

HLL BIOTECH LIMITED, CHENNAI

INTEGRATED VACCINES COMPLEX, CHENGALPATTU

nne pharmaplan	User Requirement Specifications				
	Equipment/System	Blending vessels			
	Identification #	-	Document No:	URS/BLV 01	
	Effective Date	27.03.2014	Revision#	02	

User Requirement Specifications Blending vessel

Block Code	Area	Identification #	Qty (Nos)	Capacity(WV)
F2	Bacterial Vaccine Formulation	F2-BLV-01	1	200 L
F1	Viral Vaccine Formulation-Rabies	F1-BLV-01	1	50 L
F1	Viral Vaccine Formulation-Measles	F1-BLV-02	1	50 L

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	Equipment/System	Blending vessels			
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URS Annexure List

URS Annex No.	Detail
1	Layout showing location of the Blending vessels in the Bacterial Vaccine Formulation and Viral Vaccine Formulation block
2	P&ID as separate URS annexure
3	List of preferred MAKE of components

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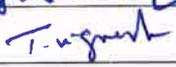
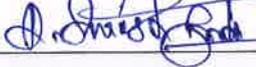
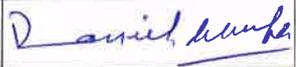
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1.0 APPROVAL SIGNATURES

This document is prepared by the Process, Validation and GMP Compliance team of "NNE Pharmaplan India" for the project "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 shall be reviewed by HBL user/s and project/ engineering team, approved by team lead of user department & QA and authorized by the appropriate Project authority.

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2.0 EQUIPMENT DESCRIPTION

The equipments described by this URS are "BLENDING VESSELS" with a working volume of 50 L, quantity 2 no's and 200L quantity 1 no.

The Blending vessel in the Bacterial Vaccine Formulation block and Viral Vaccine Formulation Block is used for blending of all required components.

The vessel shall be designed, constructed, built, installed and commissioned to hold solutions filtered, in sufficient quantity and quality. This shall include appropriate control & monitoring systems.

Design, function and control of the unit should be Current GMP compliant.

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

TABLE 1

S. No.	Description	Purpose	MOC
1	Shell	Cylindrical to hold and blend the Components	SS316L
2	Top closure	Flat Lid	SS316L
3	Bottom closure	Tori spherical dish	SS316L
4	Jacket	Temperature Maintenance	SS304
5	Insulation	To avoid heat loss	Mineral wool
6	Cladding	Outer cover to Insulation	SS304
7	Agitation	Magnetic Mixer (Bottom mounted)	SS316L

TABLE 2

S. No.	Description	Viral Vaccine Formulation Block		Bacterial Vaccine Formulation Block
		Rabies	Measles	
1	No. of Vessels	1	1	1
2	Max. working Volume	50L	50L	200 L
3	Geometric Volume	TBD	TBD	TBD
4	Min Operating Volume	8L	8L	15L
5	H/D	TBD	TBD	TBD
6	Addition ports	2	3	3

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S. No.	Description	Viral Vaccine Formulation Block		Bacterial Vaccine Formulation Block
		Rabies	Measles	
7	Peristaltic pumps	1 No. Portable, Standalone variable speed and to hold ID of 6/12 mm to 13/19mm silicon tube	1 No. Portable, Standalone variable speed and to hold ID of 6/12 mm to 13/19mm silicon tube	<ul style="list-style-type: none"> 2 Nos. fixed speed. 1 No. Portable, Standalone variable speed and to hold ID of 6/12mm to 13/19 mm silicon tube
8	Baffles	Not required	Not required	Removable type baffle required
9	Volume measurement	Platform balance	Platform balance	Load cell
10	Product transfer	Blending vessel moved from Blending room to Filling room and transferred by Flexible connections	Blending vessel moved from Blending room to Filling room and transferred by Flexible connections	Through Fixed pipeline
11	pH meter	Only monitoring	Only monitoring	Control & monitoring. pH control using Acid/Alkali
12	SCADA	NA	NA	Required
13	HMI	Required	Required	Required
14	CIP	Mobile CIP System(Not in scope)	Inbuilt CIP	Mobile CIP System(Not in scope)
15	Blending /Holding Temperature	2 °C - 8 °C	15 °C	2 °C - 8 °C
16	Blending Duration	3-6 Hrs.	3-6 Hrs.	72 Hrs.
17	Holding Duration	24 Hrs.	24 Hrs.	24 Hrs.

2.1 Blending Vessels-Viral Vaccine Formulation (Rabies and Measles)

Blending vessels are supplied along with all the necessary piping with skid, valves, instrumentation and control panels. The equipments to be mounted on Anti-static wheels with lock on legs.

2.1.1 Dosing Unit: Addition ports shall be of sterile arrangement with four-way valve assembly for SIP, draining and isolation. A temperature sensor shall be provided near the drain point of the four-way valve assembly. All ports shall have a J-tube arrangement facing the interior wall of the vessel. For all addition to the Blending vessel through sterile valve assembly from respective containers using a Portable - Variable speed Peristaltic pump to hold silicone hose ID of 6/12mm to 13/19mm. Also Necessary arrangements like hose nipple should be provided.

2.1.2 Temperature Control: The temperature during blending shall be controlled via circulation of utilities (plant steam, Cooling water, Chilled water, Brine Solution etc) in to the jacket. Temperature control during blending should be 10 °C - 25 °C (tolerance limit: ±0.1 °C) & during sterilization (tolerance limit: ±1 °C).

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Temperature control during Holding should be 2 °C - 8 °C for Rabies and 15 °C for Measles. Bottom dish jacket should be provided. Temperature maintenance shall be done with Brine solution in Rabies section and with chilled water in measles section.

- Pneumatically operated valves for steam and cooling water/ chilled water /Brine solution

2.1.3 **Pressure Control:** Pressure of the vessel and CIP/SIP steps shall be controlled by the following:

- Pressure Sensor and Transmitter for Vessel

2.1.4 **pH:** A pH Sensor should be provided.

2.1.5 **Mixer:** The vessel shall be designed with bottom mounted GMP magnetic mixer as per process requirement with AC Motor and variable frequency drive. A separate VFD control system (Plug and play) shall be provided which shall be kept in the filling area and the same shall be used during the filling operation.

2.1.6 **Vent Line/Exhaust Line:** The Process Vessel shall include a vent filter and housing. The vent filter shall be hydrophobic, and shall have 0.22 µm pore size. It shall be equipped with necessary drain arrangement. Integrity connector for in-situ integrity testing of filters shall be provided. The filter housing shall be designed for Code 7 filters.

2.1.7 **Volume Measurement:** Platform Balance should be provided. It should be able to connect directly to the control system.

2.1.8 **Flush Bottom Valve:** Zero Dead Leg type valve directly welded to vessel bottom centrally, having a PTFE diaphragm. It should be steam sterilizable type valve.

2.1.9 **Product Transfer:** Autoclavable valve assembly should be provided with in situ sterilization provision when attached to the Flush Bottom Valve.

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

2.1.11 **CIP (Cleaning – In – Place):** The vessel shall be cleaned by using an inbuilt CIP system includes centrifugal pump, necessary valves and conductivity sensor for Measles and A mobile CIP System used for Rabies. The Process Vessels shall have sufficient number of spray ball(s) to ensure cleaning of the interior surfaces. The design and location of the spray ball is the vendor's responsibility and will form a part of the Design Qualification. The system shall be tested for drainability and shall pass the spray ball coverage test in accordance with the recommendations outlined in ASME BPE-2012; part SD-4 & 5. The vendor shall ensure cleanability of the Blending Vessels.

2.1.12 **SIP (Sterilization – In – Place):** The blending vessel shall be designed for in built SIP.

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

- The vessel should be provided with ESIP features
- The exhaust air filters to be sterilized along with the vessel.
- The sampling valve and Flush bottom valve should be sterilized independently.
- All addition valve groups are sterilized along with the vessel and should be independently sterilizable.
- The sensors should be reusable and sterilizable type.
- SIP piping from header to the vessel skid: SS 316L. Ra < 0.6 µ

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- Pressure reducing valve for pure steam lines
- SIP should be automatically controlled through PLC and HMI combination.

2.1.13 **Controller:** - PLC Based Controller (Non-editable data format to be obtainable) with a 10" HMI (Displaying data trends as Graphs, synoptic view of running parameters etc)

2.1.14 **The HMI shall 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.**

- HMI screen size shall be of 10 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 Ports
- 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

2.2 Blending Vessel-Bacterial Vaccine Formulation

Blending vessel is supplied along with all the necessary piping with skid, valves, instrumentation and control panels. The equipment to be Floor mounted.

2.2.1 **Dosing Unit:** Addition ports shall be of sterile arrangement with four valve assemblies for SIP, draining and isolation. A temperature sensor shall be provided near the drain point of the four valve assembly. All ports shall have a J tube arrangement facing the interior wall of the vessel. For all addition to the Blending vessel through sterile valve assembly from respective containers using a Portable Variable speed Peristaltic pump to hold silicone hose ID of 6/12 to 13/19. Two Nos fixed speed peristaltic pump should be provided.

2.2.2 **Temperature Control:** The temperature during blending shall be controlled via circulation of utilities (plant steam, Cooling water, Chilled water, Brine etc) in the jacket. Temperature control during blending should be 10 °C - 25 °C (tolerance limit: ±0.1 °C) & during sterilization (tolerance limit: ±1 °C). Temperature control during Holding should be 2 °C - 8 °C (tolerance limit: ±0.1 °C). Bottom dish jacket should be provided. Temperature maintenance and control shall be done with chilled Brine.

- Pneumatically operated valves for steam and cooling water/ chilled water /Brine

2.2.3 **Pressure Control:** Pressure of the vessel and CIP/SIP steps shall be controlled by the following:

- Pressure Sensor and Transmitter for Vessel

2.2.4 **Mixer:** The vessel shall be designed with bottom mounted GMP magnetic mixer as per process requirement with AC Motor and variable frequency drive.

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2.2.5 **Vent Line/Exhaust Line:** The Process Vessel shall include a vent filter and housing. It should have independent sterilization facility. The vent filter shall be hydrophobic, and shall have 0.22 µm (absolute) pore size. It shall be equipped with necessary drain arrangement. Provision for in-situ integrity testing of filters shall be provided. The filter housing shall be designed for Code 7 filters.

2.2.6 **Volume Measurement:** Load cell should be provided.

2.2.7 **Flush Bottom Valve:** Zero Dead Leg type valve directly welded to vessel bottom centrally, having a PTFE diaphragm. It should be steam sterilizable type valve.

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

2.2.9 **Product Transfer:** Transfer should be done with fixed pipe. Provision for CIP /SIP of the line should be provided.

2.2.10 **CIP (Cleaning – In – Place):** The vessel shall be cleaned by using a Mobile CIP system. The Process Vessels shall have sufficient number of spray ball(s) to ensure cleaning of the interior surfaces. The design and location of the spray ball is the vendor’s responsibility and will form a part of the Design Qualification. The system shall be tested for drainability and shall pass the spray ball coverage test in accordance with the recommendations outlined in ASME BPE-2012; part SD-4 & 5. The vendor shall ensure cleanability of the Blending Vessels.

2.2.11 **SIP (Sterilization – In – Place):** The blending vessel shall be designed for in built SIP. The following principles will be applied for SIP of the system:

- The vessel should be provided with ESIP features
- The exhaust air filters to be sterilized independently and along with the vessel.
- The sampling valve and Flush bottom valve should be sterilized independently.
- All addition valve groups are sterilized along with the vessel and should be independently sterilizable.
- The sensors should be reusable and sterilizable type.
- Pressure reducing valve for pure steam lines
- SIP should be automatically controlled through PLC and SCADA combination.

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

2.2.13 **SCADA Software:** - Windows based Supervisory Control and DATA Acquisition (SCADA) Software for monitoring and control of various process parameters. The Software capable for remote logging and process control. The system should be suitable for supervisory control of at least 4 blending vessels. 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 process 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.

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2.3 General Requirement for all Blending Vessels

2.3.1 Nozzle schedule :

2.3.1.1 Top Dish

The Blending vessel top dish shall have:

- Pressure gauge
- Port for Spray ball
- Spare port (TC clamps with gasket)
- Pressure Sensor
- Rupture disc
- Light glass with halogen lamp Bolted with gasket
- Port for Compressed air inlet/ Exhaust with vent filter (TC clamps with gasket)

2.3.1.2 Upper wall side:

The Blending vessel's upper wall side generally will have:

- Jacket outlet (Non – sterile DN Union connection)
- sterile addition port
- Vertical view glass-Bolted with gasket

2.3.1.3 Lower wall side:

The Blending vessel lower wall side shall have the following ports

- Jacket inlet(Non – sterile DN Union connection)
- 25 mm Temperature sensor port (15 degree knuckle port)
- 25 mm pH sensor port(15 degree knuckle port)
- Sampling valve, sterilizable
- Spare Port – 25 mm 15 degree knuckle port

2.3.1.4 Bottom Connections

- Port for Flush bottom valve, sterilizable
- GMP Mixer

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
- Sec 5.6

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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 vendors' 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 <ol style="list-style-type: none"> If no comments against any specification shall be considered as "NO" and 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 HBL before submitting the quotes.
10.	The makes requested are standard international makes. In case of any deviation, vendor to seek clarification from HBL before submitting the offers.
11.	Refer document Installation Requirement Specification and Specific Instructions with URS; NPI_120310_IRS_S1_01
12.	Refer Tender document with URS; NPI_120310_EQP_S1_TD_04

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Specifications					Remarks
3.0 PROCESS DESCRIPTION					
3.1 Input & Charging method					
Components used for the preparation of the blending solution shall be fed into the vessel aseptically through the sterilizable valve assembly.					
3.2 Brief Process Steps					
The tanks have to be designed to prepare and store blending solution respectively in sufficient quantity.					
3.2.1	Solutions are added into the vessel through the sterilizable valve assemblies by using Peristaltic pumps				
3.2.2	After mixing the Components, the solution is maintained at 2°C to 8°C using Brine.				
3.2.3	During stirring the pH value and temperature inside the tank is measured/Controlled				
3.2.4	Samples can be drawn through sampling (Diaphragm) valve.				
3.3 Output & Discharging method					
3.3.1	Bacterial Vaccine formulation:- Product from the Blending vessel will be flushed out through the Flush bottom valve and then transferred using the Peristaltic pump through the fixed piping to the buffer vessel in the filling room				
3.3.2	Viral Vaccine formulation: - The mobile Blending vessel shall be moved from the blending room to the filling room, Later the product shall be flushed out through the Flush bottom valve and autoclavable valve assembly using air pressure through the Flexible piping to the buffer vessel.				
4.0 PRODUCTIVITY REQUIREMENT					
4.1 Change Over Time					
Not Applicable					
4.2 Others(if any)					
Not Applicable					
5.0 CONTAINMENT					
Not Applicable					
6.0 GMP REQUIREMENTS					
6.1 Process control					
6.1.1	Temperature of product during the blending				
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Specifications	Remarks
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6.1.2	Temperature of the jacket utility(both indication and control)	
6.1.3	Pressure indication(only) for the jacket using Bourdon type pressure gauge	
6.1.4	pH of the component in Blending Vessel	
6.1.5	Speed of the Mixer during the blending	
6.1.6	Level/Volume of the fluid in the vessel	
6.1.7	Flow switch for jacket utility	
6.1.8	CIP/SIP process parameters	
6.1.9	Duration of cycle(CIP,SIP)	
6.1.10	Pneumatically actuated valves in the individual Feed lines, WFI, PW, CIP, Buffer, Pure steam and discharge line.	

6.2 Failure mode detection	
-----------------------------------	--

6.2.1	Equipment shall be capable to detect the following failure, notify the operator with audio visual alarm and shutdown the process: (if it exceeds by 0-10% (i.e. tolerance limit) of the set point value):	
6.2.2	Mixing speed is out of set range	
6.2.3	pH is out of set range	
6.2.4	Temperature is out of set range	
6.2.5	Low/high pressure	
6.2.6	Low/high level/volume	
6.2.7	Abrupt change in temperature in a particular time	

6.3 In – Process control	
---------------------------------	--

6.3.1	Should have provision for sampling of product.	
6.3.2	Should have provision of indication of Blending cycle time, temperature, pH, pressure, etc through HMI/ SCADA	

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Specifications	Remarks
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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 of the product	To monitor, indicate and control the product temperature	Temperature probe with indicator and controller
Temperature of the jacket	To monitor, indicate and control the jacket temperature	Temperature probe with indicator and controller
pH	To monitor the pH of the product in blending vessel-Viral vaccine and to monitor and control the pH of the product in blending vessel-Bacterial vaccine.	pH probe/transmitter
Level	To monitor the level of the product in the vessel	Platform balance(for Viral Vaccine Formulation) & Load cell(Bacterial Vaccine Formulation)
Mixing Speed	To control GMP mixer speed	Variable frequency drive with indicator
Pressure	To monitor and control pressure of vessel	Pressure Gauge and pressure sensor and transmitter
Time	Timer control of process and monitoring CIP/SIP process	Timer (HMI)

6.5 Batch data display and record printing

Refer Installation requirement specifications

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 SIP process. | |
| 6.6.3 | All nozzles shall be flushed to the wall on closure. | |
| 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 | Utility operation shall be preferably automatic and valves shall be placed inside of aseptic | |

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Specifications	Remarks
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area.	
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6.6.7 Steam traps shall be provided where ever required at the system.	
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6.7 Specific requirements	
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6.7.1 In general the equipment has to be designed in a way to get easy and quick access to all necessary maintenance points.	
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6.7.2 Silicone tube, hose nipples should be provided wherever is necessary.	
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6.7.3 Provision should be provided to purge the holdup volume using compressed air, in the fixed pipe line from Blending vessel to filling machine.	
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6.7.4 Design Considerations: <ul style="list-style-type: none"> a) Shell working Pressure- Full Vacuum to 2.5 bar(g) b) Shell working Temperature- 20-134 °C c) Shell sterilization Temperature- 121 °C d) Shell design Pressure- Vendor to specify e) Shell design Temperature- Vendor to specify f) Jacket working Pressure- Full Vacuum to 4 bar(g) g) Jacket working Temperature- 130 °C h) Jacket design Pressure- Vendor to specify i) Jacket design Temperature- Vendor to specify 	
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6.7.5 Nozzle shell shall be seamless.	
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6.7.6 Nozzles, adaptors, instrument shall comply with ASME BPE guidelines.	
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6.7.7 For hot and cold pipe lines ¾ "thickness armafex material insulation shall be provided.	
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6.7.8 Vendor should provide essential spare parts required for minimum of 1 year and consumables for minimum of 2 years and a set of special tools if any.	
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7.0 CONSTRAINTS	
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7.1 Equipment location and available space	
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<p>These equipments will be installed in the Bacterial Vaccine Formulation and Viral Vaccine Formulation block:</p> <p>Block: <u>Bacterial Vaccine Formulation</u></p> <p>Floor: <u>Ground floor</u></p> <p>Room area: <u>55 m²</u></p> <p>Room No. <u>F2G028</u></p> <p>False ceiling height: <u>4000 mm</u></p> <p>Block: <u>Viral Vaccine Formulation-Rabies</u></p> <p>Floor: <u>Ground floor</u></p> <p>Room area: <u>30 m²</u></p> <p>Room No. <u>F1G036</u></p>	
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Specifications	Remarks
<p>False ceiling height: <u>4000 mm</u></p> <p>Block: <u>Viral Vaccine Formulation-Measles</u></p> <p>Floor: <u>Ground floor</u></p> <p>Room area: <u>34 m²</u></p> <p>Room No.: <u>F1G080</u></p> <p>False ceiling height: <u>4000 mm</u></p> <p>Physical condition of the room:</p> <ol style="list-style-type: none"> 1. Class: EU Class "B" 2. Temperature maintained: 22±2 °C 3. Differential pressure: 65Pa 4. Relative Humidity: NMT 55% RH <p>The equipment location is indicated in the relevant block of the layout enclosed as URS Annex 1.</p>	

7.2 Available Utility	
7.2.1 Plant steam - 130 °C - 150 °C at 3 – 3.5 bar (g) -----(Report requirement)	
7.2.2 Pure steam - 121 °C - 130 °C at 2.4 bar (g) -----(Report requirement)	
7.2.3 WFI (Hot loop) - 80-85 °C at 2 bar (g) -----(Report requirement)	
7.2.4 Purified Water- 28 - 30 °C at 2.5 bar (g) -----(Report requirement)	
7.2.5 Cooling water- 28 °C -30 °C at 3 bar (g) -----(Report requirement)	
7.2.6 Brine- 2 °C – 8 °C at 3 bar (g) -----(Report requirement)	
7.2.7 Chilled water- 8 °C to 12 °C at 3 bar (g) -----(Report requirement)	
7.2.8 Electricity - Vendor to specify----- (Report requirement)	
7.2.9 Compressed air- 6.0– 8.0 bar (g) -----(Report requirement)	
Note: Utility consumption to be specified by the vendor, in case if there is a deviation in the values mentioned above.	

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8.0 ABBREVIATION

Abbreviation	Definition
IVC	Integrated Vaccines Complex
HBL	HLL Biotech limited
BLV	Blending Vessel
CIP	Clean In Place
SIP	Sterilization In Place
GMP	Good Manufacturing Practices
NPI	NNE Pharmaplan India Ltd
ISO	International Standards Organization
HMI	Human Machine Interface
PLC	Programmable Logic Controller
SCADA	Supervisory control and data acquisition system
NMT	Not More Than
TBD	To be discussed
PTFE	Polytetrafluoroethylene
ASME BPE	American Society of Mechanical Engineers Bioprocessing Equipment Standards
RH	Relative Humidity
Class EU	Class European Union

9.0 REVISION INDEX

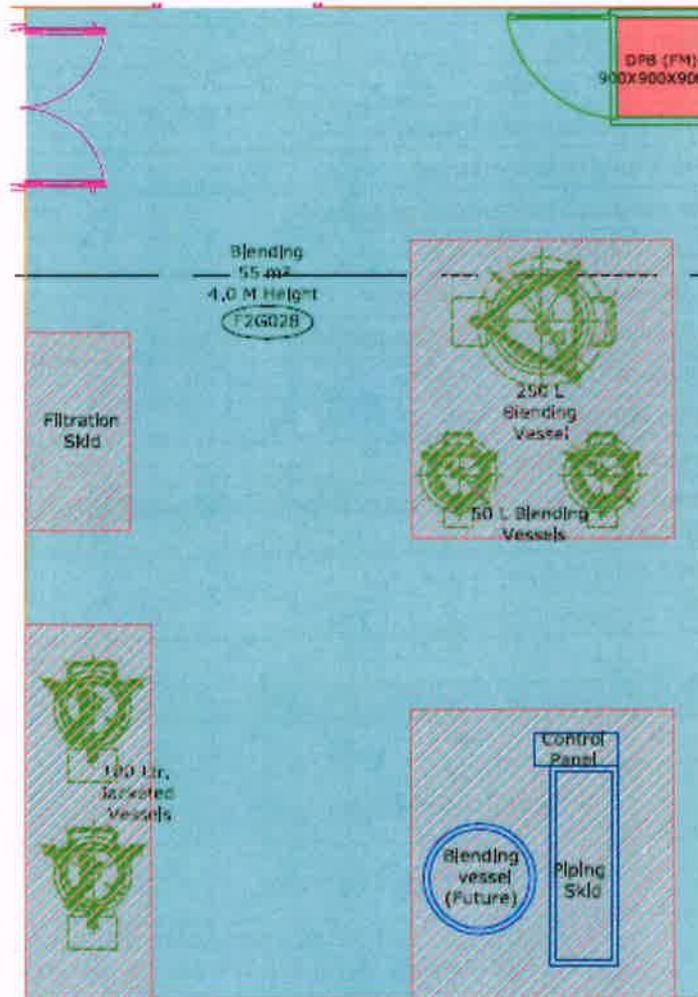
Revision	Date	Reason for Revision
00	06-03-2014	First Draft for Client's Review
01	12-03-2014	1. Page 5/20 ;Table No:02;Point No:4 min. operating volume: TBD rephrased as 8L for 50L WV and 15L for 200L W.V 2. Page 5/20; Table No: 02; Point No: 13, HMI is provided for Bacterial Vaccine formulation area. 3. Page 6/20; Table No: 02; Point No: 16, Included Holding duration time as 24 hrs. for all areas. 4. Typographical errors
02	24-03-2014	1. All Formatting errors. 2. Page 17/19; included abbreviations in Point no. 8.0. 3. Changes done as per the MOM dated 21-03-2014

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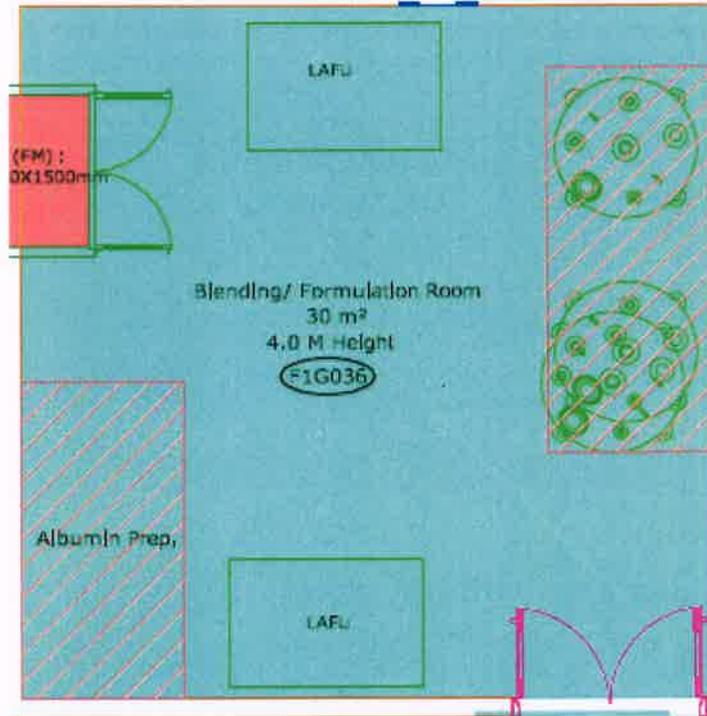
URS Annexure 1: Layout showing location of the Blending vessels in the Bacterial Vaccine Formulation and Viral Vaccine Formulation block



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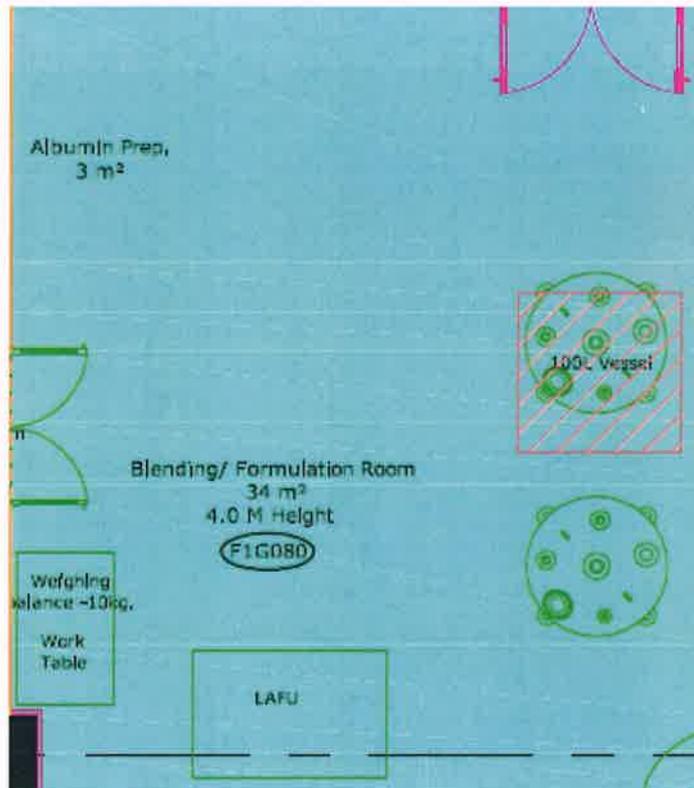
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URS Annexure 3: List of Preferred Make of components

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/ Radix
5	p H sensor	Mettler Toledo/E&H/Hamilton
6	Platform Balance	Mettler Toledo/ Sartorius
7	Load cell	Sartorius/Mettler Toledo
8	Pressure transmitter	Wika /Dwyer/Sensocon
9	Pressure regulator	Festo/SMC
10	Steam trap	Steriflow/Spirax
11	DC source	Shavision/ Yokogawa/ Emerson
B	MECHANICAL	
12	Pressure gauges	Wika/waree/Denver/Negele
13	Vent filter cartridge	Sartorius/Pall/ Millipore
14	Filter housing	Sartorius/ Pall/Millipore
15	Spray ball	Hake/Lechler/Alfa laval
16	Diaphragm valve(Manual)	Gemu / ITT
17	Ball valve(Manual)	Modentic/Saunders/Alfa laval
18	Sampling valve	Novaseptic/GEMU
19	Flush bottom valve	Novaseptic/GEMU
20	Safety relief valve	Herose/SS Spirax /Amtech valves
21	Rupture disc	Zook/Elfab/ Fike
22	Peristaltic pump	Watson Marlow/Masterflex
23	Mixer	Novaseptic/Roplan
C	PNEUMATIC	
24	Diaphragm valve(Automatic)	Gemu / ITT
25	Angle seat valve(Automatic)	Gemu / ITT

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SL.NO	DESCRIPTION	MAKE
D	ELECTRICAL	
26	Lamp	Papenmeier