User Requirement Specifications
CIP Vessel

Block Code	Area	Identification #	Quantity(Nos)	Capacity L (W.V.)
F1	Viral Vaccine Formulation block	F1-LCT 01	1	3000
F4	BCG Bulk and Formulation	F4-LCT 01	1	2000

Table of Contents

URS Annexure List

URS Annex No.	Detail
1	Layout showing location of the Technical Area of Lyophilizer in the ground floor of Viral Vaccine formulation Block and BCG bulk and formulation block.
2	List of preferred MAKE of components

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User Requirement Specifications

Equipment/System	CIP Vessel for Lyophiliser		
Identification #	-	Document No.	URS/LCT 01
Effective Date	31-03-2016	Revision#	02

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 & QA and authorized by the appropriate Project authority.

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2.0 EQUIPMENT DESCRIPTION

The equipment described by this URS is a "CIP supply Vessels" which will be located in the Technical Area of the Viral vaccine Formulation and BCG Bulk and Formulation block. The Equipment shall be fixed type and should have legs fitted on flange.

The Vessel should be suitable to take water for injection (WFI) of 85°C for CIP.

Design, function and control of the unit have to be cGMP's compliant. The general design must be hygienic, with no dead legs and no air pockets. The system must be fully drainable.

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

TABLE 1

SL. No.	Description	Purpose	MOC	Remarks from vendor
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.	Pump	To supply the WFI to the Lyophiliser are required flow rate and pressure		

TABLE 2

SL. No.	Description	Capacity/Specification	Remarks from vendor
1	No. of vessels	2 no.	
2	Type of vessel	Fixed	
3	Max. Working volume , L	3000L for F1-LCT 01 2000L for F4-LCT 01	
4	Geometric volume, L	Vendor to specify	
5	Minimum operating volume	1500 L must be maintained for complete cycle	
6	H/D ratio	2:1	
7	Addition ports	2	
9	Level/Volume Measurement	Level Sensor (DP type)	
10	Transfer Pump [Electro polished]	15 m3/hr & 3 to 4.5 bar(g)	

2.1 General design of Vessel :

Vessels are supplied along with all the necessary piping with skid, valves and instrumentation.

S NO.	DESCRIPTION	REMARKS
2.1.1	**Spray ball:** Vessels shall have sufficient number of spray ball(s) to ensure cleaning of the interior surfaces. The vendor shall ensure cleanability of the Process Vessels, 360 degree spray coverage should be ensured.	
2.1.2	**Vent Line/Exhaust Line:** The Vessel shall include a vent filter and housing. The vent filter shall be hydrophobic, shall have 0.22/0.2 µm pore size and shall have air pressure regulator. It shall be equipped with necessary drain arrangement .Provision for Integrity connector for in-situ integrity testing of filters shall be provided.	
2.1.3	**Pump:** Centrifugal pump with 15m3/hr @ 4.5 bar(g) flow rate should be provided for the transfer of the CIP solution, all necessary automation and instrumentation should be provided for functionality of the system. Pump should be provided with a drain line.	
2.1.4	**Temperature Control:** The temperature during CIP cycle / recirculation shall be controlled via circulation of utilities (plant steam, cooling water, etc.) in the jacket. Temperature control during preparation (tolerance limit: ± 2 °C) & during CIP the temperature should be >85 °C (tolerance limit: ± 1 °C)	
2.1.5	**Controller:** PLC Based Controller (Non-editable data format to be obtainable) with minimum size of 6" HMI (Displaying & recording of data trends as Graphs, synoptic view of running parameters etc). **One potential free contact** must be provided towards the Lyophiliser control system for process control and Lyophiliser CIP vessel should have provision of connecting the potential free contact in it's control system (i.e.,from Lyophiliser control system- 2 No.s potential free contact is available to receive / control the flow)	
2.1.6	**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 Requirement for Vessel

2.2.1 Nozzle schedule:

2.2.1.1 Top dish

The Vessel top dish will have:

- Sight glass
- Pressure gauge
- Spare port (TC clamps with gasket)
- Spray ball
- Rupture Disc
- Sterile vent filter

2.2.1.2 Upper wall side

- Vertical view glass
- Tank spud for DP level sensor
- Jacket outlet

2.2.1.3 Bottom dish

- Port for bottom valve
- Tank spud for DP level sensor
- Jacket inlet

Note: All the points of the IRS except below mentioned would be applicable for this equipment

- 4.1.10, 4.1.11, 4.1.13,4.1.17
- **Sec 5.1 Table 2**
- **Sl.NO 2 and 3** :FDA guidance for industry
- Sl.NO 5 CE Conformity,
- Sl.NO 7 ANSI/NSF 49-2008, ISO 14664, ISO 8362
- Sl.NO 8 ISO 14664
- Sl.NO 9 ISO 8362
- Sec 5.4.1
- Sec 5.6

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User Requirement Specifications			
Equipment/System	CIP Vessel for Lyophiliser		
Identification #	-	**Document No.**	URS/LCT 01
Effective Date	31-03-2016	**Revision#**	02

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 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.
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_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 WFI of 80-85°C is added into the vessel.	
3.2 Brief Process Steps	
3.2.1 The vessels have to be designed to collect and store WFI in sufficient quantity and quality. 3.2.2 The vessel should be connected to WFI loop with manual loop valve 3.2.3 WFI is collected and transferred using pump with required pressure and flow. 3.2.4 WFI level in tank is controlled by using level sensor (DP type), tank inlet valve and pump.	
3.3 Output & Discharging method	
3.3.1 WFI is transferred to the next process or Equipment.	
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 CIP process parameters	
6.2 Failure mode detection	
Not Applicable	
6.3 In – Process control	
Not Applicable	

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Equipment/System	CIP Vessel for Lyophiliser		
Identification #	-	Document No.	URS/LCT 01
Effective Date	31-03-2016	Revision#	02

Specifications	Remarks

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
Pressure [vessel]	To monitor the pressure of the vessel during process	Diaphragm pressure gauge
Pressure [transfer line]	To monitor, indicate, record and control the pressure of the WFI supply to the Lyophiliser	Pressure sensor with transmitter
Temperature	To monitor, indicate, record and control the temperature	Temperature sensor with transmitter
Flow rate	To monitor, indicate, record and control the flow rate of the WFI supply to the Lyophiliser	Flow meter with transmitter
Level sensor	To Control and Monitor WFI level in Vessel	Level sensor (DP type)
Conductivity	To monitor and indicate the conductivity in the loop	Conductivity sensor

6.5 Batch data display and record printing

Refer IRS(Installation requirement Specification and Specific Instructions)

6.6 GMP requirements (Others)

6.6.1 The vent filter housings in the vessel shall be provided with sterilizing grade hydrophobic filter with housing.

6.6.2 All nozzles shall be flushed to the wall on closure.

6.6.3 Utility operation shall be automatic and valves shall be placed inside of working area.

6.6.4 Isolation valves should be provided wherever necessary

6.6.5 All valves in the sterile part of the vessel should be of sanitary Diaphragm valves

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.

Specifications	Remarks
6.7.1 Nozzle shell shall be seamless.	
6.7.2 Nozzles, adaptors, instrument shall comply with ASME BPE compliant.	
6.7.3 **Design Parameters:** 6.7.3.1 Shell working Pressure: FV to 2.5 bar(g) 6.7.3.2 Shell working Temperature: 20-134°C 6.7.3.3 Shell design Pressure- Vendor to specify 6.7.3.4 Shell design Temperature- Vendor to specify 6.7.3.5 Jacket working Pressure- FV to 4 bar(g) 6.7.3.6 Jacket working Temperature- 2 - 135°C 6.7.3.7 Jacket design Pressure- Vendor to specify 6.7.3.8 Jacket design temperature-Vendor to specify	
6.7.4 Vessel shall be on 3 legs with pad plates MOC: SS 304	
6.7.5 Main tank inlet valve(Auto), Pump and Level sensor should be integrated with lyophilizer CIP control (Lyophiliser vendor scope)	
6.7.6 Drain valve(Auto) should be provided between WFI manual loop valve and main tank inlet valve	
6.7.7 **Performance criteria during FAT/SAT:[but not limited to these]** • Pressure hold test should be performed during FAT • Spray ball coverage test during FAT	
7.0 CONSTRAINTS	
)1 Equipment location and available space	
CIP vessel will be installed in the Lyophiliser technical area of Viral Vaccine Formulation block and BCG Bulk and Formulation block, Integrated Vaccines Complex, Chengalpattu, Chennai as follows: **Physical condition of the room: Viral Vaccine Formulation Block** 1. Class: General 2. Temperature maintained: < 25°C 3. Relative Humidity: Not Applicable 4. Height: 3.7 m **Physical condition of the room: BCG Bulk and Formulation Block** 1. Class: CNC 2. Temperature maintained: < 25°C 3. Relative Humidity: Not more than 60% 4. Height: 3.7 m The equipment location is indicated in the relevant block of the layout enclosed as **URS Annex 1.**	

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Identification #	-	Document No.	URS/LCT 01
Effective Date	31-03-2016	Revision#	02

Specifications		Remarks
7.2	**Available Utility**	
7.2.1	Compressed Air @ 7 bar _____ (Report requirement)	
7.2.2	WFI (Hot loop) @3.5 - 4 bar_____ (Report requirement)	
7.2.3	Pure steam _____ (Report requirement)	
7.2.4	Plant steam _____ (Report requirement)	

8.0 ABBREVIATION

Abbreviation	Definition
CIP	Clean In Place
cGMP	current Good Manufacturing Practices
NPI	NNE Pharmaplan India Ltd
P&ID	Piping Instrumentation and Drawing
URS	User Requirement Specification
GMP	Good Manufacturing Practice
NNE	Novo Nordic Engineering Pharmaplan
WFI	Water For Injection
SS	Stainless Steel
H/D	Height / Diameter
TC	Tri clover clamp
ASME	American Society of Mechanical Engineering
BPE	Bio process Engineering
DP	Differential Pressure Sensor
ISO	International organisation for Standardisation
FDA	Food & Drug Administration
TS	Technical specification
IRS	Installation Requirement Specification
MOC	Material of Construction
FAT	Factory Acceptance Test
SAT	Site Acceptance Test
IQ	Installation Qualification
OQ	Operation Qualification
NA	Not Applicable
ANSI	American National Standards Institute
NSF	National Science Foundation
CE	European Conformity

9.0 REVISION INDEX

Revision	Date	Reason for Revision
00	2015-12-08	First Draft for Client's Review
01	2016-02-17	Updated as per comments given by HBL dated 2016-02-11
02	2016-02-26	Updated as per comments given by HBL dated 2016-02-26

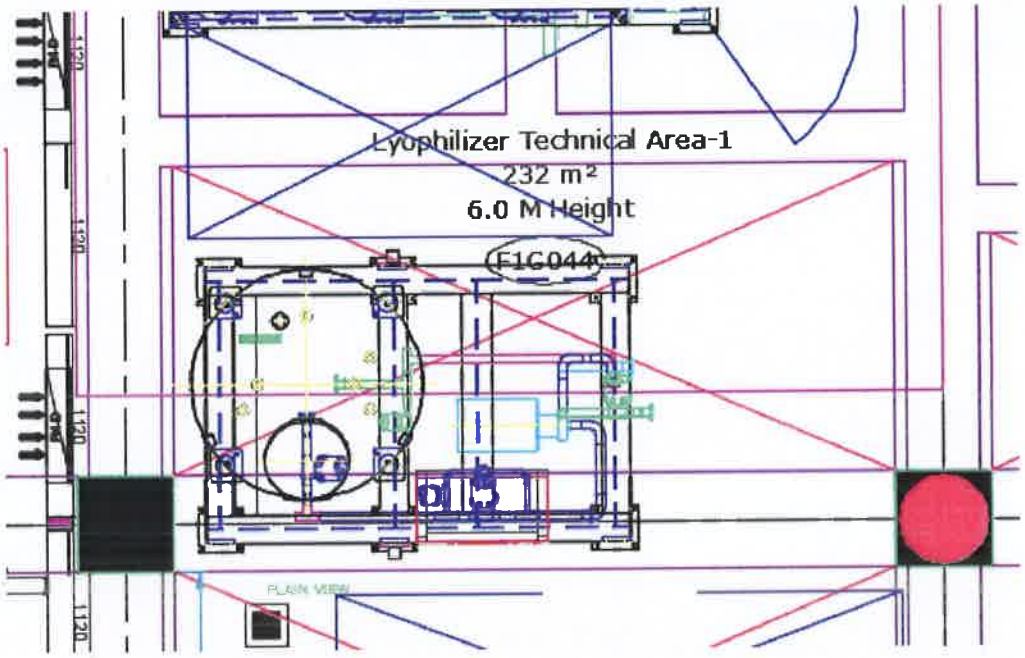
URS Annexure 2: List of preferred make of components

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.	Flexible hose	Saint Gobian/ BBS / Venair
14.		
15.	Steam trap	STERIFLOW/Forbes marshall
	PNEUMATIC	
16.	Diaphragm valve(Automatic)	GEMU / Burkert /Saunders
17.	Angle seat valve(Automatic)	GEMU / Burkert /Saunders
	ELECTRICAL	
18.	Lamp	PAPENMEIER

URS Annexure 1: LAYOUT (CIP Vessel)

Viral Vaccine Formulation Block

Note: Clear height available to install the CIP tank is 3700 mm, Vendor to design the equipment accordingly



BCG Bulk and Formulation Block