User Requirement Specifications
Media Preparation Vessel

Media Preparation Vessel

Block Code	Area	Identification #	Quantity(Nos)	Capacity L (W.V.)
R1	Measles and Rubella Bulk Block	R1-MPV 01	1	100

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URS Annexure List

URS Annex No.	Detail
1	List of preferred MAKE of components
2	Location of the equipment in the layout

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 "Media preparation vessel" which will be located in the Measles and Rubella bulk production block of HBL. The Equipment should be fixed type and should have legs fitted on flange.

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	

TABLE 2

S.No	Description	Media Preparation Vessel	Remarks
1	No. of vessels	1	
2	Type of vessel	Fixed	
3	Max. Working volume , L	100	
4	Geometric volume, L	TBD	
5	Minimum operating volume	Vendor to specify	
6	H/D ratio	1.5:1	
7	Addition port (TC type)	1	
8	Baffles (removable type)	2	
9	PRV for pure steam line	1	
10	Level/Volume Measurement	Load cell	
11	pH sensor	Monitoring and Indication	
12	Rupture Disc	Required	
13	SIP	ESIP	
		FSIP	

2.1 General design of Vessel :

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

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 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 shall be cleaned by using a mobile CIP trolley. 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-2012; 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 Requirement for Vessel

2.2.1 Nozzle schedule:

S NO.	DESCRIPTION	Remarks
2.2.1.1	**Top dish**	
	• Sight glass with illumination	
	• Powder addition port 3" (TC)	
	• 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)	
	• Port for removable dip tube(TC end) with diaphragm valve	
2.2.1.2	**Upper wall side**	
	• Safety Valve with vent valve & Pressure Gauge	
	• Jacket outlet	
2.2.1.3	**Lower wall side**	
	• Temperature sensor/ transmitter	
	• Jacket inlet	
	• pH Sensor	
	• Sampling valve	
2.2.1.4	**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. SI.NO 5 CE Conformity,
  - b. SI.NO 7 ANSI/NSF 49-2008, ISO 14664, ISO 8362
  - c. SI.NO 8 ISO 14664
  - d. SI.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 The components for the process should be added into the vessel through addition port.	
3.1.2 WFI of 80-85°C is added into the vessel.	
3.2 Brief Process Steps	
The Vessel has to be designed to prepare and store various process solutions.	
3.2.1 The components are mixed with WFI at required temperature	
3.2.2 Sampling of product from vessel during process.	
3.2.3 Prepared media is transferred to the next process by using air-pressure transfer.	
3.3 Output & Discharging method	
3.3.1 The solution is transferred to the next process.	
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

6.3.1 Should have provision for 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	To monitor, indicate, record and control the temperature	Temperature sensor with transmitter
Pressure	To indicate the pressure of the vessel during process/SIP	Pressure gauge with transmitter
pH	To monitor, indicate and record the product pH	pH 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	Load cell

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, pH 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
- Provision for manual operation
- 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 Isolation valves should be provided wherever required	
6.6.6 All valves in the sterile part of the vessel should be of sanitary Diaphragm valves	
6.6.7 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 2012 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 From user point to the equipment, food grade SIPable flexible hose (2 m, 2 Nos) with TC end to be provided for each equipment.	
6.7.6 From the equipment to the drain, food grade SIPable flexible hose (3 m, 2 Nos) with TC end to be provided for each equipment.	
6.7.7 Non sterile flexible hoses (2 m, 2 Nos) for black utility to be provided for each equipment.	
6.7.8 The equipment should be easily accessible for cleaning the product non-contact part at maintenance side of the equipment.	
6.7.9 Vessel should be on 4 legs	
6.7.10 **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	
6.7.11 Ring sparger to be provided with valves & filters	
6.7.12 All sterile flexible hoses should be silicon braided hoses	

7.0 CONSTRAINTS

7.1 Equipment location and available space

This equipment will be installed in the **Measles and Rubella Bulk Block** of IVC Vaccines manufacturing facility at HLL BIOTECH LIMITED, Chengalpattu:

Floor: Ground floor
Room Area : 27 m^2
False ceiling height: 3000 mm

Physical condition of the room:

1. Class: EU Class "C"
2. Differential Pressure:50 Pa
3. Temperature maintained: 22±2 °C
4. Relative Humidity: < 55% RH

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	Purified water @ 2 bar _____ (Report requirement)	
7.2.5	Plant Steam @ 3-8 bar _____ (Report requirement)	
7.2.6	Pure steam @ 2.5 bar _____ (Report requirement)	
7.2.7	Electricity : 415 V ± 10%, 50Hz ---------- (Report requirement)	

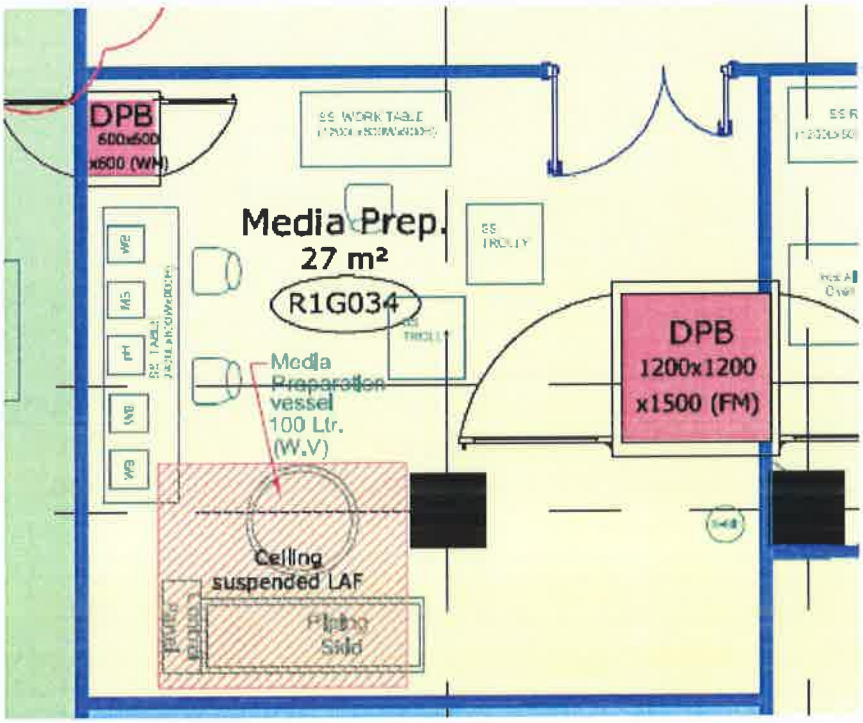
8.0 ABBREVIATION

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	05-04-2016	First Draft for Client's Review

URS Annexure 1: List of preferred make of components

SI.NO	COMPONENTS	MAKE
	INSTRUMENTATION	
1.	Temperature transmitter	Radix/ Yokogawa/Emerson
2.	Temperature sensor	NEGELE/Emerson / Wika
3.	pH sensor	Mettler Toledo/ E+H
	MECHANICAL	
4.	Pressure gauge	WIKA/Bauhlmer
5.	Rupture Disc	FIKE/ZOOK
6.	Ball valve (manual)	Modentic / Alfa laval / Gemu
7.	Spray ball	HAKE / Leckler
8.	Diaphragm valve(Manual)	GEMU/ Burkert / Saunders
9.	Sampling valve	GEMU/ Burkert / Saunders / Novaseptic
10.	Flush bottom valve	GEMU / Novaseptic
11.	Air pressure regulator	Festo / Pnuemax
12.	Magnetic mixer	Novaseptic/Roplan
13.	Flexible hose	Saint Gobian/ BBS / Venair
14.	Load cell	Mettler Toledo/Sartorius
15.	Steam trap	STERIFLOW/Forbes marshall
16.	PRV	ITT / Spirax / Jordan / Burkett
	PNEUMATIC	
17.	Diaphragm valve(Automatic)	GEMU / Burkert / Saunders
18.	Angle seat valve(Automatic)	GEMU / Burkert / Saunders
	ELECTRICAL	
19.	Lamp	PAPENMEIER

URS Annexure 2: Location of the equipment in the layout
Room No: R1G034
Room name: Media prep.