

HLL BIOTECH LIMITED, CHENNAI

INTEGRATED VACCINES COMPLEX, CHENGALPATTU

nne pharmaplan

User Requirement Specifications

Equipment/System	Biowaste inactivation system		
Identification #	-	Document No:	URS/BIS 01
Effective Date:	31-03-2016	Revision #	02



User Requirement Specifications Bio-waste Inactivation System

Equipment	Block Code	Block	Identification #	Quantity	Capacity (W.V)
Collection Tank-Rabies	B4	Rabies Bulk	B4-COL-01	1	1.5KL
Kill tank - Rabies	B4	Rabies Bulk	B4-KIL-01	1	0.5KL
Collection Tank-Multiple Bacterial	B1	Multiple Bacterial	B1-COL 01	1	6 KL
Kill Tank- Multiple Bacterial	B1	Multiple Bacterial	B1-KIL-01,B1-KIL-02	2	1KL

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	Equipment/System	Biowaste inactivation system			
	Identification #	✓	Document No:		URS/BIS 01
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URS Annexure List

URS Annex No.	Detail
1.	List of components and make
2.	Section and Elevation drawings for collection and Kill tanks locations

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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 "Integrated Vaccines Complex, Chengalpattu, Chennai" (project number: 120310) of HLL BIOTECH LIMITED (Chennai) under the authority of their Project Manager. Hence, this document before being effective should be reviewed by HBL user/s and project/ engineering team, approved by team lead of user department and QA and authorized by the appropriate Project Authority.

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2.0 EQUIPMENT DESCRIPTION

The equipment described by this URS is a Bio-waste inactivation system which will be located in the respective blocks.

Design, function and control of the unit should have cGMP compliant. The Biowaste Inactivation system shall be in compliance with biosafety level 2.

Bio-waste inactivation system consists of bio-waste drain collection tank, and kill tank with associated pumps, piping and instrumentation.

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 tank bottom valve at the outlet.

2.2 Purpose of use

Purpose of the inactivation system is to collect and inactivate bio-waste solution. The tanks shall be designed, constructed, installed and commissioned to inactivate the bio-waste material at 121 - 134°C and through chemical inactivation & send it to ETP for final treatment after cooling @ 35-45°C. This also includes appropriate control & monitoring systems.

2.2.1 General tank specifications for Collection Tanks are as under:

S No	Description	Requirement	Remarks
1	Capacity	For Multiple Bacterial - 6 KL X1No. For Rabies Bulk – 1.5 KL X 1No.	
2	MOC	SS 304	

2.2.2 General Design of Collection Tank:

The collection tank shall be an underground mounted unit designed with all piping and necessary instrumentations for the collection, storage and transfer of biological wastes to Kill tanks.

The collection tank shall be of horizontal and rectangular in shape having the required reinforcements.

The tank shall be buried underground to facilitate the collection of bio-wastes by gravity. Necessary supporting arrangements will be provided to facilitate for grouting. A normally open valve shall be provided in the inlet of the waste collection line.

S NO.	DESCRIPTION	Remarks
a.	Air supply: The collection tank shall have a sterile grade 0.22µ (absolute) hydrophobic filter with SS housing.	
b.	Cleaning: Collection tank shall be equipped with a spray ball selected to ensure full coverage of the vessel including all the ports. Provision for the	

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addition of detergent shall be available in the vessel.

c. **Pumps:** 2 nos of submerged cutter pumps shall be provided in the collection tank to transfer the bio-waste in the kill tank. The pumps shall be controlled by a feedback control loop, the feedback for which is obtained from the level sensors.

d. **Level sensor:** A level sensor shall be provided in the collection tank. Level sensor should have a 4 stage level control.

- Level 1 (LOW-LOW) - No action
- Level 2 (LOW) - Pumping to kill tank
- Level 3 (HIGH)– Audio and Visual Alarm
- Level 4(HIGH-HIGH) – Inlet valves shut off and alarm

2.2.3 General tank specifications for Kill Tanks are as under:

S No	Description	Requirement	Remarks
a.	Working volume	For Rabies Bulk– 0.5 KL X 1No. For Multiple bacterial- 1 KL X 2No.s	
b.	Min. mixing volume	For Rabies Bulk- Vendor to specify For Multiple bacterial- Vendor to specify	
c.	Shell Working Temperature Jacket working Temperature Shell working Pressure Jacket Working Pressure	0-135°C 0-135°C 0-2.5 bar(g) 0-2.5 bar(g)	
d.	MOC- Contact and Non-contact parts	SS 304	
e.	Insulation	Chloride free ceramic wool	
f.	Gaskets and O-rings	EPDM	
g.	Agitator	Top driven single mechanical seal	
h.	Rise in temperature per minute (heating capacity)	Vendor to specify (heating from ambient to 121°C)	
i.	Fall in temperature (cooling capacity)	Vendor to specify (before discharging to Hold Tank, inactivated bio-waste shall be 35°C to 45°C)	
j.	Process Cycle	<ul style="list-style-type: none"> • Transfer from collection tank to Kill tank • Inactivation • Cooling • Transfer to ETP 	

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2.2.4 General design of Kill tank:

The system consists of kill tanks designed with all piping with skid, valves, necessary instrumentations and control panels for the inactivation of biological wastes. The biological waste collected directly into the Collection tank from the process areas.

S NO.	DESCRIPTION	Remarks
a.	Cleaning: The system shall be provided with soft water inlet for collecting into the vessel and cleaning by agitation. The system shall be equipped with a spray ball selected to ensure full coverage of the vessel including all the ports. Provision for the addition of detergent / disinfectant shall be available in the vessel.	
b.	Exhaust Line: Process air shall be supplied into the vessel through the exhaust filter. A pressure regulating valve shall be provided to control the pressure of the inlet air. The vent line shall be equipped with an exhaust filter and filter housing. The filters shall be hydrophobic with a pore size of 0.22µ (absolute) equipped with SS housing and necessary drain arrangements for the removal of condensate during the sterilization.	
c.	Heating: The kill tank shall be provided with a jacket with port for plant steam inlet and condensate outlet. The heating system shall be designed to heat the contents in the Kill tank to 121°C using plant steam. During the Inactivation process, temperature will be controlled through a feedback control loop. Heating and cooling shall be done by passing plant steam or cooling water in the jacket	
	Pneumatically actuated valves for steam and cooling water/ chilled water to be provided	
d.	Agitation system: The Kill tank shall be designed with a top-mounted mechanical driven agitation system with a fixed speed geared motor. A single dry mechanical seal shall be provided to the agitator. The Kill tank shall be provided with a removable, height adjustable propeller turbine impeller suitable for mixing and good heat transfer.	
e.	Sampling valve Assembly: The side bottom of the Kill tank shall be fitted with a zero dead leg resterilizable sampling valve for sterile sampling. The diaphragm of this valve shall be made of EPDM/silicon and should be FDA compliant. The sampling valve should have a provision for independent-sterilization of the sampling point in the closed position. The sampling systems shall be equipped with a 100ml bottle with provision for venting. The autoclaved bottle can be connected to the equipment and the connection can be sterilized prior to use.	
f.	Level Measurement: Level shall be measured through a set of DP sensor [Hydrostatic]. Control shall be provided with the DP sensor and transfer pump in the collection tank.	

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g.	<p>Vessel Outlet: The Kill tank shall be fitted with a Diaphragm valve to transfer out the inactivated waste to the ETP plant. Two numbers (1 no working and 1 no standby) of centrifugal pump shall be provided in the outlet of the kill tank for transfer the inactivated material to the ETP.</p>	Distance to the nearest chamber of the ETP shall be 100 m
h.	<p>Controller: PLC Based Controller (Non-editable data format to be obtainable) with minimum size of 10" HMI (Displaying data trends as Graphs, synoptic view of running parameters etc)</p>	
i.	<p>The HMI should be touch screen type (Provision for manual operation to be provided). All settings should be user adjustable. HMI and Control Panel should be mounted on skid.</p> <ul style="list-style-type: none"> HMI must be used to enter the process details, which should appear in the print out. All critical alarms All Critical parameters & interlocks P&ID of the vessel along with instrumentation details Login details HMI screen showing simulation of valves 	

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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 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 Technical specification 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 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_120310_EQP_IRS_S1_01
XII.	Refer Tender document with URS; NPI_120310_EQP_S1_TD_16

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Specifications	Remarks				
3.0 PROCESS DESCRIPTION					
3.1 INPUT & CHARGING METHOD					
<i>Note: This section includes the charging method of bio-waste and transferring to ETP after inactivation.</i>					
<ul style="list-style-type: none"> a) Bio-waste from each block facility is transferred to their respective collection tanks under gravity as the system has been placed at the lowest point, so that the liquid waste from all process steps/cleaning units can be drained by gravity to the system respectively. b) Bio-waste is transferred to each kill tank from respective collection tank using pumps. 					
3.2 BRIEF PROCESS STEPS					
<ul style="list-style-type: none"> a) Collection of the bio-waste from separate blocks to their respective collection tanks through process drain pipes, which shall be laid with proper slope so that waste is drained by gravity. b) Once the level is achieved in collection tank, bio-waste from collection tank is transferred to the respective kill tank through submersible cutter pump c) Inactivation: All drains which are defined by risk of containing active cells (process waste) from the production (fermentation & microfiltration), CIP and cleaning facilities are led to the collection tank before being transferred to the kill tank. After achieving high level in kill tank transfer from collection tank stops and inactivation process starts. The temperature to be maintained in case of steam inactivation method is 122±1°C and pressure @1.2±0.1 bar. d) Cooling: The inactivated bio-waste is then cooled by circulating cooling/soft water. Cooling cycle shall start to obtain the temperature (about 40-50°C) before discharging to ETP. e) Sampling: The kill tank shall be provided with a sampling arrangement for collection of samples. f) Transfer: Inactivated Bio-waste shall be transferred to ETP by using centrifugal Pump. 					
3.3 OUTPUT & DISCHARGING METHOD					
Transfer of bio-waste from collection tank to Kill tank takes place through pump. After the inactivation cycle is complete the inactivated biomass is transferred to ETP through discharge pump.					
4.0 PRODUCTIVITY REQUIREMENT					
4.1 STANDARD BATCH SIZE / PROCESS TIME					
Not Applicable					
4.2 CHANGE OVER TIME (IF APPLICABLE)					
Not Applicable					
4.3 OTHER PRODUCTIVITY REQUIREMENT					
Not Applicable					
5.0 CONTAINMENT					
File Name	NPI_120310_EQP_URS_BIS 01	Start Date	16-03-2015	Page No.	Page 10 of 20

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Not applicable

6.0 GMP REQUIREMENTS

6.1 PROCESS CONTROL

The equipment must operate and control the following process parameters (Kill Tank).

6.1.1	Temperature of bio-waste inside the tanks	
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.	

6.2 FAILURE MODE DETECTION

6.2.1 Equipment should be capable to detect the following failure, notify the operator with alarm [audio & visual] 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 during 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 IN-PROCESS CONTROL

Heat inactivation temperature check

6.4 LEVEL OF INSTRUMENTATION

Content for 6.4 LEVEL OF INSTRUMENTATION			
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Sufficient and suitable instrumentation for the process, safety and productivity control as indicated in the following table:

Type of control	Purpose	Instrumentation	Failure Mode Detection	Alarm	Remark
Collection Tank					
Level measurement	To monitor the volume of the bio-waste in collection tank with interlocking	Level sensor	Low or 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 sensor	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 bio-waste in kill tank with interlocking	DP Sensor[hydrostatic]	Low or high	Yes	
Speed/Agitation	To control agitation speed	Variable frequency drive with top driven agitator	Deviating from set value	Yes	

6.5 BATCH DATA DISPLAY AND RECORD

Chart recorder / Online printer should be provided for recording heat inactivation process.

6.6 GMP REQUIREMENTS (OTHERS)

- | | | |
|-------|---|--|
| 6.6.1 | In case of inactivation sequence failure (Power, utility failures) the timer should start from zero during inactivation process. | |
| 6.6.2 | Moving parts shall be tightly sealed. | |
| 6.6.3 | All nozzles for bio-waste 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. | |
| 6.6.4 | Steam traps shall be provided wherever required. | |
| 6.6.5 | Pumps shall be provided to transfer bio-waste from collection tank to kill tank. | |
| 6.6.6 | Centrifugal pumps will be used to transfer from kill tank to ETP. These pumps shall be connected to the PLC control. The same pump shall be used for the recirculation of the | |

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cleaning fluid during cleaning. The pump shall be of non-sanitary type, leak proof and spill proof.

Pump Specification:

- I. Flow rate: Vendor to specify
- II. Operating Temperature: 50°C - 80°C
- III. MOC: SS 304
- IV. Flooded type

Vendor shall provide the specification of the pump

6.7 SPECIFIC REQUIREMENTS

6.7.1 Collection Tank

6.7.1.1 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.

6.7.1.2 Pumps shall be interlocked between inlet & outlet valves of collection tanks and level sensors of the kill tanks.

Collection Tank Pump Specification:

- I. Submergible Cutter Type
- II. Flow rate: Vendor to specify
- III. Operating Temperature: 50°C - 80°C
- IV. MOC: SS 304

Vendor shall provide the specification of the pump

6.7.1.3 Base of the tank shall be sloped towards the pump

6.7.1.4 The tank shall be provided with the following on the top:

- Manhole- 1 no.
- Bio-waste Inlet port-1 no.
- Port with sterile hydrophobic vent filter-1 no (0.22 µm hydrophobic vent filter with code 7 SS 304 filter housing)
- Level sensor -1 no.
- Port for pump – 2 no. Outlet port -1No.
- Light/sight glass – 1 no.
- Spray ball port for CIP
- Spare Port – 1 no.

6.7.2 Kill Tank Specific Requirements

6.7.2.1 In general the equipment has to be designed to assure a homogeneous temperature distribution during inactivation phase. The design should also in a way be designed to get easy and quick access to all necessary maintenance points e.g. Motors etc.

6.7.2.2 The tank shall be provided with the following on the top dish:

- Light/ Sight glass (preferably metal fused type) - 1 no
- Manhole – 1no.

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• Biowaste inlet port-1no.	
• Plant steam addition port	
• Spray ball port – 2 nos	
• Diaphragm Pressure Gauge port -1 no	
• Pressure sensor port -1no	
• Pressure relief valve-1 no	
• Exhaust port with sterile hydrophobic vent filter -1 no (0.22 µm hydrophobic vent filter with code 7 SS 304 filter housing)	
• Level sensor (DP) port – 2 nos [top spud & bottom Spud]	
• Port for the chemical/liquid addition – 1 no.	
• Spare port – 1 no	
<ul style="list-style-type: none"> • Port for Top mounted agitator: <ul style="list-style-type: none"> ➤ The agitator shaft to be provided with impellers. (or vendor to specify the design of the impeller) ➤ SS 304 bearing frame and direct motor drive arrangement ➤ Shaft seal: single mechanical dry running seal for high/ low pressure ➤ SS 304 shaft, length shall be decided by the vendor according to the height of the vessel ➤ Vendor shall specify the following: <ul style="list-style-type: none"> - Shaft diameter - Shaft length - Type of impeller - Maximum- minimum rpm range 	
6.7.2.3 The jacket shall be provided with the following: All ports shall be considered for both the tanks separately	
• Jacket Inlet	
• Jacket Outlet	
• Jacket safety valve with pressure gauge	
• Jacket/ condensate drain	
• Jacket vent valve	
6.7.2.4 The tank shall be provided with the following on the Bottom dish:	
• Tank bottom to be Tori spherically dished with a transfer line	
• Bottom discharge valve provision- 1 no	
• PT 100 temperature sensor-1 no (side wall)	

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- Sampling port with valve- 1 no (side wall)

6.7.2.5 All metallic product contact surfaces should be constructed as per ASME BPE approved SS304 grade stainless steel or better with external surface matt finish.

6.7.2.6 All metallic non-product contact surfaces should be constructed of SS304 grade with external surface matte finish.

6.7.2.7 All process pipes should be orbital welded with Boroscopy records

6.7.2.8 Basic PLC Based Controller with control panel (Displaying synoptic view of running parameters like temperature, level sensor, valve position etc.)

7.0 CONSTRAINTS

7.1 EQUIPMENT LOCATION AND AVAILABLE SPACE

This equipment will be installed outside the manufacturing Facilities at IVC Chengalpattu. Equipment to be designed as per available space provided in the annexure-2 of this URS

7.2 AVAILABLE UTILITY

7.2.1 Electricity: Vendor to specify (Report requirement)

7.2.2 Cooling Water@3.5 bar _____ (Report requirement)

7.2.3 Compressed Air/ instrument air@8-10 bar _____ (Report requirement)

7.2.4 Plant Steam @3-3.5 bar _____ (Report requirement)

7.2.5 Soft water@3-5 bar _____ (Report requirement)

Note:

- *Utility consumption to be specified by the vendor.*
- Vendor to provide Pressure reducing valves and Pressure gauges along with the equipment as per utility requirements.
- *Vendor shall also specify the utility pipe sizes and GA drawing during DQ stage.*
- Vendor to provide the all utility consumptions in detail for the equipment during pre-bid.

8.0 ABBREVIATION

Abbreviation	Definition
ANSI	American National Standards Institute
EU	European Union
FAT	Factory Acceptance Test
HBL	HLL Biotech Limited
HMI	Human Machine Interface
I/O	Input / Output
IRS	Installation Requirement Specifications
GA	General Assembly
GAMP	Good Automated Manufacturing Practice

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Abbreviation	Definition
GMP	Good Manufacturing Practice
ISO	International Standards Organisation
MOC	Material of Construction
NPI	NNE Pharmaplan India
PLC	Programmable Logic Controller
PRV	Pressure reducing valve
P&ID	Piping and Instrumentation Diagram
RPM	Revolution Per Minute
SCADA	Supervisory Control And Data Acquisition
SIP	Sterilization In-Place
SS	Stainless steel
QA	Quality Assurance
OS	Operating System
USFDA	United States Food and Drug Administration

9.0 REVISION INDEX

Revision index

Revision	Date	Reason for revision
00	2015-09-18	First Draft for Client's Review
01	2015-12-09	Updated as per comments given by HBL dated 07-12-2015
02	2016-02-26	Updated as per comments given by HBL dated 26-02-2016

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URS Annexure 1: 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	Allen Bradley/ Siemens
23.	Spray Ball	HAKE/Lechler

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User Requirement Specifications			
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	Effective Date:	31-03-2016	Revision # 02

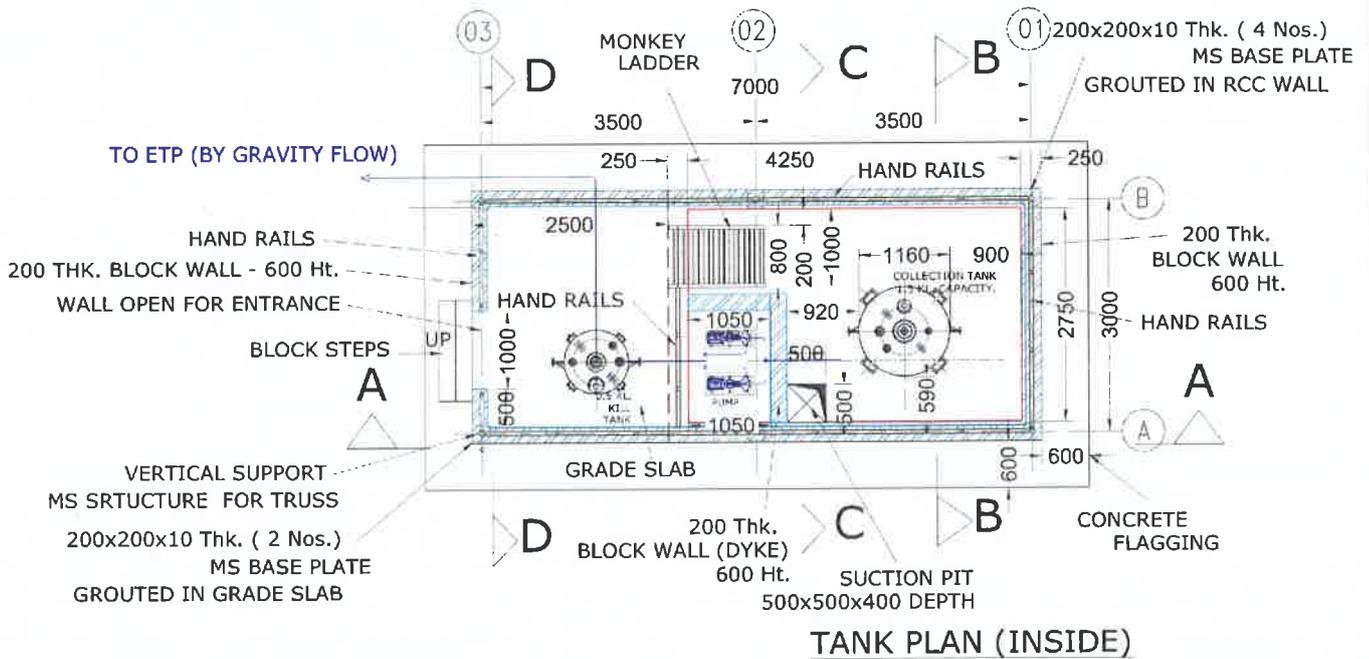


URS Annexure 2: Section and Elevation drawings for collection and Kill tanks locations

Note: Tank dimensions provided are tentative and vendor to consider only the dimensions of the civil structure for designing the equipment

1. For Rabies Bulk Block (B4)

Top View:



TANK PLAN (INSIDE)

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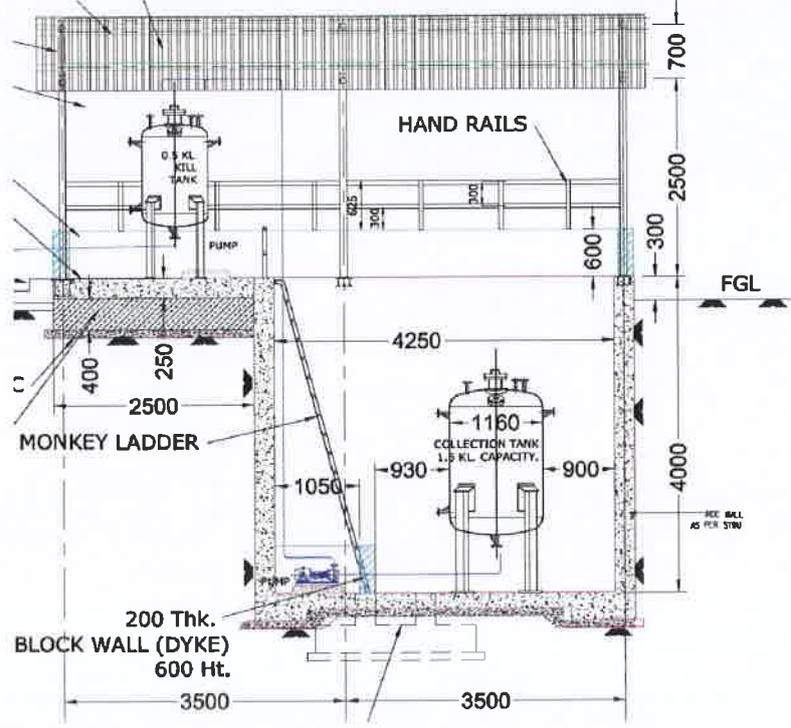
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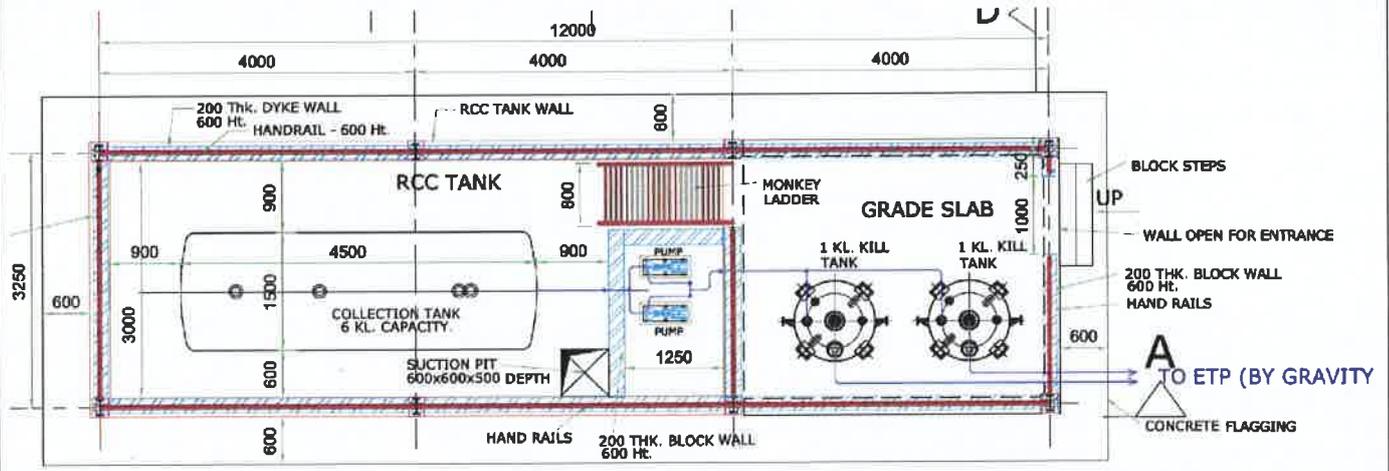


Elevation:



2. For Multiple Bacterial Bulk Block (B1)

Top View:



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Elevation:

