User Requirement Specifications Vessel

Media Preparation Vessel

Block Code	Area	Identification #	Quantity(Nos)	Capacity L (W.V.)
B4	Rabies Vaccine Bulk Production	B4-MPV 01	1	250

Buffer Preparation Vessel

Block Code	Area	Identification #	Quantity(Nos)	Capacity L (W.V.)
F1	Viral Vaccine Formulation	F1- BPV-01	1	100
F2	Bacterial Vaccine Formulation	F2- BPV-01	1	200
B4	Rabies Vaccine Bulk Production	B4-BPV-01	1	250

Mixing Vessel

Block Code	Area	Identification #	Quantity(Nos)	Capacity L (W.V.)
F2	Bacterial Vaccine Formulation	F2- MIV-01	1	150

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HLL BIOTECH LIMITED, CHENNAI

INTEGRATED VACCINES COMPLEX, CHENGALPATTU

nne pharmaplan	User Requirement Specifications				HBL
	Equipment/System	Media preparation vessel, Buffer preparation vessel and Mixing vessel			
	Identification #	-	Document No.	URS/V_01	
	Effective Date	03-11-2014	Revision#	04	

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 vessels, buffer preparation vessels and mixing 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	

TABLE 2

S.No	Description	Buffer Preparation Vessel			Media Preparation Vessel	Mixing Vessel	Remarks
		Viral Vaccine Formulation (Rabies)	Bacterial Vaccine Formulation	Rabies Vaccine Bulk	Rabies Vaccine Bulk	Bacterial Vaccine Formulation	
1	No. of vessels	1	1	1	1	1	
2	Type of vessel	Fixed	Fixed	Fixed	Fixed	Mobile	
3	Max. Working volume , L	100	200	250	250	150	
4	Geometric volume, L	TBD	TBD	TBD	TBD	TBD	
5	Minimum operating volume	25L	35L	40L	40L	30L	
6	H/D ratio	TBD	TBD	TBD	TBD	TBD	
7	Addition port (TC type)	1	1 [Sterile valve assembly]	1	1	1 [Sterile valve assembly]	
8	Baffles (removable type)	0	2	2	2	2	
9	PRV for pure steam line	1	1	1	1	1	

10	Level/Volume Measurement	Load cell	Load cell	Load cell	Load cell	NA	
11	pH sensor	Monitoring and Indication	Monitoring and Indication	Monitoring and Indication	Monitoring and Indication	Monitoring and Indication	
12	CO_2 Purging	NA	NA	NA	Required	NA	
13	Rupture Disc	Required	Required	Required	Required	Required	
14	SIP	ESIP	ESIP	ESIP	ESIP	ESIP	
		FSIP	FSIP	FSIP	FSIP	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 should be cleaned by using a mobile CIP system. 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. 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_08

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 pH is adjusted using CO_2 (only for cell culture media preparation)	
3.2.3 Sampling of product from vessel during process.	
3.2.4 Prepared media/buffer 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
Pressure	To indicate the pressure of the vessel during process/SIP	Pressure gauge
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 with lockable PU castor wheels.	
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	

7.0 CONSTRAINTS

7.1 Equipment location and available space

a) F2- BPV-01, F2- MIV-01 will be installed in the **Bacterial Vaccine Formulation** of IVC Vaccines manufacturing facility at HLL BIOTECH LIMITED,Chengalpattu as follows:

Floor: Ground floor Bacterial Vaccine Formulation
Room dimension : 5200(L)×6900(W) mm
False ceiling height: 3500 mm

Physical condition of the room:

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

b) F1- BPV-01-02 will be installed in the **Viral Vaccine Formulation** of IVC Vaccines manufacturing facility at HLL BIOTECH LIMITED,Chengalpattu as follows:

Floor: Ground floor Viral Vaccine Formulation
Room dimension : 8550(L) x 3935(W) mm
False ceiling height: 3500 mm

Physical condition of the room:

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

c) B4-BPV-01-02 will be installed in the **Rabies Vaccine Bulk Production** of IVC Vaccines manufacturing facility at HLL BIOTECH LIMITED,Chengalpattu as follows:

Floor: Ground floor Rabies Bulk
Room dimension : 6800(L) x 3950(W) mm
False ceiling height: 2700 mm

Physical condition of the room:

1. Class: EU Class "C"
2. Differential Pressure: 30 Pa
3. Temperature maintained: 22±2 ºC
4. Relative Humidity: < 55 % RH

d) B4-MPV-01-02 will be installed in the **Rabies Vaccine Bulk Production** of IVC Vaccines manufacturing facility at HLL BIOTECH LIMITED,Chengalpattu as follows:

Floor: Ground floor
Room size: 6800(L)×4150(W)mm
False ceiling height: 2700 mm

Physical condition of the room:

1. Class: EU Class "C"
2. Differential Pressure:30 Pa
3. Temperature maintained: 22±2 ºC
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	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

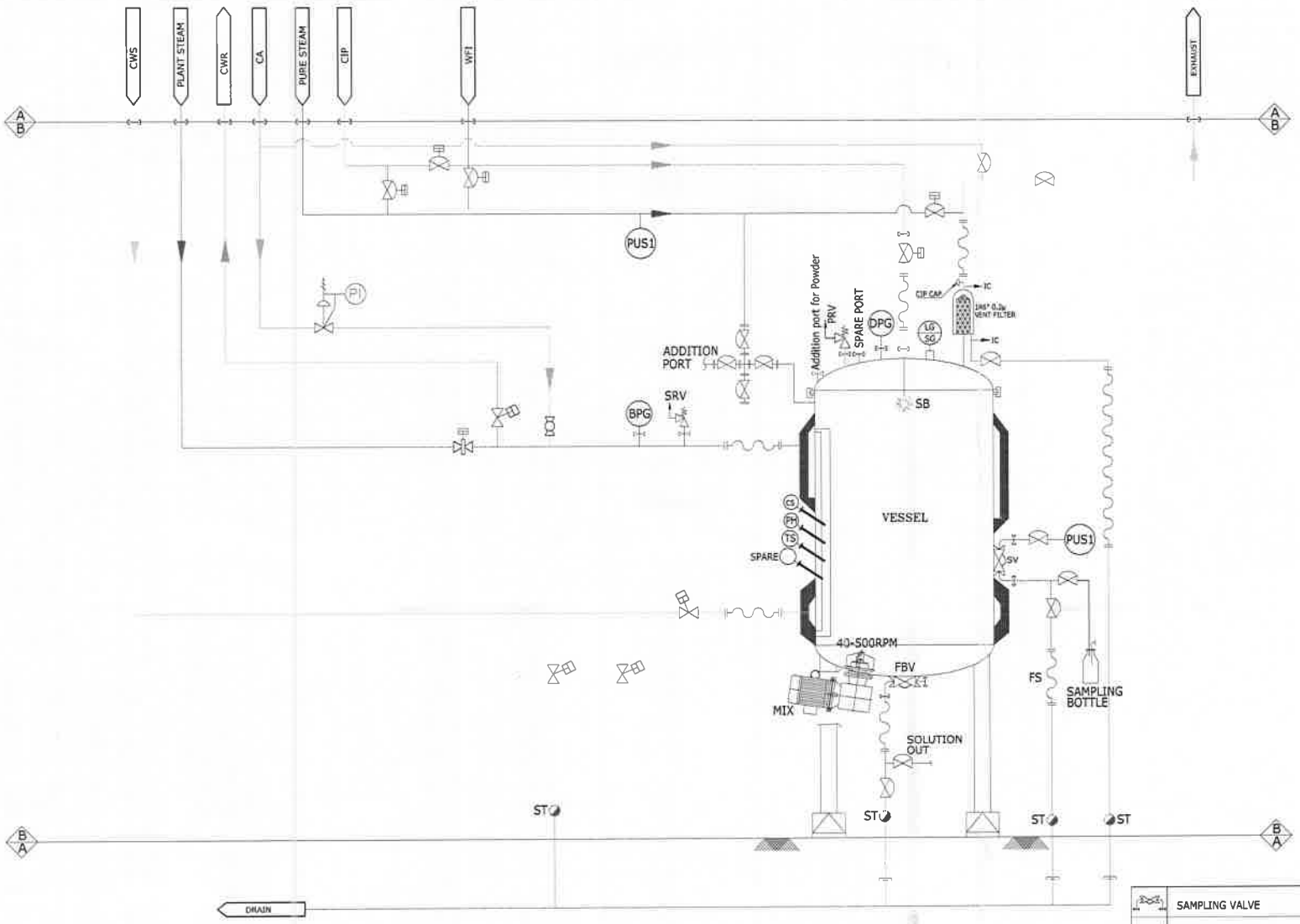
Abbreviation	Definition
V	Vessel
CIP	Clean In Place
SIP	Sterilization In Place
cGMP	current Good Manufacturing Practices
GMP	Good Manufacturing Practices
HBL	HLL Biotech Limited
NPI	NNE Pharmaplan India Ltd
TBD	To be discussed
NA	Not Applicable
ESIP	Empty vessel sterilisation in place
FSIP	Full vessel 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
CO_2	Carbon Dioxide
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	24-04-2014	First Draft for Client's Review
01	01-05-2014	Updated as per Client comments received email dated on 29.04.2014
02	06-05-2014	Updated as per Client comments received email dated on 06.05.2014
03	10-06-2014	Updated as per Client comments received email dated on 19.05.2014
04	05-07-2014	Updated as per MoM dated on 05.07.2014

URS Annexure 1: List of preferred make of components

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



LEGEND

A/B	CLIENT SCOPE / VENDORS SCOPE
	CHWR SUPPLY
	CHWR RETURN
	COOLING WATER SUPPLY
	COOLING WATER RETURN
	PLANT STEAM
	WFI
	CIP
	PURE STEAM
	COMPRESSED AIR
	DRAIN
	BIOWASTE DRAIN
	MANUAL BALL VALVE
	PRESSURE/SAFETY RELIEF VALVE
	MANUAL DIAPHRAGM VALVE
	ACTUATED BALL VALVE
	PNEUMATIC ACTUATED DIAPHRAGM VALVE
DPG	DIAPHRAGM PRESSURE GAUGE
	STEAM TRAP
	FLOAT TRAP
CS	CONDUCTIVITY SENSOR
BPG	BOURDON PRESSURE GUAGE
	TRI CLOVER CLAMP
	CONTROL PISTON VALVE
SV	MANUAL SAMPLING VALVE
FBV	MANUAL FLUSH BOTTOM VALVE
SB	SPRAY BALL
TI	TEMPERATURE INDICATOR
IC	INTEGRITY CONNECTOR
PUS1	PURE STEAM TO SV
PH	pH SENSOR
DPG	DIAPHRAGM PRESSURE GUAGE
PG	PRESSURE GUAGE
FS	FLEXIBLE HOSE
MIX	MIXER
	CONTROL ANGLE SEAT VALVE
	FLEXIBLE HOSE
	CIP CAP
	LOAD CELL
	SAMPLING VALVE
	FLUSH BOTTOM VALVE
PR	PRESSURE REGULATING VALVE

NOTE : THIS P&ID IS ONLY FOR INFORMATION. ACTUAL P&ID HAVE TO BE PROVIDED BY THE VENDOR

Rev.	Date	Changed	Checked	Kind of revision	No. Of Prints	Date	Issued To

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Originated From Org. No :

Project: **INTEGRATED VACCINES COMPLEX, HLL BIOTECH LIMITED,**

Project No.: 120310

Location: CHENGALPATTU

Description: **P & ID FOR VESSELS**

nne pharmaplan
NNE Pharmaplan India Limited
#12, Achiah Shetty Layout,
Bangalore - 560 080., INDIA.

	Date	Name
Drawn	28.04.2014	SAPL
Checked	28.04.2014	BCJP/KNKS
Approved	28.04.2014	VKKA

Scale-NTS | Units : mm | Size : A3

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