid any dead space along with the coving on all the sides and corners

6.6.15 All valves and instruments are to be physically labeled with their equipment numbers

6.7 Specific requirements

6.7.1 Indication of chamber pressure by pressure gauge and visual LED for door open/ close mounted on sterile side

6.7.2 Single hinged door standard or vertical sliding and chamber shall be horizontal type.

6.7.3 The chamber trolleys should be provided with removable shelves for more flexibility if required. The trolley shall be 2 in numbers. The top frame is on four heavy studs for level adjustment. The rails on the top frame match with the rails in the chambers. The trolley is also provided with two fixed and two swiveling castor wheels

6.7.4 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.

6.7.5 Analogue module with back up

6.7.6 Pressure relief valve (pneumatic type) shall be provided for safety purposes.

6.7.7 Automatic F0 value calculation for each temperature monitoring port

6.7.8 The chamber floor shall be on the same plane with the floor of the trolley, so that the loading carriage can directly be moved into the chamber

6.7.9 The trolley should carry two different carriages at a time and the chamber shall also accommodate two carriages.

6.7.10 Sterilization Chamber:

The chamber shall be rectangular, with smooth and rounded corners. The chamber shall be designed as per ASME pressure vessel code. The chamber shall be made of SS316L with surface roughness less than 0.5µm. The chamber shall be re-inforced with an SS 304 jacket. The sterilizer support frame for the entire structure shall be made of SS 304.

The sterilizer shall be able to reach and maintain sterilization temperature of 121 °C 134 °C. The temperature shall be settable parameter.

6.7.11 Chamber Doors:

Steam Sterilizers shall have sliding door with automatic closing and opening. The door shall be made of SS 316L with internal surface roughness less than 0.8µm.

The door gaskets shall be made of high temperature resistant silicone rubber with rounded corners

6.7.12 Door Safety


The following door safety features shall be provided for operator safety:

Door Process Lock to prevent opening of doors when the process is on

Door obstructive sensor to be provided

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6.7.13 Validation port:

The chamber shall be provided with two validation ports with tri-clamp connections and with special leak tight ferrules for insertion of 16 flexible temperature sensor

6.7.14 Vacuum Break Filter:

A 0.2-micron vacuum break filter shall be provided on the sterile side for pressure equalization after vacuum creation

6.7.15 All the valves at sterile side must be diaphragm valve.

6.7.16 During FAT/SAT the following need to be demonstrated:

- All probes to reach $121^{\circ}\text{C} \pm 3^{\circ}\text{C}$ within 30 sec of the first probe for above 800L capacity chamber and 15 sec for below 800 L Chamber capacity.
- Not more than 2°C difference between any two probes during hold time.
- Temperature Recorders shall have accuracy of at least 1% over range 50°C to 150°C .
- Pressure recorders shall have accuracy of $\pm 1.6\%$ over the range of 1 bar to 3 bar.
- Pressure recorders shall have an accuracy of at least 0.01 bar.

7.0 CONSTRAINTS

7.1 Equipment location and available space

This equipment will be installed in **DPT vaccine manufacturing Facility at PII, Coonoor.**

Floor: Ground floor Sterility media preparation and Microbiology block

Room size: 2.850 m X 1.80 m

Room height: 5.5 m

False ceiling height: 3 m

Room :Technical area

- Room will be Non hazardous
- Class- General
- Pressure differential: NA
- Temperature maintained: $22^{\circ}\text{C} \pm 2^{\circ}\text{C}$
- Relative humidity: $<55 \pm 5\%$ RH

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

7.2 Available utility

- Electricity: _____ (Report Requirement)
- Pure steam: 3 bar (Report Requirement)
- Plant Steam: 3-3.5 bar (Report Requirement)
- Chilled water/ soft water : Supply: 6-7degC, Return: 11-12deg C (or depends on process) / Amb (Report Requirement)
- Compressed air / nitrogen pressure: 8-10 bar g (Report Requirement)

Note: Vacuum system to be supplied by the Vendor

Vendor to inform if there are any changes in the utilities required and shall plan accordingly.

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8.0 ABBREVIATION

List of abbreviations

HTM	Health Technical Memorandum
ISO	International Standard Organisation
LAF	Laminar Air Flow
PLC	Programmable Logic Controller
NNE	Novo Nordisk Engineering
SAT	Sterilisation Autoclave
SS	Stainless steel
URS	Users requirement specification
HMI	Human Machine Interface

REVISION INDEX

Revision	Date	Reason for revision
00	2012-09-12	First Draft for Client's Review
01	2013-03-25	Format changed as per HLL requirement
02	2013-06-04	As per MOM dtd 9.04.2013 & 10.04.2013 with HLL/PIIC
03	2013-06-27	As per the comments from HLL by email dtd 2013-06-17

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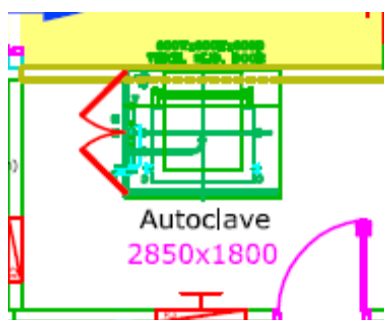
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URS Annexure 1: LAYOUT POSITION

Sterilization - Autoclave Technical area, Room dimension (2850x1800) mm



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SL.NO	DESCRIPTION	MAKE
A	INSTRUMENTATION	
1.	PLC /HMI	Allen Bradley/ Siemens
2.	Operator Interface	Allen Bradley/ Siemens
3.	Temperature transmitter	Radix/ Yokogawa/ Emerson
4.	Pressure transmitter	Siemens/ Jumo/ Wika
5.	RTD sensors	Radix/ Wika/ Waaree Instruments
6.	Temperature indicator controller	Radix/ Wika/ Waaree Instruments
7.	Printer	Epson/ HP/ Canon
8.	DC source	Shavision/ Yokogawa/ Emerson
9.	Photocell sensor	P & F/ Optex/ Metler
B	MECHANICAL	
1.	Automatic Angle Valve	Crane/ Saunder/ Gemu
2.	Manual Ball Valve	President/ Modentic/ Fluidine
3.	Needle Valve	President/ Modentic/ Fluidine
4.	Safety Valve	Teleflo/Herose/ Ciprani Harrison
5.	Pressure Reducing Valve	Klinger/ Forbes Marshall/ Armstrong International
6.	Non Return Valve	Leader/ Modentic/ Alfa Laval
7.	Pressure Gauges	Forbes Marshall/ Wika/ Waaree Instruments
8.	Pressure & Vacuum Switch	Orion/ Wika/ Emerson
9.	Level Switch	Mahalaxmi/ Endress & Hauser/ Emerson
10.	Steam Trap	Spirax/ Steriflow/ ITT

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SL.NO	DESCRIPTION	MAKE
11.	Vacuum Break Filter	Sartorius/ Pall/ Millipore
12.	Vacuum Pump	Newgenre/PPI/ Falcon Pumps
C	PNEUMATIC	
1.	Pneumatic door operating cylinder	Janatics/Rotex/ Parker
2.	Solenoid valves for door	Janatics/ Festo/ Parker
3.	Solenoid valves for Gasket	Patcon/ Festo/ Danfoss
4.	Solenoid valves for Process Valves	Janatics/ Festo/ Emerson
5.	Filter Regulator Lubricator	Janatics/ Festo/ Ingersoll
6.	Diaphragm valve (sterile side)	GEMU
D	ELECTRICAL	
1.	Limit switches	Bohmen/Siemens/ Emersen
2.	Switch gear and Relays	Siemens/ L&T/ Schneider
3.	Miniature circuit breaker	Siemens/ Havells/ Legrand
4.	Rotary switch	L&T/ Siemens/ Schneider
5.	Indication lamps	Technik / Mimic/ Schneider