User Requirement Specifications
Continuous Centrifuge

Block Code	Area	Identification #	Quantity(Nos.)	Capacity, LPH
B1	Multiple Bacterial Bulk Block – Hep B	B1-CCF-01	1	50 to 500
B1	Multiple Bacterial Bulk Block – Hib	B1-CCF-02	1	50 to 500

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2	List of preferred MAKE of components

HLL BIOTECH LIMITED, CHENNAI

INTEGRATED VACCINES COMPLEX, CHENGALPATTU

nne pharmaplan	User Requirement Specifications				HBL HLL BIOTECH LIMITED
	Equipment/System	Continuous Centrifuge			
	Identification #	-	Document No.	URS/CCF 01	
	Effective Date	19-11-2015	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 shall 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 in this URS is "Continuous Centrifuge". This system will be used in the harvest step. The high speed centrifugal Continuous centrifuge is connected directly from the fermenter/Vessel. The bio-waste stream from the centrifuge shall be transferred to the bio-waste system. For Hib after inactivation the vessel connected to the centrifuge for the separation of supernatant.

TABLE 1:Basic Specification

SL. No.	Description	Purpose	Remarks
1.	Self-cleaning bowl	Suitable for fully automatic cleaning in place	
2.	Opening and closing of bowl	For discharging the solids for controlled partial ejection	
3.	Gapless discs	For high sanitary requirements	
4.	Turbidity meter	For monitoring the discharge	
5.	Vibration monitoring system	To monitor the vibration in the system during process	

TABLE 2: Specific Requirements

The equipment will be designed to achieve a maximum recovery of the final product. Product losses must be minimized.

SL. No.	Description	Specification	Remarks from vendor
1.	Throughput	50-500 LPH	
2.	PCV value of product at inlet	10% - 15%	
3.	PCV value of product at outlet	Vendor to specify	
4.	Disk Diameter	Vendor to specify	
5.	No. of disks	01	
6.	Speed (rpm)	7000-12000 rpm	
7.	Sludge Tank	Sludge tank required for collection of pellet. Minimum capacity1.4L Solid Discharge shall be collected in the sludge tank.	Minimum capacity 1.4 L
8.	View Glass	At the upstream and downstream of centrifuge for viewing clarity of the centrifuged bulk	
9.	Self-cleaning bowl	Suitable for fully automatic cleaning in place	
10.	CIP – cleaning in place	CIP for the bowl / inlet and outlet lines / Solid Discharge i.e. the entire system	

		shall be done in fully automatic mode	
11.	SIP – steam in place	Automatic SIP of the bowl / inlet and outlet lines / Solid Discharge i.e. the entire system shall be possible by injecting pure steam through upstream piping of the centrifuge lead through the filters and outlet from the downstream lines.	Steaming temperature ≥ 100℃
12.	Opening and closing of bowl	For discharging the solids for controlled partial ejection	
13.	Gapless discs	The disk design as gapless welded space for highest sanitary requirements	Disk design: gapless welded spacers for highest sanitary vibration control should be provided.
14.	Vibration monitoring system	To monitor the vibration in the system during process and control should be provided.	
15.	Bowl capacity	The bowl capacity shall be minimum 8L.	

2.1 General design of Continuous Centrifuge :

S No.	Description	Remarks from vendor
2.1.1	**Inlet Zone**: It accelerates the product feed up to the speed of the rotating bowl. It shall prevent foaming and degradation of product. Provision for open outlets (TC ended) shall be considered for inlet of the process fluid.	
2.1.2	**Disk Stack Area**: Disc design shall be such that the process flow is evenly spread among all the disc for efficient separation process.	
2.1.3	**Liquid Discharge area**: feed once separated must be conveyed out of the Continuous Centrifuge, without any change of temperature in process and other required parameters. Provision for two open outlets (TC ended) in T shape shall be considered One outlet will be used for transferring liquid out of the Continuous Centrifuge tanks to the collection tank / process drain. Other will be used to recirculate the supernatant discharge back to the feed input vessel. Both the outlets shall be provided with pneumatic valves which shall be controlled by the readings of the Turbidity sensor. • If Turbidity Reading ≤ set point – Output of the tank will be routed to the collection tank / process drain. • If Turbidity Reading > set point – Output of the tank will be recirculated back to the feed vessel.	

	Turbidity sensor reading shall provide input to control the back pressure for product inlet and outlet. **Note: It must also be possible to operate the valves manually based on visual observations in the view glass.**	
2.1.4	**Solid Discharge area**: After separation, the cell mass / solid gets collected in the sludge collection tank. A nozzle or open ports in the bowl periphery shall be considered to remove the collected solid to the sludge tank in a controlled interval and the sludge tank capacity should be vendor to specify.	
2.1.5	**Continuous Centrifuge System**: Product is fed to the centrifuge at a constant flow rate. Cell material sediments in the Continuous Centrifuge. Sediment ejections are performed at regular intervals to the sludge tank.	
2.1.6	All parts (valves, transmitters, etc) should be easy to access and removable to facilitate routine maintenance.	
2.1.7	All critical instruments used for process control or registration must be calibrated and calibration certificates provided. Calibration of process critical instrumentation shall be easily accessible.	
2.1.8	All connections should be made with sanitary connections (with the exception of instrument air connection)	
2.1.9	The system must be designed to fail in safe mode and to recover from safe mode without risk of contamination or product loss.	
2.1.10	All points of use, mechanical, instrument, control and electrical items or components (including cables) must be identified by a secure, legible, permanently marked, conditions resistant label or tag.	
2.1.11	Emergency button shall be provided to stop the machine in gradually deceleration mode for product and operator protection	
2.1.12	The installed wheels on control module must be made of material that does not damage the clean room floors.	
2.1.13	All process air and gases used in contact with product must be filtered through a 0.2 µm filter	
2.1.14	It must be possible to identity check of any incoming materials, intermediates etc. used in production to ensure traceability to batch report.	
2.1.15	It must be possible to CIP all equipment and piping in product contact	
2.1.16	After CIP, the process equipment must be drained automatically establishing a flow route to drain.	
2.1.17	The Continuous Centrifuge must be active and the backpressure must be regulated to set-point during CIP	
2.1.18	Level probes should be provided in solid tank when the solid are discharged in closed system.	
2.1.19	The product connection shall be: tri clamp or sterile screw coupling.	
2.1.20	The equipment should be provided with vibration maintaining system.	
2.1.21	Spray nozzles in the hood and solids discharge tank shall be provided as an additional requirement for CIP.	

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 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 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_EQP_IRS_S1_01
12.	Refer tender document NPI_120310_EQP_S1_TD_19
13.	All product contact part should made up of high-alloyed stainless steel comply with cGMP requirements.
14.	Set of special tools for equipment maintenance shall be provided.

Specifications	Remarks
3.0 PROCESS DESCRIPTION: For Hepatitis Type b vaccine	
Step 1: Cell washing – Centrifugation	
3.1 Input & Charging method (Continuous Centrifuge)	
3.1.1 The Harvest from the 500L fermentor will be collected in 1200 L harvest vessel wherein it is mixed with Lysis buffer.	
3.1.2 The input to the centrifuge shall be provided from 1200 L Harvest vessel.	
3.1.3 The heavy phase and sludge shall be forced towards the periphery of the bowl, while the light phase shall be flow towards the center of the bowl, from where it shall be pumped out.	
3.2 Brief Process Steps	
3.2.1 Inlet zone must accelerate the process fluid up to the speed of the rotating bowl.	
3.2.2 Inlet zone must prevent foaming, minimize temperature rise and avoids disturbances of the separation processes taking place in the bowl.	
3.2.3 Turbidity meter and view glass must be installed for monitoring and controlling the discharge. If the turbidity is above the set point the outlet shall be recirculated to the 1200 L feed vessel.	
3.3 Output & Discharging method	
3.3.1 Product of Interest: cell mass / solids collected in the sludge tank and supernatant – to be drained	
3.3.2 Separated liquid shall be discharged from the vertical Continuous Centrifuge by overflow or by built in centripetal pumps	
3.3.3 The separated liquid will be recirculated to the feed vessel or drained through process drain which shall be controlled through turbidity sensor.	
3.3.4 Continuous / Intermittent solid discharge section must be installed to remove the collected solids to the sludge tank.	
Step 2: Clarification:	
3.4 Input & Charging method (Continuous Centrifuge)	
3.4.1 The inactivated cell volume of 500 L is fed as input to the Continuous Centrifuge.	
3.4.2 The heavy phase and sludge shall be forced towards the periphery of the bowl, while the light phase shall be flow towards the center of the bowl, from where it shall be pumped out.	
3.5 Brief Process Steps	
3.5.1 Inlet zone must prevent foaming, minimize temperature rise and avoids disturbances of the separation processes taking place in the bowl.	
3.5.2 Turbidity meter and view glass must be installed for monitoring and controlling the discharge. If the turbidity is above the set point the outlet shall be recirculated to the 1200 L feed vessel.	
3.5.3 Continuous / Intermittent solid discharge section must be installed to remove the collected solids to sludge tank that shall be drained to the process drain.	

Specifications	Remarks
3.6 Output & Discharging method	
3.6.1 Product of Interest: Supernatant and Cell mass / solid / will drained.	
3.6.2 Separated liquid shall be discharged from the vertical Continuous Centrifuge by overflow or by built in centripetal pumps	
3.6.3 The separated liquid will be recirculated to the feed vessel or which shall be controlled through turbidity sensor.	
4.0 PROCESS DESCRIPTION: For Haemophilus influenzae type b Vaccine	
Centrifugation	
4.1 Input & Charging method (Continuous Centrifuge)	
4.1.1 The input to the centrifuge shall be provided from 500 L Harvest vessel.	
4.1.2 The heavy phase and sludge shall be forced towards the periphery of the bowl, while the light phase shall be flow towards the center of the bowl, from where it shall be pumped out.	
4.2 Brief Process Steps	
4.2.1 Inlet zone must accelerate the process fluid up to the speed of the rotating bowl.	
4.2.2 Inlet zone must prevent foaming, minimize temperature rise and avoids disturbances of the separation processes taking place in the bowl.	
4.2.3 Turbidity meter and view glass must be installed for monitoring and controlling the supernatant. If the turbidity is above the set point the outlet shall be recirculated to the 500 L feed vessel.	
4.3 Output & Discharging method	
4.3.1 Product of Interest: Supernatant collected in the vessel and unwanted product cell mass / solids – to be drained or collect in sludge tank.	
4.3.2 Separated liquid shall be discharged from the vertical Continuous Centrifuge by overflow or by built in centripetal pumps.	
4.3.3 The separated liquid will be recirculated to the feed vessel and collect in process vessel which shall be controlled through turbidity sensor.	
4.3.4 Continuous / Intermittent solid discharge section must be installed to remove the collected solids to the sludge tank and drained through process drain.	
5.0 PRODUCTIVITY REQUIREMENT	
5.1 Change Over Time	
Not Applicable	
5.2 Others(If any)	
Not Applicable	

Specifications	Remarks
6.0 CONTAINMENT	
Not Applicable	
7.0 GMP REQUIREMENTS	
7.1 Process control	
The equipment must operate and control the following process parameters.	
7.1.1 Temperature , pressure , flow rate and Turbidity control	
7.1.2 It must be possible to manually change the CIP priority and CIP recipe.	
7.1.3 There must be a specified cooling time after the sanitization / steam In place of the Continuous Centrifuge.	
7.2 Failure mode detection	
Equipment shall 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):	
7.2.1 Coolant pressure	
7.2.2 Coolant flow rate	
7.2.3 Emergency air pressure	
7.2.4 Temperature deviation during sanitization	
7.2.5 Cooling timer failure during sanitisation	
7.2.6 Deviation from the set point flow during separation process	
7.2.7 Temperature Alarm	
7.2.8 Flow Alarm	
7.2.9 Turbidity Alarm	
7.2.10 Time Alarm	
7.2.11 Back Pressure Alarm	
7.2.12 Rotational speed Alarm	
7.3 In – Process control	
7.3.1 The flow through the Continuous Centrifuge must be regulated to a set point 50 to 500 LPH	
7.3.2 The back pressure for the Continuous Centrifuge at the supernatant outlet must be regulated to a set point range of 5-7 bar.	
7.3.3 The turbidity at the supernatant outlet must be regulated to a set point range.	

	Specifications	Remarks
7.3.4	The speed of rotation for the ball in the Continuous Centrifuge must be controlled to 7000 to 12000 rpm.	
7.3.5	The separation of the harvest must produce a cell free application liquid.	
7.3.6	Sanitization of Continuous Centrifuge, and connecting pipes must ensure a temperature of 100 ℃ for ≥30 min.	
7.3.7	After CIP of Continuous Centrifuge, the inside surface (plates inside the Continuous Centrifuge) must be visually clean.	

7.4 Level of Instrumentation

Sufficient and suitable instrumentation for the process, safety and productivity control as indicated in the following table:

Type of control	Purpose	Instrumentation
Pressure	At the upstream and downstream of centrifuge to control the back pressure of centrifuged bulk, auto calibrated pressure system	Pressure transmitters / indicators / controller.
Turbidity	At the downstream of centrifuge to monitor and control the turbidity of centrifuged bulk	Turbidity sensor / meter
Pressure	To indicate the seal cooling liquid pressure.	Pressure transmitters / indicators
Pressure	To indicate supply pressure for liquid for bowl lifting.	Pressure transmitters / indicators / Controller
Temperature	At the downstream of centrifuge to monitor and control the temperature of centrifuged bulk. Temperature transmitter shall be provided at all required phase of centrifuge.	Temperature sensor with transmitter / controller
Temperature	To measure temperature during sanitisation	Temperature sensor with transmitter / controller
Level	in solid tank to monitor the amount of solids generated	Load cell / Vender to specify
Flow rate	At upstream and downstream of centrifuge to monitor the flow of centrifuged bulk	Flow transmitters / indicator / controller.

Specifications				Remarks
	Flow rate	To monitor flow rate of Seal cooling liquid / Operating liquid for bowl lifting	Flow transmitters / indicator / controller.	
	Speed	To monitor rotating speed of the bowl	Speed indicator controller	

7.5	**Batch data display and record printing**	
7.5.1	Batch data printing should include these parameters, but not limited to these, • Time, Temperature, pressure, turbidity, flow rate volume. • Operator name and space for signing	
7.5.2	SS 304 Control panel (IPC) with 21 CFR the following (not limited to these) • Display of time, temperature, pressure, Turbidity, flow rate and RPM • Provision for manual operation, CIP/SIP time duration, Emergency stop Button Also refer IRS	
7.6	**GMP requirements (Others)**	
7.6.1	All product contact parts shall be sanitary type and made from SS 316 L.	
7.6.2	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 steaming process. All nozzle connection should comply with dead leg requirement	
7.6.3	All nozzles shall be flushed to the wall on closure.	
7.6.4	Steam traps shall be provided where ever required at the system.	
7.6.5	Isolation valves should be provided wherever necessary	
7.6.6	All gaskets should be made up of food grade/Silicone/EPDM	
7.6.7	Continuous Centrifuge should meet ASME standards, ASME section VIII,DIV.1,ASME BPE 2012,bio-procecessing equipment, GAMP 5, a risk based approach to compliant ,US FDA 21 CFR part 11 for electronic records and electronic signatures, GAMP for validation of automation system, IEC 60529 standards for protection of panel enclosure.	
7.7	**Specific requirements**	
In general the equipment has to be designed in a way to get easy and quick access to all necessary maintenance points.		
7.7.1	Vendor to provide the range of rotational speed of the bowl in the Continuous Centrifuge and shall be settable	
7.7.2	Separate drain for Bio-waste and condensate shall be provided with necessary isolation valves & NRV.	
7.7.3	Back pressure in the Continuous Centrifuge during separation (vendor to provide the maximum allowable pressure details)	
7.7.4	Sufficient lubrication shall be provided to the motor and pressure and flow regulator	
7.7.5	Emergency air connection to provide back up for the lubrication air system	

Specifications	Remarks
7.7.6 Peristaltic pump is required for infeed of intermediate solution and for the outfeed of the fractions	
7.7.7 Inlet zone must accelerate the process fluid up to the speed of the rotating bowl.	
7.7.8 Inlet zone must prevent foaming, minimises temperature increases and avoids disturbances of the separation processes taking place in the bowl.	
7.7.9 Continuous/Intermittent solid discharge section must be installed to remove the collected solids.	
7.7.10 Cleaning: • External surfaces and possible open vents should be resistant to at least 70% IPA • WFI, buffer, solution shall be used to rinse and sanitised the system. User will provide the cleaning agents and supplier shall give the compliance report of the cleaning agents coming in product contact surfaces	
8.0 CONSTRAINTS	
8.1 Equipment location and available space	
This equipment will be installed in the **Multiple Bacterial Bulk Block** of Integrated vaccines complex, HLL BIOTECH LIMITED,Chengalpattu as follows: **B1-CCF 01:** **Floor:** Ground floor **Section :** Hepatitis-B (Hep-B) **Room No. :** B1G009 **Room dimension :** 4282 X 4045 mm **False ceiling height:** 3000 mm **B1-CCF 02:** **Floor:** Ground floor **Section :** Haemophilus influenzae type-b (Hib) **Room No. :** B1G008 **Room dimension :** 5100 X 3000 mm **False ceiling height:** 3000 mm The equipment location is indicated in the relevant block of the layout enclosed as **URS Annex 1.**	
8.2 Available Utility	
8.2.1 Process Air _____ (Report requirement)	
8.2.2 CIP Supply _____ (Report requirement)	
8.2.3 Chilled water (7 to 12 deg. C) ----- (Report requirement)	
8.2.4 Purified water ---------- (Report requirement)	
8.2.5 WFI (Hot loop) @ 2 bar [80-90 ºC] _____ (Report requirement)	

Specifications	Remarks
8.2.6 Pure steam @ 2.5 bar _____ (Report requirement)	
8.2.7 Electricity : (Report requirement)	

9.0 ABBREVIATION

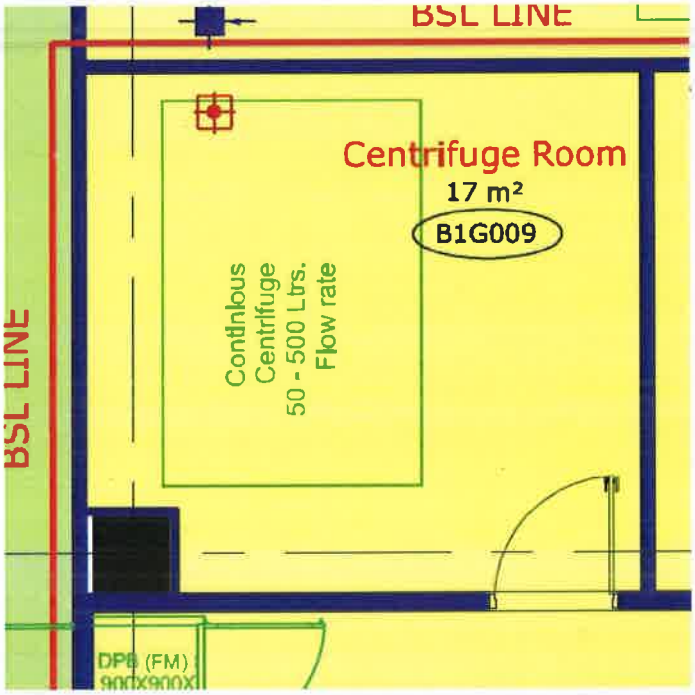
Abbreviation	Definition
cGMP	current Good Manufacturing Practices
CIP	Clean In Place
FAT	Factory Acceptance Test
GMP	Good Manufacturing Practices
HBL	HLL Biotech Limited
HMI	Human machine interface
IRS	Installation Requirement Specification
LPM	Litre per minute
NA	Not Applicable
NPI	NNE Pharmaplan India Ltd
PRV	Pressure Reducing Valve
SAT	Sight Acceptance Test
SIP	Sterilization In Place
TBD	To be discussed
TEFC	Totally Enclosed and Fan cooled
URS	User Requirement Specification
CCF	Continuous centrifuge
PCV	Packed Cell Volume

10.0 REVISION INDEX

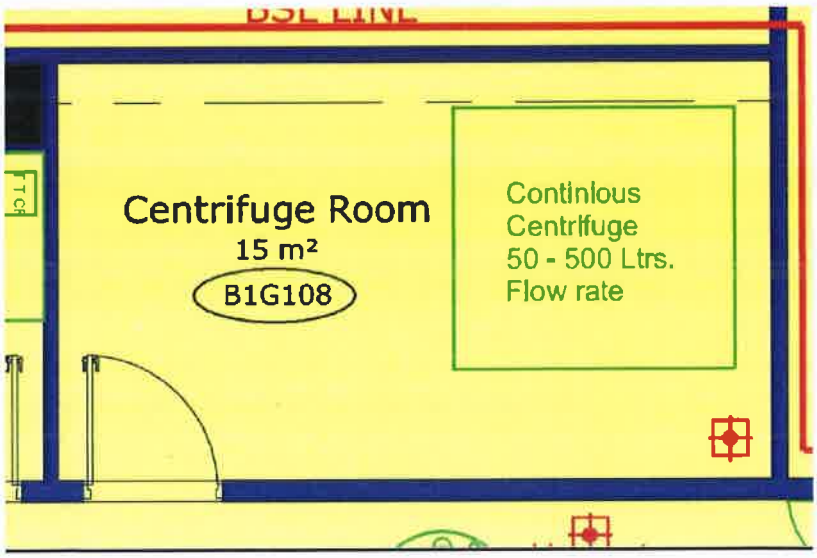
Revision	Date	Reason for Revision
00	05-08-2015	New Document
01	21-10-2015	Updated as per comments given by HBL dated on 07-09-2015

URS Annexure 1: LAYOUT OF MULTIPLE BACTERIAL BULK BLOCK

B1-CCF 01: Centrifuge Room (B1G009), Hepatitis - B



B1-CCF 02: Centrifuge Room (B1G108), Haemophilus influenzae type - b



URS Annexure 2: 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/E&H/Anderson-negele
4	Temperature sensor	Negele/ Radix/E&H/Yocogawa
5	Turbidity sensor	Mettler Toledo/Hamilton/E&H
6	Pressure transmitter	Wika /Dwyer/Siemens
7	IPC	Allen Bradley/ Siemens
8	Flow sensor	E&H/ Burkert
B	MECHANICAL	
12	Pressure gauges	Wika/waree/Denver/Negele
13	Vent filter cartridge (Sludge tank)	Sartorius/Pall/ Millipore
14	Vent Filter housing (sludge tank)	Sartorius/ Pall/Millipore
15	Pressure regulator	Festo/SMC
16	Diaphragm valve(Manual)	Gemu / ITT
17	Sanitary PRV	Jordan / Forbes Marshall
18	Ball valve(Manual)	Modentic/Saunders/Alfa laval
19	Safety relief valve jacket	Herose/SS Spirax /Amtech valves
20	Bowl	Zook/Elfab/ Fike
21	Steam trap	Steriflow / Spirax.
22	Back pressure Control valve	GEMU, Saunders.
C	PNEUMATIC	
23	Diaphragm valve(Automatic)	Gemu /SED/Saunders/Burkert
24	Angle seat valve(Automatic)	Gemu /Saunders/Burkert