User Requirement Specifications

Media Preparation Vessel

Block Code	Area	Identification #	Quantity(Nos)	Capacity L (W.V.)
F4	BCG Bulk and Formulation	F4-MPV 01	1	30
B1	Multiple Bacterial Bulk-HepB	B1-MPV 01	1	400
B1	Multiple Bacterial Bulk-Hib	B1-MPV 02	1	500

Buffer Preparation Vessel

Block Code	Area	Identification #	Quantity(Nos)	Capacity L (W.V.)
F4	BCG Bulk and Formulation	F4-BPV 01	1	30
B1	Multiple Bacterial Bulk-HepB	B1-BPV 01_02	2	600
B1	Multiple Bacterial Bulk-Hib	B1-BPV 03	1	500

Harvest Vessel

Block Code	Area	Identification #	Quantity(Nos)	Capacity L (W.V.)
B1	Multiple Bacterial Bulk-HepB	B1-HRV 01	1	1200
B1	Multiple Bacterial Bulk-Hib	B1-HRV 02	1	500

Sublot Vessel

Block Code	Area	Identification #	Quantity(Nos)	Capacity L (W.V.)
B1	Multiple Bacterial Bulk-HepB	B1-SLV 01_03	3	600

Adsorption & desorption Vessel

Block Code	Area	Identification #	Quantity(Nos)	Capacity L (W.V.)
B1	Multiple Bacterial Bulk-HepB	B1-ADS 01_03	3	600
B1	Multiple Bacterial Bulk-HepB	B1-DDS 01	1	600

Holding vessel

Block Code	Area	Identification #	Quantity(Nos)	Capacity L (W.V.)
B1	Multiple Bacterial Bulk-HepB	B1- HDV 01	1	1200
B1	Multiple Bacterial Bulk-HepB	B1- KCV 01	1	1200
B1	Multiple Bacterial Bulk-HepB	B1-BHV 01-02	2	200

Mobile Hot water Recirculation System

Block Code	Area	Identification #	Quantity(Nos)	Capacity L (W.V.)
B1	Multiple Bacterial Bulk-HepB	B1- HRS 01	1	-

Pressure vessel

Block Code	Area	Identification #	Quantity(Nos)	Capacity L (W.V.)
B1	Multiple Bacterial Bulk-HepB	B1- PVE 01	1	1000
B1	Multiple Bacterial Bulk-Hib	B1- PVE 02	1	500

Aerosol Preparation Vessel

Block Code	Area	Identification #	Quantity(Nos)	Capacity L (W.V.)
B1	Multiple Bacterial Bulk-HepB	B1- APV 01	1	200

Table of Contents

URS Annexure List

URS Annex No.	Detail
1	Vessel Design Specifications
2	List of preferred MAKE of components

nne pharmaplan	User Requirement Specifications				HBL
	Equipment/System	Process vessels			
	Identification #	-	Document No.	URS/V_02	
	Effective Date	31-03-2016	Revision#	01	

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 Process vessel which will be located in the respective blocks. The Equipment should be fixed and mobile type and should have legs fitted on flange/Castor wheels.

Design, function and control of the unit should have cGMP compliant. The general design must be hygienic, with no dead legs and no air pockets.

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

TABLE 1

S. No.	Description	Purpose	MOC	Remarks
1.	Shell	Cylindrical	SS316L	
2.	Top closure	Torispherical dish	SS316L	
3.	Bottom closure	Torispherical dish	SS316L	
4.	Jacket	For temperature maintenance	SS304	
5.	Insulation	To avoid heat loss	Mineral wool	
6.	Cladding	Outer cover for insulation	SS304	
7.	Mixer	Bottom mounted magnetic mixer	SS316L	

2.1 General design of Vessel :

Vessels are supplied along with all the necessary piping with skid, valves, instrumentation and Control panels. **Refer Annexure 01** for design requirement for each vessels.

S NO.	DESCRIPTION	Remarks
2.1.1	**Addition Unit:** Addition ports should be of sanitary arrangement with necessary valve and steam trap **arrangements**.	
2.1.2	**Powder Addition port:** Vessel should have a 3" Powder addition port with TC end connection.	
2.1.2	**Spray ball:** Vessels should have sufficient number of spray ball(s) to ensure cleaning of the interior surfaces. The vendor should ensure cleanability of the Process Vessels, 360 degree spray coverage inside the vessel should be ensured.	
2.1.3	**Vent Line/Exhaust Line:** The Vessel should include a vent filter [0.22 Micron] and SS housing. The vent filter should be of sterilizing grade, code 7 type filters. It should be equipped with necessary drain arrangement. Provision for Integrity connector for in-situ integrity testing of filters should be provided. Process air line should have Air-pressure regulator.	
2.1.4	**Temperature Control:** The temperature during preparation should be controlled via circulation of utilities (plant steam, cooling water, chilled water etc.) in the jacket. Temperature control during preparation (tolerance limit: ± 2 °C) & during sterilization the temperature should be 122 °C (tolerance limit: ± 1 °C)	
	Pneumatically actuated valves for steam and cooling water/ chilled water to be provided	
2.1.5	**Mixer:** The vessel should be designed with bottom mounted GMP magnetic mixer. Motor should be Variable speed 50-400 RPM with magnetic drive. Suitable for liquids up to pH1-14 and temperature of 134 °C.	

2.1.6	**Sampling valve:** It should be zero dead leg type valve attached directly to the lower wall of the vessel, with a provision for independent SIP. The diaphragm should be of PTFE type.	
2.1.7	**Flush bottom valve:** It should be steam sterilizable with Zero Dead Leg type valve and directly welded to vessel bottom centrally. The diaphragm should be of PTFE type.	
2.1.8	**CIP (Cleaning – In – Place)**: The Vessel should have 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 should be tested for drainability and should pass the spray ball coverage test in accordance with the recommendations outlined in ASME BPE-2015; part SD-4 & 5.The vendor should ensure cleanability of vessels.	
2.1.9	**SIP (Sterilization – In – Place):** The following principles to be followed 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. • Flush bottom valve, sampling valve and addition valve assembly should be sterilized independently. • The sensors should be reusable and sterilizable type.	
2.1.10	**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)	
2.1.11	**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.** • HMI must be used to enter the process details, which should appear in the print out. • All critical alarms • All Critical parameters & interlocks • 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 General Design of Mobile Hot Water Recirculation Sytsem

System shall be supplied along with all the necessary piping with skid, valves. **Refer Annexure 01** for design requirement for the Mobile hot water recirculation system. Mobile Hot water recirculation system shall cater from vessel capacity of 600L to 1000L.

S NO.	DESCRIPTION	Remarks
2.2.1	**Heat Exchanger:** One no. of shell and tube heat exchanger shall be provided with steam inlet valve and condensate drain with steam trap.	
2.2.2	**Pump:** One no. of centrifugal pump for the recirculation of water shall be provided.	
2.2.3	**Temperature Sensor and transmitter**: One no. of temperature sensor and transmitter shall be provided for the monitoring and control of the temperature.	
2.2.4	**Temperature control:- It shall have a closed loop system with circulation pump and** The temperature during preparation should be controlled via circulation of utilities (plant steam) in the jacket. Temperature control during process (tolerance limit: ± 2 °C)	

2.3 General Requirement for Vessel

2.3.1 **Nozzle schedule:**

S NO.	DESCRIPTION	Remarks
2.3.1.1	**Top dish**	
	• Sight glass with illumination	
	• Powder addition port 3" (TC) (Refer Annexure-01)	
	• Diaphragm pressure gauge and pressure sensor	
	• Spare port (TC clamps with gasket)	
	• Spray ball	
	• Sanitary rupture disc	
	• Sanitary vent filter housing	
	• Addition port (TC type)	
2.3.1.2	**Upper wall side**	
	• Safety Valve with vent valve & Pressure Gauge[Jacket]	
	• Jacket outlet	
2.3.1.3	**Lower wall side**	
2.3.1.4	• Temperature sensor/ transmitter	
	• Jacket inlet	
	• Sampling valve	
2.3.1.5	**Bottom dish**	
	• Flush bottom valve	
	• 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
- **Sec 5.1**
  a. Sl.NO 5 CE Conformity,
  b. Sl.NO 7 ANSI/NSF 49-2008, ISO 14664, ISO 8362
  c. Sl.NO 8 ISO 14664
  d. Sl.NO 9 ISO 8362
- Sec 5.6

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 any 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 become necessary the item must be clearly stated.
4.	In case that the requirement includes a question or request or information from the vendor, the answer / information should be stated in the "REMARKS" column.
5.	The final version of this document including the vendor's comments will become basis of a potential purchase order or contract.
6.	The Technical Specification serves to define a summary of all vendor's requirements concerning scope of delivery and services.
7.	The vendor is responsible for technically unobjectionable function of the equipment. This TS is not intended to dictate a technical design to the vendor. If agreed upon with the vendor, the vendor can apply his practically proven design.
8.	Special Instruction a. If no comments against any specification should be considered as "NO" and b. If there is no reply / comments against the complete URS by the vendor then it should 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 Specifications and Specific Instructions" with URS NPI_120310_EQP_IRS_S1_01
12.	Refer tender document NPI_120310_EQP_S1_TD_16

Specifications	Remarks
3.0 PROCESS DESCRIPTION	
3.1 Input & Charging method	
3.1.1 **Refer Annexure 01**	
3.2 Output & Discharging method	
3.2.1 **Refer Annexure 01**	
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	
The equipment must operate and control the following process parameters:	
6.1.1 Temperature of product during the process	
6.1.2 Speed of the Mixer during process	
6.1.3 CIP/SIP process parameters	
6.2 Failure mode detection	
Equipment should be capable to detect the following failure, notify the operator with alarm and shutdown the process: (if it exceeds by 0-10% (i.e. tolerance limit) of the set point value):	
6.2.1 Mixing speed is out of set range	
6.2.2 Abrupt change in temperature in a particular time	

6.3 In – Process control

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	To monitor, indicate, record and control the temperature	Temperature sensor
Pressure	To monitor, indicate, record and control the pressure of the vessel during process/SIP	Pressure sensor
Mixing Speed	To monitor, indicate, record and control GMP mixer speed	Variable frequency drive with indicator
Level/Volume measurement	To monitor, indicate, record and control of the product in the vessel	Refer Annexure-01

6.5 Batch data display and record printing

6.5.1 Batch data printing should include the following parameters	
• Batch ID, Product name, Time, Temperature, Volume and RPM	
• Operator name and space for signing	
6.5.2 SS 304 Control panel (HMI) with the following (not limited to)	
• Display of temperature, pH and RPM	
• Manual operation must be available through HMI	
• CIP/SIP time duration	
• Emergency stop Button	

6.6 GMP requirements (Others)

6.6.1 The filter housing in the vessel should be provided with sterilizing grade code 7 type filter.	
6.6.2 All nozzle connection should be sanitary type and special attention should be given in shape and dimension of the nozzle and connection to realize efficient cleaning and sterilization process. All nozzle connection should comply with dead leg requirement.	
6.6.3 All nozzles should be flushed to the wall on closure.	
6.6.4 Steam trap should be provided where ever required at the system.	
6.6.5 Flexible hose(Min quantity 2 m) shall be provided for transfer of product from the vessels wherever applicable as per the mode of transfer.(Refer Annexure 01)	
6.6.6 Isolation valves should be provided wherever required	
6.6.7 Spare IO's shall be considered in all the vessels.	

6.6.8 All valves in the sterile part of the vessel should be of sanitary Diaphragm valves	
6.6.9 All gaskets should be made up of food grade [Viton/Silicone/EPDM]	
6.7 Specific requirements	
In general the equipment has to be designed in a way to get easy and quick access to all necessary maintenance points.	
6.7.1 Nozzle shell should be seamless.	
6.7.2 Nozzles, adaptors, instrument should comply with ASME BPE 2015 compliant.	
6.7.3 Total motor drive assembly with SS304 cover	
6.7.4 **Design Parameters:**	
6.7.4.1 Shell working Pressure- FV to 2.5 bar(g)	
6.7.4.2 Shell working Temperature- 2 - 134°C	
6.7.4.3 Shell sterilization Temperature- 121°C	
6.7.4.4 Shell design Pressure- Vendor to specify	
6.7.4.5 Shell design Temperature- Vendor to specify	
6.7.4.6 Jacket working Pressure- FV to 4 bar(g)	
6.7.4.7 Jacket working Temperature- 2 - 135°C	
6.7.4.8 Jacket design Pressure- Vendor to specify	
6.7.4.9 Jacket design temperature-Vendor to specify	
6.7.5 The equipment should be easily accessible for cleaning the product non-contact part at maintenance side of the equipment.	
6.7.6 Vessel should be on 3 legs with lockable PU castor wheels. (Refer Annexure 01)	
6.7.7 **Performance criteria during FAT/SAT and not limited to following requirement:** • Pressure hold test should be performed during FAT • ESIP,FSIP & Spray ball coverage test during FAT • All FAT/SAT IQ,OQ as per IRS	
7.0 CONSTRAINTS	
7.1 Equipment location and available space	
Refer Annexure 01: Vessel Design Specifications	
7.2 Available Utility	
7.2.1 Cooling Water @3 bar _____ (Report requirement)	
7.2.2 Compressed Air @ 8 bar _____ (Report requirement)	
7.2.3 WFI (Hot loop) @ 2 bar _____ (Report requirement)	
7.2.4 Plant Steam @ 3-8 bar _____ (Report requirement)	
7.2.5 Pure steam @ 2.5 bar _____ (Report requirement)	

7.2.6 Electricity : 2 kW (Report requirement)

8.0 ABBREVIATION

Abbreviation	Definition
V	Vessel
CIP	Clean In Place
SIP	Sterilization In Place
cGMP	current Good Manufacturing Practices
GMP	Good Manufacturing Practices
HBL	HLL Biotech Limited
NPI	NNE Pharmaplan India Ltd
TBD	To be discussed
NA	Not Applicable
ESIP	Empty vessel sterilisation in place
FSIP	Full vessel sterilisation in place
RPM	Revolutions per minute
KW	Kilo Watt
TC	Tri-clover Clamp
FAT	Factory Acceptance Test
SAT	Sight Acceptance Test
IQ	Installation Qualification
IRS	Installation Requirement Specifications
OQ	Operation Qualification
URS	User Requirement Specification
CIP/SIP	Clean In Place /Sterilisation In Place
HMI	Human Machine Interface

9.0 REVISION INDEX

Revision	Date	Reason for Revision
00	03-09-2015	First Draft for Client's Review
01	25-09-2015	Updated Clients Comments dated 21.09.15

URS Annexure 2: List of preferred make of components

SI.NO	COMPONENTS	MAKE
	INSTRUMENTATION	
1.	Temperature transmitter	Radix/ Yokogawa/Emerson
2.	Temperature sensor	NEGELE /Emerson/Wika
3.	DP sensor with transmitter	E+H/Emerson/Burkert
	MECHANICAL	
4.	Pressure gauge	WIKA/Denver/Negale
5.	Filter housing	Sartorius/ PALL/Millipore
6.	Filter Cartridge	Sartorius/ PALL/Millipore
7.	Rupture Disc	FIKE/ZOOK
8.	Spray ball	HAKE
9.	Diaphragm valve(Manual)	GEMU / Burkert /Saunders
10.	Sampling valve	GEMU / Burkert /Saunders/Novaseptic
11.	Flush bottom valve	GEMU / Novaseptic
12.	Air pressure regulator	Festo/SMC/Janatics
13.	Magnetic mixer	Novaseptic/Roplan
14.	Flexible hose	Saint Gobian/ BBS / Venair
15.		
16.	Steam trap	STERIFLOW/Forbes marshall
	PNEUMATIC	
17.	Diaphragm valve(Automatic)	GEMU / Burkert /Saunders
18.	Angle seat valve(Automatic)	GEMU / Burkert /Saunders
	ELECTRICAL	
19.	Lamp	PAPENMEIER

HLL Biotech Limited, Chennai

Integrated Vaccines Complex, Chengalpattu

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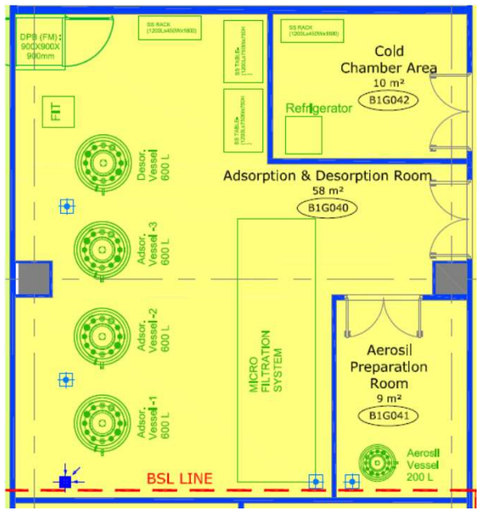
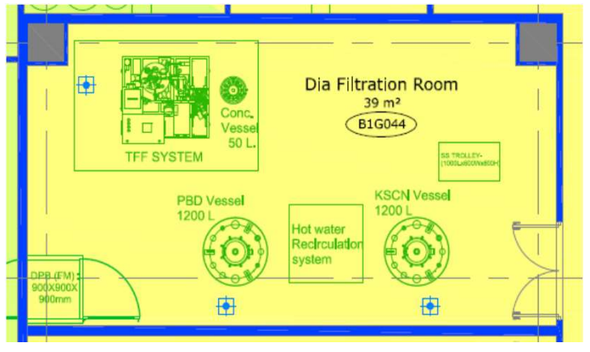
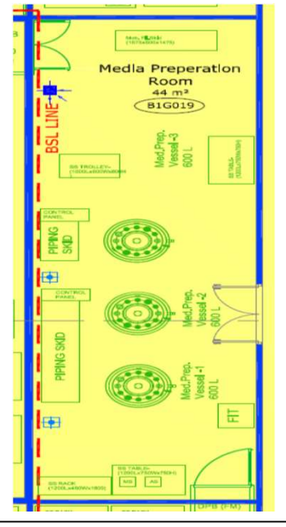
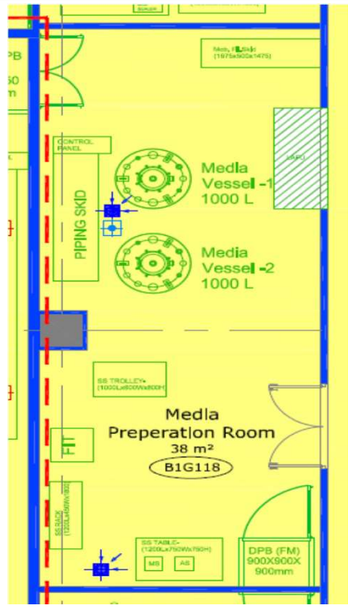
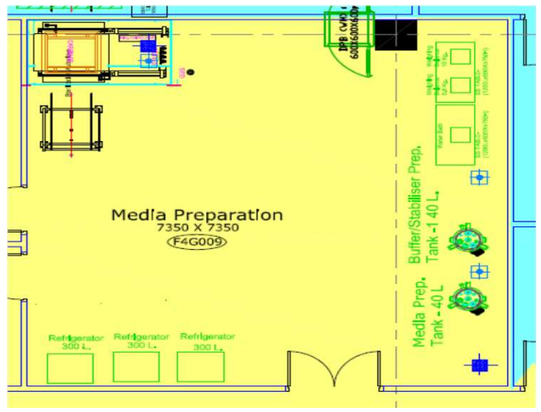
Document Name:	Annexure 1 - Vessel Design Specification & Layout reference
Document No.	Annexure 1
Revision No.	01

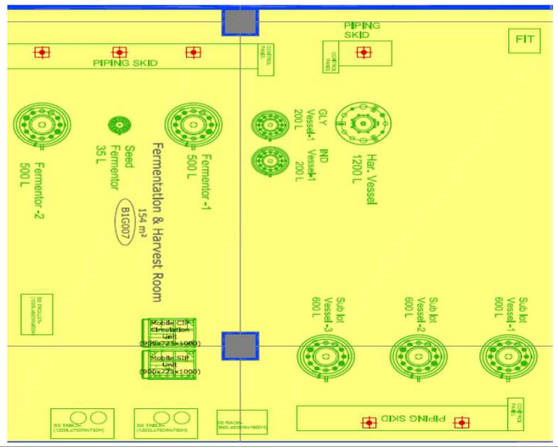
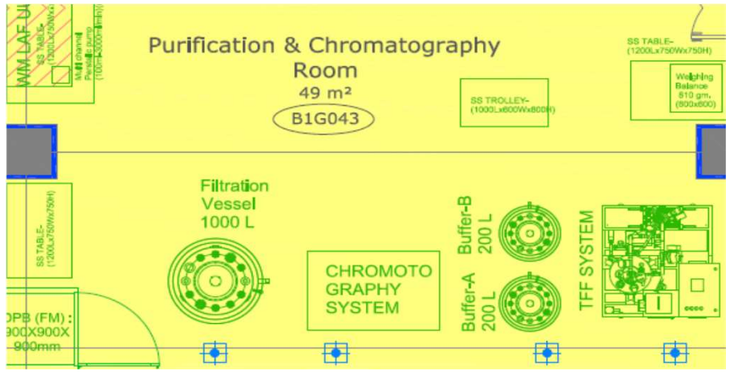
HLL BIOTECH LIMITED (Subsidiary of HLL Lifecare Limited, A Government of India Enterprise)

	Description	Multiple Bacterial Bulk Block -Hep B												Multiple Bacterial Bulk Block - HIB				BCG Vaccine Bulk and Formulation
		Harvest vessel	Sublot Vessels	Adsorption Vessels	Desorption Vessels	PBD Holding Vessels	KSCN Holding Vessels	Media Prep. Vessels	Buffer Prep. Vessels	Buffer Holding Vessel	Filtration pressure vessel	Aerosil Prep. Vessels	Mobile Hot water Recirculation system	Media Prep. Vessels	Buffer Prep.Vessel	Harvest Vessels	Product Collection Pressure Vessel	Media & Buffer Prep. Vessels
		B1-HRV 01	B1-SLV 01_03	B1-ADS 01_03	B1-DDS 01	B1-HDV 01	B1-KCV 01	B1-MPV 01	B1-BPV 01_02	B1-BHV 01_02	B1-PVE 01	B1-APV 01	B1-HRS 01	B1-MPV 02	B1-BPV 03	B1-HRV 02	B1-PVE 02	F4-MPV 01 F4-BPV 01
1	No. of vessels/system	1	3	3	1	1	1	1	2	2	1	1	1	1	1	1	1	2
2	Type of vessel	Fixed	Fixed	Fixed	Fixed	Fixed	Fixed	Fixed	Fixed	Fixed	Fixed	Fixed	Mobile	Fixed	Fixed	Fixed	Fixed	Mobile
3	Max. Working volume , L	1200	600	600	600	1200	1200	400	600	200	1000	200		500	500	500	500	30
4	Geometric volume, L	Vendor to specify	Vendor to specify	Vendor to specify	Vendor to specify	Vendor to specify	Vendor to specify	Vendor to specify	Vendor to specify	Vendor to specify	Vendor to specify	Vendor to specify		Vendor to specify	Vendor to specify	Vendor to specify	Vendor to specify	Vendor to specify
5	Minimum operating volume, L	250	150	150	150	250	250	80	120	60	Vendor to specify	60		150	80	150	80	Vendor to specify
6	H/D ratio	1.5:1	1.5:1	1.5:1	1.5:1	1.5:1	1.5:1	1.5:1	1.5:1	1.5:1	1.5:1	1.5:1		1.5:1	1.5:1	1.5:1	1.5:1	1.5:1
7	Powder addition port (TC type)	No	No	No	No	No	No	Yes	Yes	No	No	No		Yes	Yes	No	No	Yes
8	Addition port (TC type) (one addition port & one spare port)	2	2	2	2	2	2	2	2	2	2	2		2	2	2	2	2
9	Baffles (removable type)	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes		Yes	Yes	Yes	Yes	Yes
10	Liquid Filter (0.45µ) with Housing	No	No	No	No	No	No	No	No	No	No	No		Yes	No	No	No	No
11	PRV for pure steam line	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes		Yes	Yes	Yes	Yes	Yes
12	Rupture disc	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes		Yes	Yes	Yes	Yes	Yes
13	Level/Volume Measurement	DP sensor	DP sensor	DP sensor	DP sensor	Vertical view glass with level marking	Vertical view glass with level marking	DP sensor	DP sensor	Vertical view glass with level marking	Vertical view glass with level marking	Vertical view glass with level marking		Level sensor	Level sensor	Level sensor	Level sensor	Vertical view glass with level marking
14	Acid addition port	No	No	No	No	No	No	No	No	No	No	No		No	No	No	No	No
15	Alkali addition port	No	No	No	No	No	No	No	No	No	No	No		No	No	No	No	No
16	Sampling port	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes		Yes	Yes	Yes	Yes	Yes
17	Sampling mode	Sterile	Sterile	Sterile	Sterile	Non sterile	Non sterile	Non sterile	Non sterile	Non sterile	Sterile	Non sterile		Non sterile	Non sterile	Sterile	Sterile	Non sterile (sampling valve integrated with the flush bottom valve)
18	Pressure Gauge	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes		Yes	Yes	Yes	Yes	Yes
19	Agitator Type and RPM	Bottom driven magnetic mixer with 50-400 RPM	Bottom driven magnetic mixer with 50-400 RPM	Bottom driven magnetic mixer with 50-400 RPM	Bottom driven magnetic mixer with 50-400 RPM	Bottom driven magnetic mixer with 50-400 RPM	Bottom driven magnetic mixer with 50-400 RPM	Bottom driven magnetic mixer with 50-400 RPM	Bottom driven magnetic mixer with 50-400 RPM	Bottom driven magnetic mixer with 50-400 RPM	Bottom driven magnetic mixer with 50-400 RPM	Bottom driven magnetic mixer with 50-400 RPM		Bottom driven magnetic mixer with 50-400 RPM	Bottom driven magnetic mixer with 50-400 RPM	Bottom driven magnetic mixer with 50-400 RPM	Bottom driven magnetic mixer with 50-400 RPM	Bottom driven magnetic mixer with 50-400 RPM
20	Temperature Probe and transmitter(Vessel)	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
21	pump												Yes					
22	Heat Exchanger												Yes					
23	Roughness factor (RA), Product Contact parts	0.6 µm	0.6 µm	0.6 µm	0.6 µm	0.6 µm	0.6 µm	0.6 µm	0.6 µm	0.6 µm	0.6 µm	0.6 µm		0.6 µm	0.6 µm	0.6 µm	0.6 µm	0.6 µm
24	Roughness factor (RA), Non -Product Contact parts	≤1.2 µm	≤1.2 µm	≤1.2 µm	≤1.2 µm	≤1.2 µm	≤1.2 µm	≤1.2 µm	≤1.2 µm	≤1.2 µm	≤1.2 µm	≤1.2 µm		≤1.2 µm	≤1.2 µm	≤1.2 µm	≤1.2 µm	≤1.2 µm
25	CIP	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes		Yes	Yes	Yes	Yes	Yes
26	ESIP	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes		Yes	Yes	Yes	Yes	Yes
27	FSIP	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	No		Yes	Yes	Yes	Yes	Yes
28	Vent filter assembly	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes		Yes	Yes	Yes	Yes	Yes
29	View glass with light	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes		Yes	Yes	Yes	Yes	Yes
30	Level Of Automation	Semi automatic	Semi automatic	Semi automatic	Semi automatic	Semi automatic	Semi automatic	Semi automatic	Semi automatic	Semi automatic	Semi automatic	Semi automatic	Semi automatic	Semi automatic	Semi automatic	Semi automatic	Semi automatic	Semi automatic
31	HMI	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	NO	Yes	Yes	Yes	Yes	Yes
32	PLC	Common PLC		Common PLC	Common PLC	Common PLC		Common PLC		Common PLC		Common PLC with adsorption vessels		Common PLC		Common PLC		NO
33	Input and Charging	Components/Buffer for the process shall be added through the addition port	Components required for the process shall be added through the addition port	Components required for the process shall be added through the addition port	Components required for the process shall be added through the addition port	Components required for the process shall be added through the addition port	Components required for the process shall be added through the addition port	components for the process shall be added through the powder addition port and make up can be done by adding WFI	components for the process shall be added through the powder addition port and make up can be done by adding WFI	Components required for the process shall be added through the addition port	Components required for the process shall be added through the addition port	Components required for the process shall be added through the addition port		components for the process shall be added through the powder addition port and make up can be done by adding WFI	components for the process shall be added through the powder addition port and make up can be done by adding WFI	Components required for the process shall be added through the addition port	Components required for the process shall be added through the addition port	components for the process shall be added through the powder addition port and make up can be done by adding WFI
34	Mode of transfer to next process/ vessel	Pipeline transfer to Cell disruption system and continous centrifuge using air pressure	Pipeline transfer to continous centrifuge by using air pressure	By using flexible hose to desorption vessel	By using flexible hose to further process	By using Flexible hose to UF systems	By using Flexible hose to Dia filtration systems	Pipeline transfer to fermenter using air pressure	Pipeline transfer to process vessel by using air pressure	By using Flexible hose to Chrom systems	By using Flexible hose to Chrom systems	By using Flexible hose to nalgene cans		Pipeline transfer to fermenter by using air pressure	Pipeline transfer to UF system by using air pressure.	Pipeline transfer to continous centrifuge by using pump.	By using Peristaltic pump	

HLL Biotech Limited, Chennai								
Integrated Vaccines Complex, Chengalpattu								
nne pharmaplan®					Document Name:	Annexure 1 - Vessel Design Specification & Layout reference	HBL HLL BIOTECH LIMITED (Subsidiary of HLL Lifecare Limited) (A Government of India Enterprise)	
					Document No.	Annexure 1		
					Revision No.	01		

S. No.	Equipment name	Block Code	Area	Identification #	Equipment location and available space	Physical condition of the room:	Layout	Remarks
1	Adsorption Vessels	B1	Multiple Bacterial Vaccine Bulk (Hepatitis - B)	B1-ADS 01_03 B1-DDS 01	Floor: Ground floor Multiple Bacterial Vaccine Bulk Block - Hepatitis B section Room No. : B1G040 Room dimension : 58 m2 False ceiling height: 3000 mm	1. Class: EU Class “C” 2. Differential Pressure:20 Pa 3. Temperature maintained: 22±2 ºC 4. Relative Humidity: < 55% RH		
2	PBD & KSCN prep. Vessels	B1	Multiple Bacterial Vaccine Bulk (Hepatitis - B)	B1-HDV-01 B1-KCV-01	Floor: Ground floor Multiple Bacterial Vaccine Bulk Block - Hepatitis B section Room No. : B1G044 Room dimension : 39 m2 False ceiling height: 3000 mm	1. Class: EU Class “C” 2. Differential Pressure:20 Pa 3. Temperature maintained: 22±2 ºC 4. Relative Humidity: < 55% RH		
3	Media & Buffer Prep. Vessels	B1	Multiple Bacterial Vaccine Bulk (Hepatitis - B)	B1-MPV-01 B1-BPV 01-02	Floor: Ground floor Multiple Bacterial Vaccine Bulk Block - Hepatitis B section Room No. : B1G019 Room dimension : 44 m2 False ceiling height: 3000 mm	1. Class: EU Class “C” 2. Differential Pressure:20 Pa 3. Temperature maintained: 22±2 ºC 4. Relative Humidity: < 55% RH		

S. No.	Equipment name	Block Code	Area	Identification #	Equipment location and available space	Physical condition of the room:	Layout	Remarks
4	Aerosil Prep. Vessels	B1	Multiple Bacterial Vaccine Bulk (Hepatitis - B)	B1-APV 01	Floor: Ground floor Multiple Bacterial Vaccine Bulk Block - Hepatitis B section Room No. : B1G041 Room dimension : 9 m2 False ceiling height: 3000 mm	1. Class: EU Class “C” 2. Differential Pressure:5 Pa 3. Temperature maintained: 22±2 ºC 4. Relative Humidity:NA		
5	Media & Buffer Prep. Vessels	B1	Multiple Bacterial Bulk Block - HIB	B1-MPV 02 B1-BPV 03	Floor: Ground floor Multiple Bacterial Vaccine Bulk Block - Hepatitis B section Room No. : B1G118 Room dimension : 38 m2 False ceiling height: 3000 mm	1. Class: EU Class “C” 2. Differential Pressure:20 Pa 3. Temperature maintained: 22±2 ºC 4. Relative Humidity: < 55% RH		
6	Media & Buffer Prep. Vessels	F4	BCG Vaccine Bulk and Formulation	F4-MPV-01, F4-BPV-02	Floor: Ground floor BCG Vaccine Bulk and Formulation Block - BCG Room No. : F4G009 Room dimension : 54 m2 False ceiling height: 3000 mm	1. Class: EU Class “C” 2. Differential Pressure:20 Pa 3. Temperature maintained: 22±2 ºC 4. Relative Humidity: < 55% RH		

S. No.	Equipment name	Block Code	Area	Identification #	Equipment location and available space	Physical condition of the room:	Layout	Remarks
7	Harvest Vessels and Sublot Vessels	B1	Multiple Bacterial Vaccine Bulk (HepatitisB)	B1-SBV-01, B1-SBV-02, B1-SBV-03, B1-HRV-02	Floor: Ground floor Multiple Bacterial Vaccine Bulk Block - Hepatitis B section Room No. : B1G007 Room dimension : 154 m2 False ceiling height: 4000 mm	1. Class: EU Class “C” 2. Differential Pressure:20 Pa 3. Temperature maintained: 22±2 ºC 4. Relative Humidity: < 55% RH		
8	Filtration Pressure vessel and Buffer Hold vessel	B1	Multiple Bacterial Vaccine Bulk (HepatitisB)	B1-PSV-02 B1-BHV 01_02	Floor: Ground floor Multiple Bacterial Vaccine Bulk Block - Hepatitis B section Room No. : B1G043 Room dimension : 49 m2 False ceiling height: 3000 mm	1. Class: EU Class “C” 2. Differential Pressure:20 Pa 3. Temperature maintained: 22±2 ºC 4. Relative Humidity: < 55% RH		
9	Harvest and Product Collection vessel	B1	Multiple Bacterial Vaccine Bulk (HIB)	B1-PVE-02 B1-HRV-02	Floor: Ground floor Multiple Bacterial Vaccine Bulk Block - HIB Room No. : B1G106 Room dimension : 128 m2 False ceiling height: 4500 mm	1. Class: EU Class “C” 2. Differential Pressure:20 Pa 3. Temperature maintained: 22±2 ºC 4. Relative Humidity: < 55% RH