

HLL LIFECARE LIMITED, CHENNAI

Revival of BCG Vaccine Laboratory, Guindy, Chennai

HLL pharmaplan	User Requirement Specifications				
	Equipment/System	Bio-waste Inactivation System			
	Identification #	K1-KIL01	Document#		URS/ K1-KIL01
	Effective Date	2013-04-15	Revision#		07

User Requirement Specifications Bio-waste Inactivation System Equipment ID: K1-KIL01

EQUIPMENT TAG	EQUIPMENTS	QUANTITY	CAPACITY (G.V)
K1-KIL01	COLLECTION TANK	1 NO	500L
	KILL TANK	1 NO	250L

Revision index

Revision	Date	Reason for Revision
00	09.12.2011	First Draft for Client's Review
01	2012-10-16	Format changed as per HLL requirement
02	2012-11-06	HLL comments incorporated
03	2012-11-07	Following changes as per MOM dated 2012-11-08: 1. Top mounted agitator in collection and kill tank is added, bottom mounted agitator removed from kill tank.

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		<p>2. One spray ball each extra is added in collection and kill tank because of top mounted agitator.</p> <p>3. Recirculation loop from collection and kill tank is removed.</p> <p>4. Plant Steam removed from collection tank.</p> <p>5. Temperature transmitter from collection and kill tank drain removed.</p> <p>6. Separate Stand by pump is provided for collection to kill tank and kill tank to ETP transfer with manual isolation valve.</p> <p>7. Recirculation line is added from kill tank to collection tank to transfer HOT water for rinsing of collection</p>
04	2013-01-08	<p>Following changes as per MOM dated 2013-01-10:</p> <p>Collection tank :</p> <ol style="list-style-type: none"> 1. Diaphragm Pressure gauge is removed 2. Safety relief valve is removed 3. Electrical tracing from vent filter is removed 4. Vent filter shall be of open type, no valves shall be provided at the exhaust 5. Compressed air line and valve to Exhaust vent filter is removed <p>Common Points</p> <ol style="list-style-type: none"> 6. 6.3 Level Of Instrumentation Collection and Kill tank Instrumentation mentioned separately 7. 6.6.2 Diaphragm Pressure Gauge to be included for Kill Tank only Level Sensor required instead of level transmitter 8. 6.6.7 jacket vent to be included in Kill Tank 9. HLL has insisted for PID/ relay based controller for Biowaste Inactivation System instead of PLC controller 10. Sampling valve is deleted from Kill tank
05	2013-02-12	<p>Following changes as per email dated 2013-02-12:</p> <ol style="list-style-type: none"> 1. PID/ relay based controller to be changed to PLC control with display synoptic view of running parameters like temperature, level sensor, valve positions etc. 2. Software, if used to generate, process, store the quality critical data must be validated and comply to 21CFR part 11 requirement 3. Level sensor shall have the provision to set the level parameter along with high, low and medium concept to perform the auto transfer even at minimal volume.
06	2013.04.04	<p>Following major changes incorporated as per HLL comments in the URS: email dated 2013.04.03</p> <ol style="list-style-type: none"> 1. Top mounted agitator for collection tank is removed 2. Working temperature changed to 134°C 3. Before discharging to ETP, the temperature range of the inactivated biowaste changed to 35°C to 45°C 4. Optional H/D ratio of 1.5:1 is removed

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		5. Basic PLC based controller system is included
07	2013.04.15	<p>As per HLL comments by mail dated 2013.04.13 following changes are incorporated</p> <ol style="list-style-type: none"> 1. Spray ball MOC (SS316L)is deleted 2. Line containing "TC clamp" in the List of MAKE of components is deleted.

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URS Annexure List

URS Annex No.	Detail
1.	Layout showing the location of installation of the Biowaste Inactivation System
2.	Tentative P&ID for Bio-waste Inactivation System
3.	List of preferred MAKE of components

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1.0 Approval signatures

This document is prepared by the Process & Validation and GMP compliance team of “NNE Pharmaplan India for the project “Revival of BCG Vaccine Manufacturing Facility” (**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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2.0 Equipment description

Bio-waste inactivation system consists of biowaste drain collection tank, Kill tank with associated piping and instrumentation. The kill system shall be in compliance with Biosafety Level2.

- The equipment described by this URS has following
 - a) 1 no. Collection Tank – Gross volume - 500 L
 - b) 1 no. Kill tank – Gross volume – 250 L with jacket
 - c) 1 no. transfer pump (transfer from collection to Kill tank)
 - d) 1 no. transfer pump (transfer from collection to Kill tank) – Stand by
 - e) 1 no. discharge pump/ recirculation pump (during rinsing/ cleaning)
 - f) 1 no. discharge pump/ recirculation pump (during rinsing/ cleaning) – Stand By
 - g) 2 no. 0.22 µ/ 0.2µ hydrophobic vent filter – one for collection tank and another for kill tank.
 - h) Fixed piping
 - i) All necessary equipment (hoses, fittings, piping) for execution of the system
 - j) Instrumentation and control system
 - k) Audio-visual alarm signals are required
- The tanks mentioned above should be designed as cylindrical vessel with double wall, floor standing on 3 legs, dished bottom, Torispherical welded lid.
- The system to be provided with valves for plant steam inlet, compressed air inlet and cooling water inlet & outlet. All control valves required for controlling the temperature during inactivation process responding to signal from temperature transmitter on the lower sidewall of the vessel based on the temperature set point. The system shall have provision for WIP. The system shall activate an alarm when the collection tank, kill tank are full.
- The system shall be designed to operate automatically through basic PLC with necessary control. Suitable alarms shall be provided for intimation in case of failure of the services or system. Interlock shall be provided to ensure that the system does not discharge the contents in case inactivation cycle has not been completed.
- The process waste is drained by gravitation which shall be collected into the collection tank.
- The system shall be connected to the following types of drain into the production area:
 - Process Drain from process room, chemical inactivation room etc.
 - Condensate drain from Autoclaves

Design, function and control of the unit have to be GMP compliant.

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

S. No.	Description	Purpose (COLLECTION TANK)	Purpose (KILL TANK)
1.	Shell	To hold the Biowaste Solutions	To inactivate the Biowaste Solutions at 121-134°C.
2.	Jacket	Not Applicable	To be used for cooling or heating the solution
3.	Insulation	To protect the outer surface	To Prevent heat loss during FSIP and Process
4.	Cladding	To protect insulation from contamination	To protect insulation from contamination

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5.	Agitation	Not Applicable	Top mounted agitator
6.	Provisions for different nozzle connections	To be used for WIP/ biowaste drain etc	To be used for WIP/plant steam/ biowaste etc
7.	Any pneumatic Valve in harvest line	To transfer the contents	To flush the system completely
8.	Level sensor	Level sensor with controller	Level sensor with controller

2.1 General Requirements

The general design must be hygienic, with no dead legs and no air pockets. The bio-waste inactivation system must be fully drainable with flush bottom valve at the outlet.

The system must have its own control unit with an operator panel located next to the units.

2.2 Purpose of use

Stainless steel tanks used to inactivate biowaste solution. The tanks shall be designed, constructed, installed and commissioned to inactivate the biowaste material minimum at 121-134°C & send it to ETP for final treatment after cooling @ 35-45°C at least. This includes also appropriate control & monitoring systems.

2.2.1 General vessel specifications for 500L (Collection Tank) are as under:

Geometric volume	500 L
Working temperature range	37°C – 134°C
Surface Finish	Internally Electro polished up to <0.8 Ra
	Externally Mechanically polished up to <1.2 Ra/ 180grit
	Stainless steel piping interior Ra≤ 0.8 Microns

H / D ratio	1.2/1
Shell ID	810mm
Shell Length(TL-TL)	972mm

Vessel Quality Certification : ASME BPE

Vessel Material - SS AISI 304

Top – torispherical lid

Bottom – torispherical

2.2.2 General vessel specifications for 250L (Kill Tank) are as under:

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Geometric volume	250 L
Working temperature range	37°C – 134°C
Rise in temperature per minute (heating capacity)	Vendor to specify (heating from ambient to 121°C)
Fall in temperature (cooling capacity)	Vendor to specify (before discharging to ETP, inactivated biowaste shall be 35°C to 45°C)
Temperature control deviation	±0.5°C
Surface Finish	Internally Electro polished up to <0.8 Ra
	Externally Mechanically polished up to <1.2 Ra/ 180grit
	Stainless steel piping interior Ra ≤ 0.8 Microns

H / D ratio	1.2/1
Shell ID	643mm
Shell Length(TL-TL)	771mm

Vessel Quality Certification - ASME BPE

Vessel Material - SS AISI 304

Design – Cylindrical at full vacuum

Top – torispherical lid

Bottom – torispherical

Agitator: The vessel shall be designed with top mounted agitator with dry mechanical seal, gear box and AC motor. The impellers shall be of standard type.

Spray Ball: Must be positioned properly to assure that all ports in top dish of vessel get properly sprayed and clean all the internal surfaces. So 2 no. of static spray ball shall be selected for the proper cleaning.

Controller: Basic PLC Based Controller with control panel (Displaying synoptic view of running parameters like temperature, level sensor, valve position etc). Vendor to perform a criticality assessment to assess the applicability of the system to Part 11 regulation. Software, if used to generate, process, store the quality critical data must be validated and must comply 21 CFR Part 11 requirements.

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 an deviation a comment must be inserted or enclosed as

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	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 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 vendors' 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.	<p>Special Instruction</p> <p>a. If no comments against any specification shall be considered as "NO" and</p> <p>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.</p>
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 HLL before submitting the quotes.
X.	The makes requested are standard international makes. In case of any deviation, vendor to seek clarification from HLL before submitting the offers.
XI.	Refer document Installation Requirement Specification and Specific Instructions with URS; NPI_110729_IRS_BCG_01
XII.	Refer Tender document with URS; NPI/110729/EQP/TD/07

Specifications	Remarks
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Specifications	Remarks
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3.0 Process Description

3.1 Input & Charging method

Note: This section also includes the charging method of biowaste and transferring to ETP after inactivation.

- a) Bio-waste from the bulk floor (first floor) is transferred to collection tank through gravity as the tanks at the ground floor so that the liquid waste from all process steps/cleaning units can be drained by gravity to the system.
- b) Bio-waste is transferred to inactivation tank from collection tank using centrifugal pump, once the level is achieved. **Level sensor provides the signal to the pump.(Start is activated by the level sensor of the collection and inactivation tank accordingly-Run by Min and maximum philosophy)**

3.2 Brief Process Steps

- a) Collection of the biowaste to collection tank through process drain pipe, which shall be laid with proper slope so that waste is drained by gravity.
- b) Once the high level is achieved in collection tank. Biowaste from collection is transfer to kill tank through centrifugal pump (both kill tanks & collection tank shall be interlocked for high level, low level, and safe mode of operation)
- c) **Agitation:** once proper level is achieved in kill tank, agitator starts mixing the contents.
- d) **Inactivation:** After achieving high level in kill tank pump stops and inactivation process start, plant steam valve opens and get the desired temperature for inactivation. Inactivation temperature till 90 °C-95°C is achieved by using Plant steam in jacket and later by both the addition of steam directly to tank and by jacket. Allow the biowaste to hold it for sometime (**procedures will be defined during PQ or internal validation SOP**) at 121°C. The temperature shall be controlled by ON/OFF Valves.
- e) The temperature to maintained is 122.5±1°C and pressure @1.2±0.1 bar
- f) **Cooling:** after holding time is completed and it is ensured that, the biowaste is inactivated completely. Start cooling cycle to get the temperature (i.e.. 35-45°C) before discharging to ETP.
- g) Transfer the Inactivated biowaste to ETP by using centrifugal pump.

3.3 Output & Discharging method

Transfer of bio-waste from collection tank to inactivation tank. After the inactivation cycle is complete the inactivated biomass transferred to ETP.

4.0 Productivity Requirement

4.1 Desired/ suggested capacity

Collection tank (Gross Volume) : 500L
Kill Tank (Gross Volume) : 250L

4.2 Standard batch size

Minimum volume to be handled:
 Collection tank : Vendor to specify

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Kill tank: Vendor to specify	
4.3 Change Over Time (if applicable)	
Not Applicable	
4.4 Other Productivity Requirement	
Not Applicable	
5.0 Containment	
Not Applicable	
6.0 GMP requirements	
6.1 Process control	
The equipment must operate and control the following process parameters.	
6.1.1 Temperature of biowaste inside kill tank	
6.1.2 Pressure inside the kill tank during sterilization and cooling	
6.1.3 Adjustable agitation speed during the inactivation process	
6.1.4 Level control for filling up of the tank (LL-for Low level. HL-for High level)	
6.1.5 Exhaust vent filter (to release the excess gases through hydrophobic vent filter, 0.2μ) and condensate shall be drained back into the tank.	
6.2 Failure mode detection	
Equipment shall be capable to detect the following failure, notify the operator with alarm and shutdown the process:	
6.2.1 Motor overload	
6.2.2 Emergency stop activated	
6.2.3 Steam pressure higher than the safe limit	
6.2.4 Drop in temperature inactivation hold period	
6.2.5 Drop in inactivation control temperature below acceptable temperature band during hold period.	
6.2.6 End of cycle	
6.3 Level of instrumentation	
Sufficient and suitable instrumentation for the process, safety and productivity control as indicated in the following table:	

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Type of control	Purpose	Instrumentation	Failure Mode Detection	Alarm
Collection Tank				
Level measurement	To monitor the volume of the biowaste in collection with interlocking	Level sensor	Low /high, or Deviating from set value	Yes
Kill Tank				
Temperature	To monitor, indicate and control the vessel temperature	Temperature probe with indicator and controller	Low or high	Yes
Pressure	To monitor, indicate the vessel pressure	Pressure transmitter	Low or high	Yes
Pressure	To monitor, indicate the jacket pressure	Pressure gauge	Low or high	Yes
Level measurement	To monitor the volume of the biowaste in collection with interlocking	Level sensor	Low /high	Yes
RPM	To control agitation speed	VFD	Deviating from set value	Yes

6.4 Batch data display and record printing

Refer IRS (Installation requirement Specification and Specific Instruction)

6.5 GMP requirements (Others)

- 6.5.1 After power recovery the timer should start from zero during inactivation process
- 6.5.2 Transfer line shall be washed once in 6 months through whole system by filling up with water and flushing.
- 6.5.3 The filter housings in the vessel shall be provided with integrity connectors for in-situ integrity testing of the vent filters .Vent shall be provided with sterilizing grade hydrophobic filter 0.22µm with suitable arrangement for WIP and FSIP and in place integrity testing.

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6.5.4 Moving parts shall be tightly sealed.	
6.5.5 All valves shall be of leak proof Ball valves and Angle seated valves,	Changed
6.5.6 All nozzles for biowaste contact parts shall be provided with sanitary valve which shall be flushed to the wall on closure and inside surface of the valves can be cleaned during WIP.	
6.5.7 Steam traps shall be provided wherever are required.	
6.5.8 Actuated ball valve, actuated angled piston valve, manual diaphragm valve and automatic diaphragm valve shall be provided according to the requirement	
<p>6.5.9 Centrifugal pumps shall be provided to transfer effluent from collection tank to kill tank and from kill tank to ETP area. These pumps shall be connected to the control panel. The same pump shall be used for the recirculation of the cleaning fluid during cleaning. The pump shall be of non-sanitary type, leak proof and spill proof.</p> <p>Pump Specification:</p> <ol style="list-style-type: none"> I. Flow rate: 2m³/ hr II. Operating Temperature: 50°C - 60°C III. MOC: SS 304 IV. Flooded type 	
6.6 Specific requirements	
A. COLLECTION TANK (1NO.) SPECIFIC REQUIREMENT	
6.6.1 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.	
6.6.2 The vessel shall be provided with the following on the Top lid :	
• Light/sight glass (preferably metal fused type) – 1 no	
• Hand hole – 1 no.	
• Effluent addition port-1no.	
• Spray ball port – 2 no	
• Exhaust port with sterile vent air filter-1 no Code 7 sterile hydrophobic vent filter and cartridge 0.2 micron hydrophobic of suitable size in SS304 construction. It shall also provided with filter integrity provision	
• Level sensor – 1 no	
• Spare Port – 2no.	
6.6.3 The vessel shall be provided with the following on the Bottom dish :	
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<ul style="list-style-type: none"> Vessel bottom to be Torispherically dished with a transfer line 	
<ul style="list-style-type: none"> Pneumatic valve for discharge. 	
B. KILL TANK (1NO.) SPECIFIC REQUIRMENT	
6.6.4 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.	
6.6.5 The vessel shall be provided with the following on the Top lid :	
<ul style="list-style-type: none"> Top mounted agitator – 1 no. 	
<ul style="list-style-type: none"> Light/sight glass (preferably metal fused type) & Hand hole- 1 no 	
<ul style="list-style-type: none"> Effluent addition port-1no. 	
<ul style="list-style-type: none"> Spray ball port - 1 no 	
<ul style="list-style-type: none"> Pressure Transmitter -1 no 	
<ul style="list-style-type: none"> Safety relief valve-1 no 	
<ul style="list-style-type: none"> Exhaust port with sterile vent air filter-1 no Code 7 sterile hydrophobic vent filter and cartridge 0.2 micron hydrophobic of suitable size in SS304 construction. It shall also provided with electrical tracing and filter integrity provision 	
<ul style="list-style-type: none"> Level Sensor-1 no 	
<ul style="list-style-type: none"> Spare port – 2no. 	
6.6.6 The jacket shall be provided with the following:	
<ul style="list-style-type: none"> steam inlet 	
<ul style="list-style-type: none"> chilled water inlet 	
<ul style="list-style-type: none"> chilled water return 	
<ul style="list-style-type: none"> Jacket safety valve with pressure gauge 	
<ul style="list-style-type: none"> Jacket/ condensate drain 	
<ul style="list-style-type: none"> Jacket Vent valve 	
6.6.7 The vessel shall be provided with the following on the Bottom dish :	
<ul style="list-style-type: none"> Vessel bottom to be Torispherically dished with a transfer line 	
<ul style="list-style-type: none"> Pneumatic valve for discharge. 	
<ul style="list-style-type: none"> Knuckle port with PT 100 temperature sensor-1 no (side wall) 	

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<p>6.6.8 The Top mounted agitator assembly shall consist of:</p> <ul style="list-style-type: none"> • Variable speed 40-600 rpm A.C.motor. • Dry mechanical seal, gear box & AC motor. The impellers shall be of standard type, Suitable for liquids up to pH 2-13, Temp 134°C 	
<p>6.6.9 Design Parameters (Common for Collection and Kill Tank):</p> <ul style="list-style-type: none"> • Shell working Pressure- Atmospheric pressure • Shell working Temperature- 20-134°C • Shell sterilization Temperature- 121-134°C • Shell design Pressure- Full Vacuum to 3.5 bar(g) • Shell design Temperature- 0-150°C • Jacket working Pressure- 3.5 bar(g) • Jacket working Temperature- 150°C • Jacket design Pressure- Full vacuum to 4.5 bar(g) • Jacket design Temperature- Vendor to specify 	
<p>6.6.10 Cleaning and sanitization shall be done semi-automatically (WIP with soft water and sanitization with hot water):</p> <ul style="list-style-type: none"> • Kill Tank: <ol style="list-style-type: none"> a. The vessel shall be connected to soft water for rinsing. If required acid-alkali can be added manually. b. the vessel shall be sanitized with the help of hot water which will be achieved with plant steam in shell and jacket as well • Collection Tank: <ol style="list-style-type: none"> a. The vessel shall be connected to soft water for rinsing. If required acid-alkali can be added manually. b. The vessel shall be sanitized with Hot water which will be done in kill tank with the help of plant steam. Discharge pump shall be connected to collection tank from kill tank to recirculate Hot water for sanitization. c. Transfer lines along with pumps will also be rinsed during the recirculation of Hot water in between collection tank and kill tank. 	
6.6.11 All metallic product contact surfaces should be constructed as per ASME BPE approved SS304 grade stainless steel with external surface matt finish.	
6.6.12 All metallic non-product contact surfaces should be constructed of SS304 grade with external surface matte finish.	
6.6.13 All process pipes should be orbital welded with Boroscopy records.	
6.6.14 Level sensor shall have the provision to set the level parameter along with high, low and medium concept to perform the auto transfer even at minimal volume.	
<p>6.6.15 Spray ball:</p> <ul style="list-style-type: none"> • Spray ball/s for covering entire area with 360° spray) (Vendor to specify the design). Systems with WIP shall be designed for 100% coverage of the internal surface areas. • Spray ball coverage test should be performed during FAT/SAT. 	

HLL LIFECARE LIMITED, CHENNAI

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User Requirement Specifications				
HLL Pharmaplan	Equipment/System	Bio-waste Inactivation System		
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	Effective Date	2013-04-15	Revision#	07
				

Specifications	Remarks
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<p>6.6.16 Pump specification for 2 no. transfer pump from collection tank to kill tank and 2 no. discharge/ recirculation pump from kill to ETP/ collection tank for recirculation. The pump should be of non-sanitary type, leak proof and spill proof.</p> <ul style="list-style-type: none"> Flow rate: 2m³/hr Operating temperature: 50-60°C MOC: SS 304 Flooded type 	
<p>6.6.17 Basic PLC Based Controller with control panel (Displaying synoptic view of running parameters like temperature, level sensor, valve position etc). Vendor to perform a criticality assessment to assess the applicability of the system to Part 11 regulation. Software, if used to generate, process, store the quality critical data must be validated and must comply 21 CFR Part 11 requirements</p>	
<p>6.6.18 Vendor shall provide the FRL (Filter, regulator, lubricator), automatic valve assembly and air pressure switch for instrument air. Connections to automatic diaphragm valve shall be in vendor scope.</p>	

7.0 Constraints

7.1 Equipment location and available space

<p>This equipment will be installed in the Biowaste area of Revival of BCG Vaccine Laboratory at BCGVL, Guindy, Chennai.</p> <p>Equipment Location: Floor: <u>FG046</u> Room dimension : 3350mm x 5800mm The equipment location is indicated in the relevant block of the layout enclosed as Annex-1.</p> <p>Physical condition of the rooms: <u>Biowaste Inactivation Room:</u></p> <ol style="list-style-type: none"> 1. Room may be hazardous 2. Class: General 3. Under Negative Pressure (Supply and Exhaust Air) 	
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7.2 Utility

a) Electricity : <u>12.5 kW</u> (Report requirement)	
b) Chilled Water @ 3.5 bar _____ (Report requirement)	
c) Soft water @ 3-5 bar _____ (Report requirement)	
d) Compressed Air/ instrument air @ 8-10 bar _____ (Report requirement)	
e) Plant Steam @ 3-3.5 bar _____ (Report requirement)	

Utility consumption to be specified by the vendor.
Vendor shall also specify the utility pipe sizes and GA drawing during DQ stage.

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8.0 Abbreviation

Terms	Abbreviation
BCGVL	BCG Vaccines Laboratory
HMI	Human Machine Interface
HLL	HLL Lifecare Limited
ISO	International Standards Organization
KIL	Kill Tank
MOC	Material Of Construction
NPI	NNE Pharmaplan India
PLC	Programmable Logic Controller
RPM	Revolutions Per Minute
WIP	Wash In Place
°C	Degree Centigrade

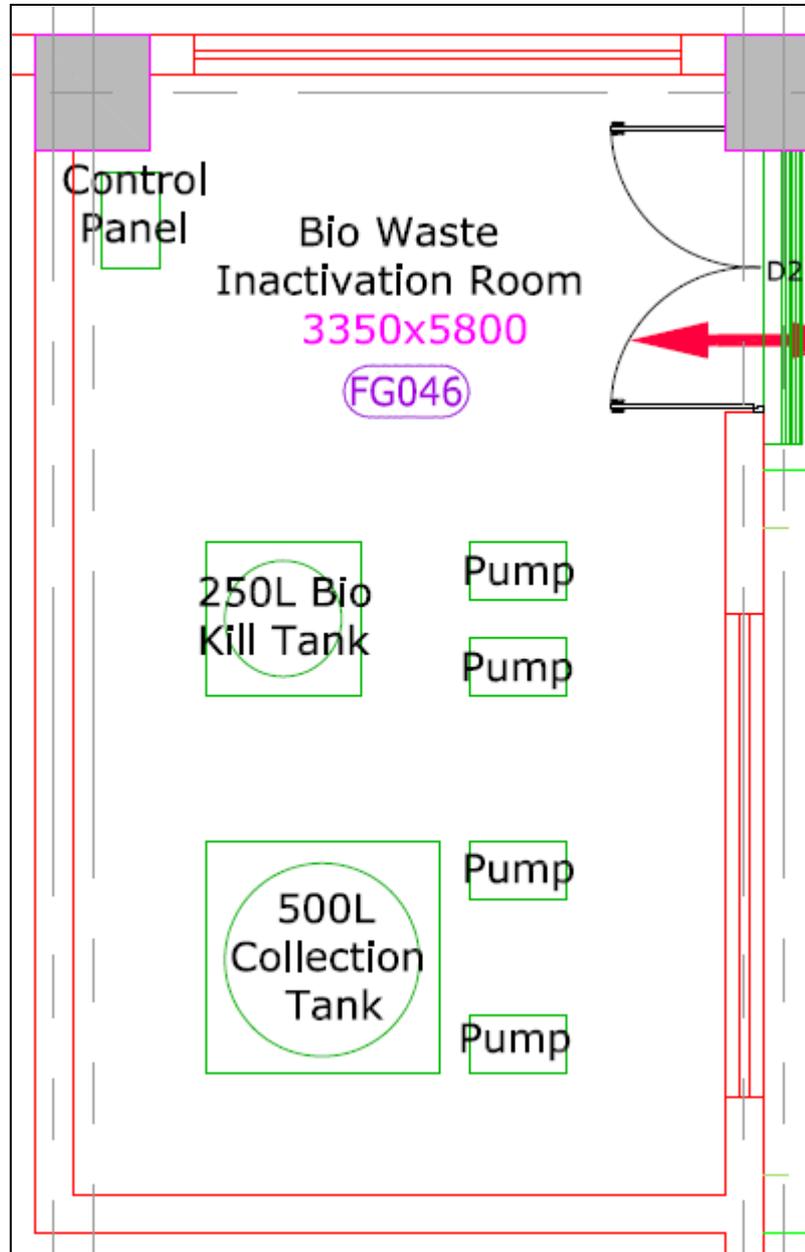
HLL LIFECARE LIMITED, CHENNAI

Revival of BCG Vaccine Laboratory, Guindy, Chennai

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URS Annexure 1: LAYOUT POSITION



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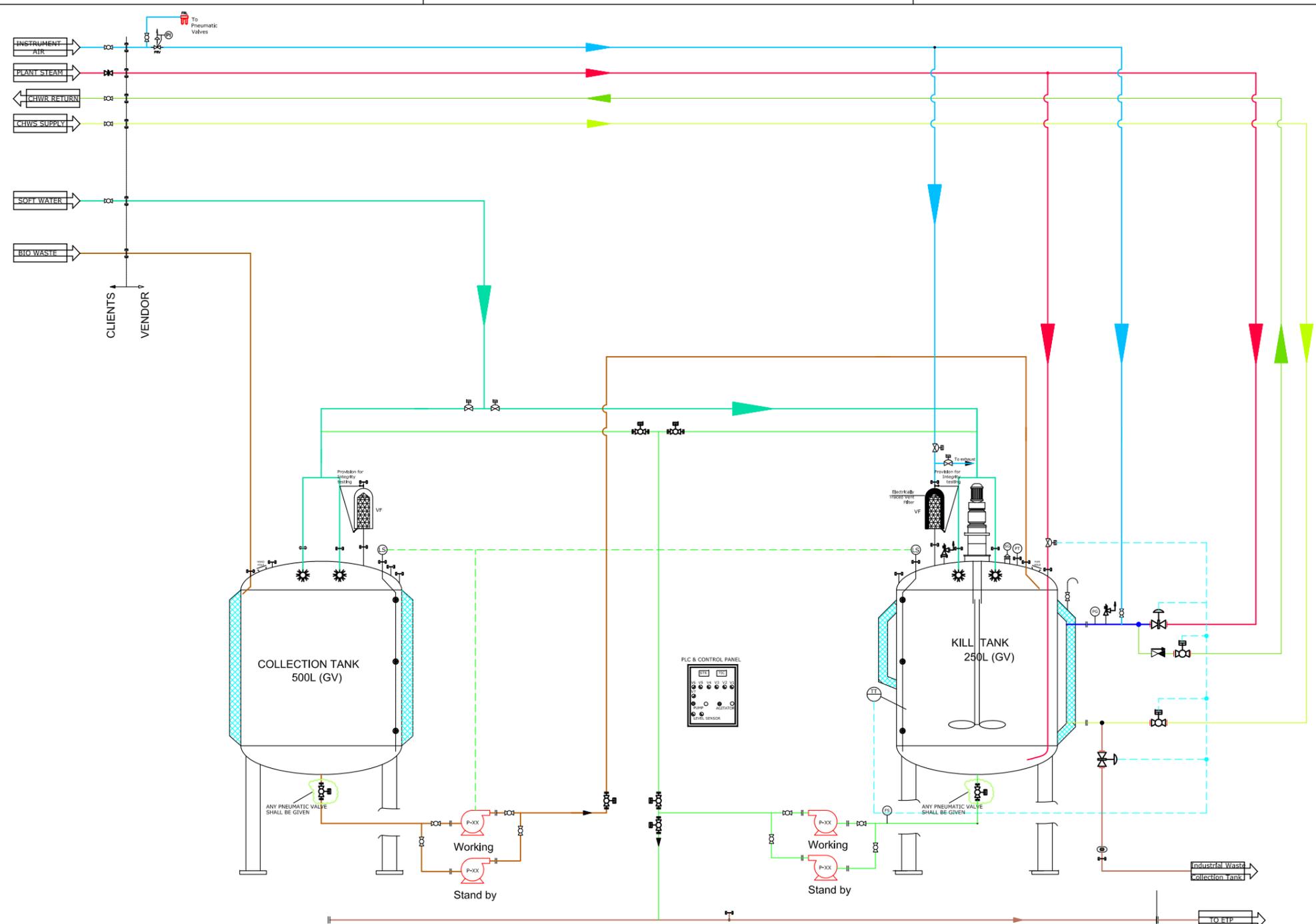
Revival of BCG Vaccine Laboratory, Guindy, Chennai

nne pharmaplan	User Requirement Specifications				
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	Identification #	K1-KIL01	Document#		URS/ K1-KIL01
	Effective Date	2013-04-15	Revision#		07

URS Annexure 3: List of preferred make of components

S. No	Description	Make
1.	Ball Valve	President/ modentic/ fluidline
2.	diaphragm Valve	Gemu/ Saunders(Crane)/Burkert
3.	Pneumatic valve(in harvest line)	Alfalaval/Saunders(Crane)
4.	Float Trap	Spirax/ Steriflow/ ITT
5.	Actuated Piston Valve	Gemu/Saunders(Crane)/Burkert
6.	NRV	Leader/ alfalaval
7.	Temperature sensor,PT 100 (For Vessel)	Negele/Radix/E&H/Rose mount
8.	Temperature Controller	Radix/ wika/ waaree instruments
9.	Flow Switch	Microset/Negele/Davis instruments
10.	FRL	Janatics/ Festo/ Ingersoll
11.	Pressure Regulator	Metal Work Pneumatic/Festo/Norgren
12.	Top Driven Agitator	Inoxpa/IKA/PRG
13.	Gauge	Forbe marshal/ wika/ waaree instruments
14.	Vent Filter Cartridge	Sartorius/ pall/ millipore
15.	Electrical Tracing for Vent Filter	PALL
16.	Filter Integrity Connector	Sartorius/ pall/ millipore
17.	Safety Relief Valve	Teleflo/ heroes/ ciprani harrison
18.	Variable Frequency Drive	Siemens/ABB
19.	Centrifugal Pump	Inoxpa/Grundfos/Alfalaval
20.	Level Sensor	MicroSet/ E&H/WIKA
21.	Level transmitter	MicroSet/E&H/WIKA
22.	PLC with IO Modules and HMI touch Panel	Mitsubishi/ Allen Bradley/ Siemens
23.	Spray Ball	HAKE/Lechler

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—	CHWR SUPPLY
—	CHWR RETURN
—	COOLING WATER SUPPLY
—	COOLING WATER RETURN
—	COMPRESSED AIR
—	PURE STEAM
—	PLANT STEAM
—	CIP
—	EXHAUST GAS
—	NITROGEN GAS
—	BIOWASTE DRAIN
—	DRAIN
—	CONDENSATE DRAIN

BIOWASTE INACTIVATION SYSTEM

LEGEND

Symbol	Description	Symbol	Description	Symbol	Description
	Manual Ball Valve		Check Valve		TEMP. TRANSMITTER
	Actuated Ball Valve		Safety Relief Valve		FLOW SWITCH
	Manual Diaphragm valve		Triclover Connector		FILTER INTEGRATION TEST
	Actuated Diaphragm valve		Level Sensor		
	Sampling Valve		PRESSURE TRANSMITTER		
	Flush Bottom Valve		Sight Glass		
	Float Trap		Spray Ball		
	Actuated Piston Valve		Pressure Regulating Valve		

Note: This is an indicative drawing, final P&ID shall be given by the vendor.

03	2013-01-10	NVNG/NHSC	NVNG	Following changes as per MOM dated 2013-01-10: Collection tank : 1. Diaphragm Pressure gauge is removed 2. Safety relief valve is removed 3. Electrical tracing from vent filter is removed 4. Vent filter shall be of open type, no valves shall be provided at the exhaust 5. Compressed air line and valve to Exhaust vent filter is removed 6. Jacket vent to be included in Kill Tank 7. Sampling valve is deleted			
02	2012-11-09	NVNG/NHSC	NVNG	Following changes as per MOM dated 2012-11-09: 1. Top mounted agitator in collection and kill tank is added, bottom mounted agitator removed from kill tank. 2. One spray ball each extra is added in collection and kill tank because of top mounted agitator. 3. Recirculation loop from collection and kill tank removed. 4. Plant Steam removed from collection tank. 5. Temperature transmitter from collection and kill tank drain removed. 6. Separate Stand by pump is provided for collection to kill tank and kill tank to ETP transfer with manual isolation valve. 7. Recirculation line is added from kill tank to collection tank to transfer HOT water for rinsing of collection tank			
01	2012-11-06	SMBY/NHSC	NVNG	1. working and standby pump shown separately 2. SIP manual purging on transfer line provided			
Rev.	Date	Changed	Checked	Kind of revision	No. Of Prints	Date	Issued To
File name :							
Originated From Drg. No :							
Project:				Project No.:		nne pharmaplan	
BCG VACCINES LABORATORY, GUINDY, CHENNAI				110729		NNE Pharmaplan India Limited	
HLL LIFECARE LIMITED				Location		# 12, Achiah Shetty Layout, Bangalore - 560 080., INDIA.	
CHENNAI							
Description:				Date	Name		
P&ID FOR BIOWASTE INACTIVATION SYSTEM				28.03.2012	SAPL		
				28.03.2012	SMBY/ NHSG		
				28.03.2012	NVNG		
Scale-NTS				Units : mm	Size : A3		
Drawing no:				NPI/110729/EQP(P&ID)/K1-KLT 01		Rev.	
						03	