User requirement specifications
Microbial fermentor

Process Code	Area	Equipment code	Qty(Nos)	Capacity
T	TETANUS	T-FER01	2	500L G.V.
		T-FER02		500L G.V.

URS Annexure List

URS Annex No.	Detail
1.	Layout showing the location of the Microbial fermentor in Tetanus Block
2.	Tentative P&ID for Tetanus Microbial fermentor
3.	List of preferred make of components

nne pharmaplan®	User Requirement Specifications			
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	Effective Date #	2013-06-27	**Revision#**	07

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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 "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

The equipment described by this URS is a **"Microbial fermentor".** A Microbial fermentor is a special vessel that are designed for creating the optimal conditions for growth micro-organisms, based on controlling a number of parameters like temperature, pH etc . The Microbial fermentor including control panel will be installed in a clean room of Class "C".

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

2.0.1. Table-1

S. No.	Description	Purpose	MOC
1.	Shell	Cylindrical, for fermentation	SS316L
2.	Top closure	Torispherical dish	SS316L
3.	Bottom closure	Torispherical dish	SS316L
4.	Jacket	Hollow type; For temperature control	SS3304
5.	Insulation	To avoid heat loss	Mineral wool
6.	Cladding	Cladding to be welded to insulation around the jacket	SS304
7.	Mixer (top mounted - Vibromixer)	For mixing the process fluid constantly & keep uniform solution and to avoid dead air pocket and release toxic gasses	SS316L
8.	Height/Diameter Ratio	1.2:1	-

2.0.2. Table 2

Sl.NO	Description	Specification
1.	Geometric volume	500L
2.	Maximum working volume	400L
3.	Quantity	2 No
4.	Min mixing volume	200L
5.	Fermentation temperature	35 ± 1.0 ℃
6.	Rise in temperature (heating capacity)	4 deg C/min
7.	Fall in temperature (cooling capacity)	4 deg C/min
8.	Temperature control deviation	±0.1°C

9.	Surface Finish	Internally Electro polished Ra ≤ 0.6 µm, conforming to SFC4, according to ASME BPE(2009)
		Externally Mechanically polished up to Ra <1.2µm matt finish for the jacket. Top and bottom dish - mirror finish.
		Stainless steel piping interior Ra≤ 0.6 µm, conforming to SFC4, according to ASME BPE(2009)

2.0.3. The fermentor shall be skid mounted which should be supplied along with all the necessary piping, valves and instrumentation. The equipment must be designed for closed operation with the following specifications:

a. **Dosing Unit for Inoculum:** Inoculum will be added to the fermentor by flexible hose through the sterile valve assembly and individual Peristaltic pump .

b. **Dosing Unit for Acid:** Acid will be added to the fermentor by flexible hose through the sterile valve assembly and individual Peristaltic pump. The pH shall be controlled by using :

- In-situ sterilizable pH gel electrode, connecting cable and pH controller (Same for acid and alkali)
- By the addition of acid

c. **Dosing Unit for Alkali:** Alkali will be added to the fermentor by flexible hose through the sterile valve assembly and individual Peristaltic pump. The pH shall be controlled by using

- By the addition of Alkali

d. **Dosing unit for Media:** Media shall be brought into the Microbial fermentor room from fixed piping with the help of pump and then it should be insitu sterilized (media sterilisation temperature 115 ºC for 30min with a range of 115-134 ºC for ESIP) and rapid cool down to the temperature (35±0.1 ºC).

e. **DO monitoring**:

- By using In-situ amperometric DO probe

f. **Process air and Nitrogen Supply System:** system consists of Overlay Line with Process air and Nitrogen gas with the flow rate of 2-50 LPM

Aeration system is to be equipped with,

- Sterilizable SS housing with 0.2/0.22 micron sterile filter, which is to be sterilized along with vessel.
- Pressure reducing valve
- Mass flow controller(MFC)
- Rotameter

Filter cartridges of 0.2µm (absolute) pore sizes along with their housings are provided to ensure sterile gas. Cartridges should be sterilizable (as a part of the SIP cycle while housings are made from SS316L having internal surface finish similar to that of Microbial fermentor vessel. Filter housing is provided with necessary drain arrangements. A CIP cap is provided for 0.2 µ (absolute) pore size filter, so that the filters can be removed and housing replaced with the cap during the CIP of the vessel.

g. **Temperature Control:** The temperature during fermentation shall be controlled via circulation of utilities (plant steam, Cooling water, Chilled water, etc) in the jacket with electric heater or steam and a circulation pump. Temperature control during cultivation 35-37^{0}C (tolerance limit: ±0.1 ºC) & during sterilization (tolerance limit: ±0.1 ºC)

- The system consists of closed loop pressurized thermostat system with recirculation pump 2 heat exchangers for heating and cooling alternatively which provides a high flow through the hollow vessel jacket and ensures fast temperature control at high accuracy with PT 100 probe (sterilizable).
- Electrical heater ,Heat exchanger and steam for cooling water & chilled water for operation temperature
- Safety relief valve for jacket
- Bourdon type pressure gauge for jacket utility
- Pneumatically operated valves for steam and cooling water/ chilled water

h. **Pressure control:** Pressure of the vessel and CIP/SIP steps shall be controlled by the following:

- Compound Pressure gauge for vessel and Pressure transmitter
- Back pressure control valve in the exhaust line

i. **Mixer**: The vessel shall be designed with top mounted mixer as per process requirement. The mixer shall be vibro mixer type. It works on reciprocating motion The mixer shall be gear free to ensure smooth operation. Mechanism should provide minimum shear even at high speeds. The supporting structure shall be included to hang or support the motor from the top:

- Vibromixer:
  - Vendor to specify the design of the vibromixer
  - Dimensions of each component shall be provided
  - Frame and housing.
  - Shaft, length shall be decided by the vendor according to the height of the vessel
  - Diameter of the disc/ stirrer plate
  - The Amplitude of the mixer shall be 150V approximately.
  - Interconnection shall be provided with the sensoric arrangement of the system.
  - The vibromixer shall be connected to the PLC/ HMI to operate
  - MOC of Vibromixer:
    - Non-product side: SS 304 frame or housing
    - Product Side: SS 316L shaft of the mixer; SS 316L disc/ stirrer plate
    - PTFE or FDA approved - Diaphragm
    - Vibromixer specs: Movement - one cone upwards and one cone downwards: Vibromixer speed 55% vibration however, vendor to confirm.
    - Vibromixer type; E3; Vertical Vibration @ 50 times - 60 times per second with amplitude controller. Power requirements: 220V; 3.3 A; 50 Hz. (applicable for Blending vessel in pertussis and formulation)
    - Ingress protection: IP 65
    - AMPLITUDE – 0 TO 300 VOLTS
    - COS ϕ 0.27

j. **Vent Line/Exhaust Line:** Fermentor vent line includes:

- an exhaust condenser,

- a sterile hydrophobic vent filter.
- A Rupture disc is mounted on Fermentor vessel to relieve excess pressure during operations.
- Back pressure control valve in vent/exhaust line (Also mentioned under pressure control)
- Incinerator should be compact should have cyclone effect to remove moisture. The condensate will be collected and decontaminated before final disposal. Vent filter line/ exhaust line shall be equipped with electric incinerator to avoid release of toxic gases into the environment and also, to avoid foul smell produced during the fermentation process. Temperature for incinerator shall be 400ºC and above. The design of the incinerator shall be provided by the vendor

k. **Flush Bottom Valve:** It should be zero dead leg type valve attached directly to the at the bottom of the vessel, with a provision for sterilization. The diaphragm shall be of PTFE type.

l. **Sampling valve:** It should be zero dead leg type valve attached directly to the lower wall of the vessel, with a provision for sterilization. The diaphragm shall be of PTFE type.

m. **CIP (Cleaning – In – Place):** CIP shall be done using the CIP Trolley.

- SS 316L Spray ball shall be provided for the cleaning of the interior of the vessel and all the nozzles on the top lid and nozzles, ports on the vessel.
- 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 balls shall be selected for the proper cleaning.

n. **SIP (Sterilization – In – Place) :**

The following principles will be applied for SIP of the system:

- The vessel should be provided with ESIP/FSIP features
- The exhaust air filters to be sterilized along with the vessel.
- The sampling valve and Flush bottom valve can be sterilized independently.
- All addition valve groups for media, inoculum, acid, alkali are sterilized along with the vessel and also should be independently sterilizable.
- The sensors should be reusable and sterilizable type.
- Pressure reducing valve for steam lines
- SIP should be automatically controlled through PLC and HMI combination .

o. **Controller:** - PLC Based Controller(Non-editable data format to be obtainable)with a 15” HMI (Displaying data trends as Graphs, synoptic view of running parameters etc).

p. **SCADA software:** Common SCADA for the fermenters shall be provided**.**

Windows based supervisory Control and DATA Acquisition Software for monitoring and control of various process parameters. The Software capable for remote logging and process control. The system suitable for supervisory control for multiple fermenters. The system, designed for process validation, batch management features, multi-parameter display, time based programming of set points, regulation of process by both measured and calculated variables (by using equations), equation writing and its integration for control of fermenter parameters, ability to set both high and low limits and alarms, graphic / plotting, off-line data integration (Non-editable data sheet and batch reports). Options for manual override of all values, set-points and Process parameters during the process.

q. **The HMI shall be touch screen type (Provision for manual operation also to be provided). All setting shall be user adjustable.**

- HMI screen size shall be of 15 inches
- Human machine interface must be used to enter the process details, which should appear in the print out.
- All critical alarms
- All Critical parameters & interlocks
- Addition of the inoculum, media, acid, alkali
- All Recipes/ sequences (Process, CIP, SIP, transfer etc.)
- P&ID of the vessel along with instrumentation details
- Login details
- HMI screen showing simulation of valves

2.0.4. Nozzles to be provided :

1. Top Dish

The Microbial fermentor Top dish will have:

- Port for Light/Sight Glass –Bolted with gasket.-1 No
- Port for Hand hole – flushed flange with O-rings.-1 No
- Port for Vibromixer-1 No
- Port for Rupture disc-1 No
- Port for Compound Pressure Gauge -1 No
- Port for Pressure sensor along with Pressure transmitter- 1No
- Ports for Spray Ball- TC clamps with gasket- 2Nos
- Port for exhaust Outlet Condenser with reusable, sterilizable Filter (hydrophobic vent filter 0.2µm) -1 No
- 25 mm Spare port-1 No
- Automatic back pressure control valve-1 No

2. Upper wall side:

The Microbial fermentor's upper wall side normally will have :

- Port for the addition of seed with sterile valve group.-1 No
- Port for the addition of media with sterile valve group. .-1 No
- Port for the addition of acid with sterile valve group. .-1 No
- Port for the addition of base with sterile valve group. .-1 No
- 25 mm port for overlay air .-1 No
- Port for DP sensor.-1 No
- 25 mm Spare port.-1 No

3. **Lower wall side:**

   The Microbial fermentor lower wall side shall have the following ports and elements shall be placed and fastened there:

   - Ports for temperature sensor (e.g. PT 100)-1 No
   - Ports for pH sensor-1 No
   - Port for Sampling valve -1 No
   - 25 mm Spare port-1 No

4. **Bottom Connections**

   - Port for flush bottom valve –1 No
   - Port for DP sensor-1 No

5. **Jacket Connection**

   - **Jacket Bottom:** Jacket Inlet port, jacket drain
   - **Jacket Upper side:** Jacket outlet port, jacket relief valve,

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

- 4.1.10 , 4.1.11, 4.1.13,4.1.17
- **Sec 5.1 Table 2**
  - SI.NO 2 and 3 :FDA guidance for industry
  - 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 (< 0.5m Ra for filling line and < 0.8m Ra for lyophiliser) and external surface matte finish (< 1.2µ Ra).

  For surface finish values refer the point 9 under Sec 2.0.2 Table 2 mentioned in the URS
- Sec 5.6

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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. I n case of an deviation a comment must be inserted or enclosed as a separate annexure by referring to the respective URS specification number.
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 an 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 vendor's 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.	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.
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_110831_IRS_PII_01
XII.	Refer Tender document with URS; NPI/110831/EQP/TD/02

Specifications	Remarks
3.0 PROCESS DESCRIPTION	
3.1 Input & Charging method *Note: This section also includes the charging method of process media along with charging method for material input.*	
3.1.1 Media solution from the pressure vessel will be transferred to the fermenter with the help of peristaltic pump/pressure transfer. And Insitu sterilisation of the media shall take place and rapid cooling of the media. 3.1.2 Inoculum from flasks shall be transferred through sterile flexible piping with all requirements with the help of peristaltic pump (e.g. triclover clamps etc) provision for sterilization and assurance with an RTD in the drain line. 3.1.3 Acid and base solution is added to the vessel to adjust the pH automatically according to set point. 3.1.4 Temperature of the broth has to be adjusted to the working temperature with the help of utilities. 3.1.5 All the inlet ports to have sterile cross assemblies.	
3.2 Brief Process Steps	
A) The tanks have to be designed for preparation of media and propagation of microbial organisms respectively. 3.2.1 Transfer of inoculum, media, nutrient, acid, alkali to the Microbial fermentor. 3.2.2 The temperature of the media is maintained by circulating the utilities in the jacket using heat exchanger, appropriate pumping system and temperature sensors. 3.2.3 Process parameters like vibromixer amplitude, pH, pressure, air flow, nitrogen-flow and temperature are measured, during the process; samples can be taken through sampling valves.	
3.3 Output & Discharging method	
3.3.1 The fermented broth shall be transferred to the micro filtration system through fixed SS piping with the help of pressure.	
4.0 PRODUCTIVITY REQUIREMENT	
4.1 Desired/ suggested capacity	
Maximum working volume – 400L	
4.2 Standard batch size	
Max: 400L Min: 200L GV: 500L	
4.3 Change over time	
Not Applicable	

Specifications	Remarks
4.4 Others(if any)	
Should have provision of indication of fermentation temperature, pH, air flow, nitrogen flow, pressure and vibromixer amplitude per second	
5.0 Containment	
Not Applicable	
6.0 GMP REQUIREMENTS	
6.1 Process control	
6.1.1 The Microbial fermentor shall essentially have the necessary provisions for adjustment / control for the following critical process parameters:	
i) Temperature of the process	
ii) Pressure within the vessel	
iii) DO(Only monitoring)	
iv) pH	
v) Rate of flow of process Air and Nitrogen gas (Overlay)	
vi) Duration of CIP and temperature ,pressure during CIP	
vii) RPM of agitator	
viii) Pneumatically actuated individual valves for the clean utilities like Pure steam, CIP,PW and WFI at the header.	
6.2 Failure mode detection	
A. Equipment shall be capable to detect the following failure, notify the operator with an alarm (if it exceeds by 0-10% (i.e. tolerance limit) of the set point value):	
a) Vibromixer amplitude is out of set range	
b) pH is out of set range	
c) Temperature is out of set range	
d) Low/high pressure	
e) Air flow being out of range	
f) Low/high volume	
g) Abrupt change in temperature in a particular time (at constant operating temperature)	
B. Equipment shall shutdown the process (if it exceeds tolerance limit of the set point value)	

Specifications	Remarks
6.3 In – Process control	
i) Sampling of product solution.	
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 vessel	To monitor, indicate and control the fermentation temperature.	Temperature probe with indicator and controller
Temperature jacket	To monitor, indicate and control the jacket temperature	Temperature probe with indicator and controller
pH	Monitor and control of pH (2-12)	pH probe/transmitter
Volume	To monitor control volume	DP sensor
Mixing	To control and provide shear less mixing	Vibromixer
Pressure	To monitor, indicate and control the vessel pressure.	Pressure transmitter with indicator and controller
Time	Timer control of process and monitoring CIP/SIP process	Timer (HMI)
Process Air and Process gas	Air flow and Nitrogen flow	Mass flow controller (MFC) and Rotameter
Pump	To dose inoculum, media, acid, alkali etc	Peristaltic pump (3 nos)

6.5 Batch data display and record printing		
Refer IRS (Installation requirement Specification and Specific Instruction)		
6.6 GMP requirements (Others)		
6.6.1	The air housings in the vessel shall be provided with Staubli connectors for in-situ integrity testing of the vent filters.	
6.6.2	All nozzle connection shall be sanitary type and special attention shall be given in shape and dimension of the nozzle and connection to realize efficient cleaning and steaming process.	
6.6.3	All nozzles shall be provided with sanitary valve which shall be flushed to the wall on	

Specifications		Remarks
	closure and inside surface of the valves can be cleaned during CIP.	
6.6.4	Nozzle length shall be minimized (less than 2D) to avoid cold spot during steam sterilization.	
6.6.5	Bottom discharge and sampling valve shall be zero dead leg type.	
6.6.6	Vent shall be provided with sterilizing grade hydrophobic filter with suitable arrangement for CIP/SIP and provision for in place integrity testing.	
6.6.7	Utility operation shall be preferably automatic and valves shall be placed inside of aseptic area.	
6.6.8	Steam traps shall be provided where ever is required in the system .	
6.7	**Specific requirements**	
6.7.1	Seed Transfer through sterile steam cross assembly from the seed Microbial fermentor in the same room.	
6.7.2	Nozzle shell shall be seamless.	
6.7.3	Nozzle connection to be Triclover.	
6.7.4	Nozzles, adaptors, instrument shall comply to ASME BPE compliant.	
6.7.5	Total motor drive assembly with SS304 cover with TEFC eff 1.	
6.7.6	Mechanical Lifting device shall be provided to lift the top lid and to support the top mounted vibromixer. The supporting structure shall be included to hang or support the motor from the top (Vendor to specify mechanism).	
6.7.7	Manifold and necessary hose nipples, silicon tubes shall be provided at the top of the spray balls to connect CIP recipe/WFI, clean steam along with the pneumatic diaphragm valve operated directly through HMI.	
6.7.8	Sufficient space shall be provided from the bottom of the vessel for the cleaning and connection.	
6.7.9	**Design Considerations:** • Jacket design Pressure: (designed for Full vacuum) vendor to specify • Jacket design Temperature: vendor to specify • Jacket working Pressure: Full Vacuum to 4 bar(g) • Jacket working Temperature: 2℃ to 135℃. • Vessel design Pressure: (designed for Full vacuum) vendor to specify • Vessel design Temperature: vendor to specify • Vessel sterilization Temperature: 121℃ • Vessel working Pressure: Full Vacuum to 2.5 bar(g) • Vessel working Temperature: 25℃ to 134℃.	
6.7.10	1 No. of fixed speed Peristaltic pump is required for Media, Inoculum addition with the pump head compatible with the tube size:12/17 mm.	

Specifications	Remarks
6.7.11 2 Nos. of fixed speed Peristaltic pump is required for acid and alkali addition with the pump head compatible with the tube size:3.8/7 mm	
6.7.12 **Cabling** All cabling and pneumatic tubing within the individual skid will be performed by Vendor. Cabling and pneumatic tubing is routed via stainless steel protective pipes with open ends. Segregation between power cables and signal cables will be provided. Motor cabling between the individual skids and the MCC's in the technical area will be performed by vendor, however cable ways and wall penetrations will be provided by the Customer. Ethernet cabling for the dedicated Control Network will be provided by Vendor, however cable ways and wall penetrations will be provided by the Customer. Line voltage supply for the individual cabinet will be provided by the Customer as follows: • 230 V AC and 230 V UPS (for controls) for each Local Control Cabinet • 415VAC for each Motor Control Cabinet	
6.7.13 **Performance Criteria Required for FAT/SAT**	
Media hold with process simulation including all peripheral equipments during SAT	
Pressure hold test to be performed before every SIP	
Spray ball coverage Test during FAT	
Thermal mapping	
All control system simulation and tuning of control loops	
All FAT/SAT,IQ,OQ as per IRS	
7.0 CONSTRAINTS	
7.1 Equipment location and available space	
This equipment will be installed in the **DPT vaccine manufacturing Facility at PII, Coonoor.** **Equipment Location:** Fermentation room (B2G027) **Block:** Tetanus Block **Floor:** Ground Floor **Room Size:**93.10 m^2 **False Ceiling height:** 4000 mm **Physical condition of the rooms:** 1. Room will be non-hazardous 2. Class: EU Class "C" 3. Differential Pressure:10 Pa 4. Temperature maintained: 22±2 ºC 5. Relative Humidity: NMT 55% RH The equipment location is indicated in the relevant block of the layout enclosed as **URS Annex-1.**	

Specifications	Remarks
7.2 Available Utility	
a) Plant steam @ 3–3.5 bar (g) and 130^{0}C-150^{0}C----------(Report requirement)	
b) Pure steam @2.4 bar (g) and 121^{0}C-130^{0}C----------(Report requirement)	
c) WFI (Hot loop) @2 bar(g) and 80^0-85^{0}C ----------(Report requirement)	
d) Cooling water @3 bar(g) and 28^{0}C-30^{0}C ----------(Report requirement)	
e) Chilled water @ 7℃ to 12℃----------(Report requirement)	
f) Electricity – 415V/3ph/50Hz, 240V/1ph/50Hz	
g) Compressed air @ 6.0– 8.0 bar (g)	
Note: Utility consumption to be specified by the vendor, in case if there is any deviation in the values mentioned above.	

8.0 ABBREVIATION

Abbreviation	Definition
^{0}C	Degree Centigrade
FER	Microbial fermentor
HMI	Human Machine Interface
ISO	International Standards Organization
MOC	Material Of Construction
NPI	NNE Pharmaplan India Ltd
PII	Pasteur Institute of India
PLC	Programmable Logic Controller
PID	Proportional Integral Derivative
QA	Quality Assurance
SS	Stainless steel
NMT	Not More Than

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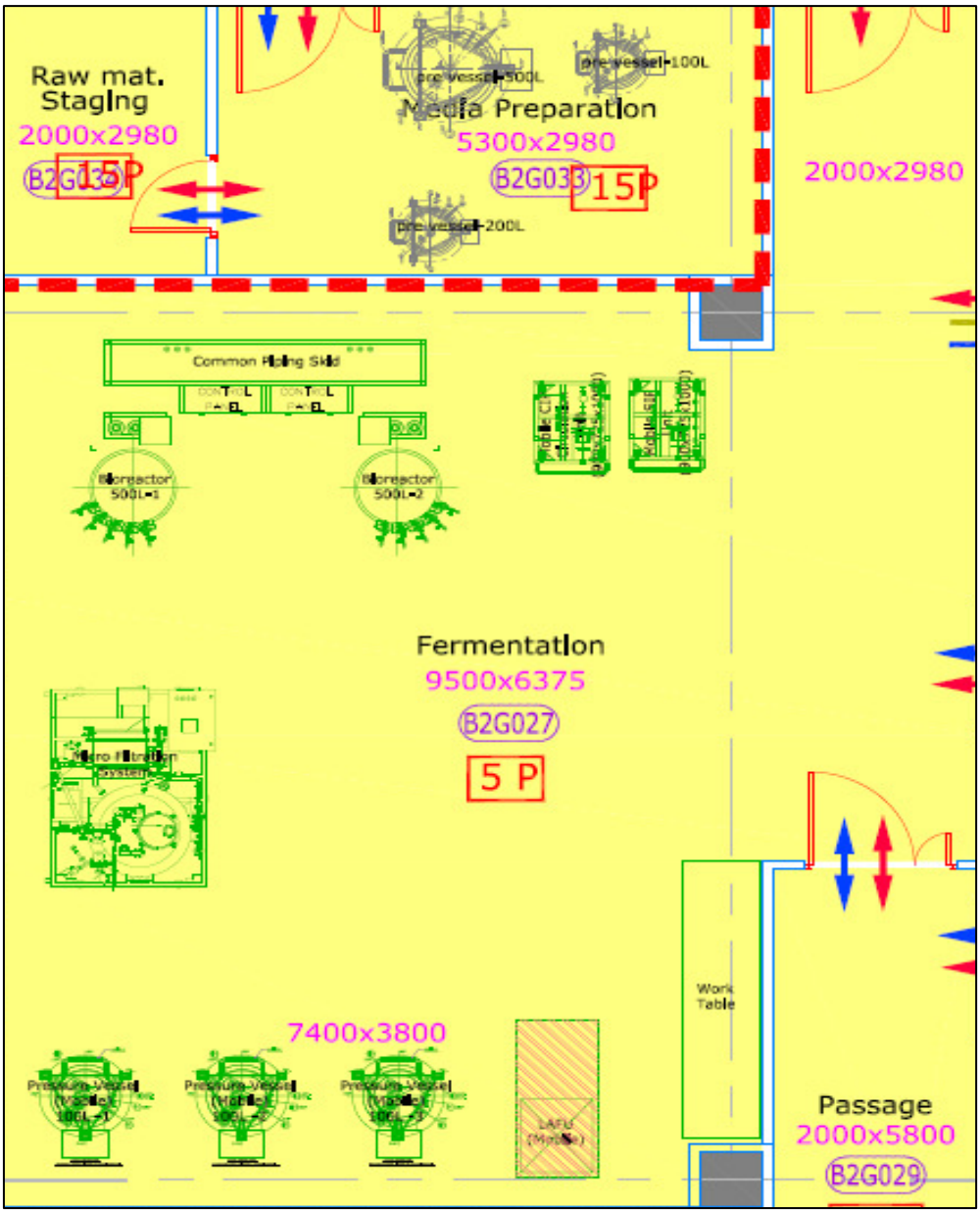
REVISION INDEX

Revision	Date	Reason for Revision
00	2012-05-18	1st draft for client's review
01	2012-10-18	Format changed as per HLL requirement
02	2013-01-24	HLL comments incorporated, received during the workshop dated 22nd and 23rd January 2013
03	2013-02-28	PIIC comments incorporated received on 26th February 2013
04	2013-04-26	As per HLL comments dated on 25th April 2013 by mail.
05	2013-05-15	As per the Telephonic discussion with HLL on 2013.05.13.Following major changes are incorporated: • Jacket MOC changed to SS304 • 1 peristaltic pump is required fort the addition of inoculum, media and 2 Peristaltic pump required for the addition of acid and alkali • Electrical heater, heat exchanger and steam required fro temperature control. Bourdon type pressure gauge for jacket is included under temperature control. • HMI screen size changed as 15" • Repeated points under SIP details are deleted • No. of cycles for CIP,SIP deleted under process control • Port for addition of inoculum provided on the upper wall side • Input and charging of media modified in sec 3.1 • Sec 6.1 Under process control, No. of cycles(CIP,SIP) deleted • Sec 6.4 Level of instrumentation ➢ No. of pumps changed to 4 • Point 6.7.10 Peristaltic pump specifications modified as 1 No. of fixed speed peristaltic pump for the addition of inoculum and media with size:12 x17 mm • Point 6.7.11 2 No.of Peristaltic pump for the addition of acid and alkali with tube size:3.8/7 mm • URS Annex 3: List of preferred MAKE of components modified ➢ Sl.No 3 Agitator removed ➢ Sl.No 6 Pressure sensor deleted ➢ Sl.No 9 pressure regulator-FESTO retained ➢ Sl.No 22 and 23: Sampling valve and Flush bottom valve: GEMU included ➢ Sl.No 31 Control panel deleted from the list ➢ Sl.No 34 Electrical motor deleted
06	2013-06-21	As per comments from HLL by email on 2013-06-12
07	2013-06-27	As per the comments received from HLL over telephone on 2013-06-27 ➢ Sec 2.0.3 n) SIP • Included that the addition valve groups shall be Independently sterilizable ➢ 2.0.4 SCADA • Non editable data format included ➢ 6.7.6 Hydraulic lifting device for lid is replaced by mechanical lifting device

URS Annexure 1: LAYOUT OF TETANUS BLOCK

Room No : B2G027



URS Annexure 3: 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	Temperature sensor	NEGELE
5	p H sensor	METTLER TOLEDO/E&H/Hamilton
6	Pressure transmitter	Wika /Dwyer/Sensocon
7	Pressure regulator	FESTO
8	Temperature indicator	Radix/ Wika/ Waaree instruments
9	Steam trap	STERIFLOW/ITT
10	Printer	Epson/ HP/ Canon
11	DC source	Shavision/ Yokogawa/ Emerson
12	Rupture Disc	Zook / Elfab/Fike
B	**MECHANICAL**	
12	Pressure gauges	WIKA/Denver/Negele
13	Pre air filter cartridge	Sartorius/ PALL/ Millipore
14	Vent filter cartridge	Sartorius/ PALL/ Millipore
15	Filter housing	Sartorius/ PALL/Millipore
16	Spray ball	HAKE
17	Diaphragm valve(Manual)	GEMU/ Burkert
18	Ball valve(Manual)	Modentic/Saunders/Alfa laval
19	Non return valve	Modentic/Saunders/Alfa laval
20	Sampling valve	Novaseptic/GEMU
21	Flush bottom valve	Novaseptic/GEMU
22	Safety relief valve	HEROSE/SS Spirax /Amtech valves
23	Sanitary Rupture disc	ZOOK/Elfab
24	Flow switch	Orion/ Wika/Emerson
25	Rotameter	GEMU/Allborg
26	Peristaltic pump	Watson Marlow/Masterflex
27	Vibro mixer	BBI / Graber & Pfenninger / Rutten engineering

C	**PNEUMATIC**	
28	Diaphragm valve(Automatic)	GEMU / ITT
29	Angle seat valve(Automatic)	GEMU / ITT
D	**ELECTRICAL**	
30	Lamp	PAPENMEIER
31	Heater	Common wealth