

HLL BIOTECH LIMITED, CHENNAI

INTEGRATED VACCINES COMPLEX, CHENGALPATTU

HLL Pharmaplan	User Requirement Specifications				 HLL BIOTECH LIMITED (A Subsidiary of HLL Lifescare Limited) (A Government of India Enterprise)
	Equipment/System	Ultra Filtration System			
	Identification #	-	Document No	URS/ UFS 02	
	Effective Date	18-04-2016	Revision#	01	

USER REQUIREMENT SPECIFICATIONS Ultra Filtration System

Block Code	Area	Identification #	Quantity
B1	Multi Bacterial Block (Hib)	B1-UFS-01,02,03,04	04 No.s
B1	Multi Bacterial Block (Hep-B)	B1-UFS- 05,06	02 No.s

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URS Annexure List

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URS Annexure List

URS Annex No.	Detail
1.	List of preferred makes of the components

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1.0 APPROVAL SIGNATURES

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 by this URS is an "Ultra Filtration System". This system will be used for the Concentration and Diafiltration of antigen (HiB or Hep-B) which will be collected from the retentate.

System should be movable equipped with antistatic lockable wheels and should also be provided with a skid to rest the equipment when in operation.

2.1 General Specifications

TABLE 1

Specification	HiB				Hep B	
	B1-UFS-01	B1-UFS-02	B1-UFS-03	B1-UFS-04	B1-UFS-05	B1-UFS-06
Purpose	Crude PRP Concentration, Diafiltration and Buffer Exchange	Purified PRP Concentration and Diafiltration	PRP concentration /TT Concentration / PRP ADH concentration	Final PRP-TT concentration and Buffer exchange	Concentration and Diafiltration	Concentration
Membrane	PES	PES	PES	PES	PES	PES
Surface Area (m ²)	1	5	0.5	2.5	3	0.5
Pump	In Built	In Built	In Built	In Built	In Built	In Built

2.2 Operating Conditions:

TABLE 2

Parameters	HiB				Hep B	
	B1-UFS-01	B1-UFS-02	B1-UFS-03	B1-UFS-04	B1-UFS-05	B1-UFS-06
Working Temperature range	2-8°C	2-8°C	2-8°C	2-8°C	2-8°C	2-8°C
Effective filtration area of the membrane (m ²)	0.5 to 5 m ²	0.5 to 5 m ²	0.1 to 0.5 m ²	0.5 to 5 m ²	0.5 to 5 m ²	0.1 to 0.5 m ²
Maximum number of cassettes to be hold	10	10	5	10	10	5
Flow rate (L/Min)	2	2	1	2	2	2

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Initial Volume (L)	500	7-25	2-8	20	800	150
Concentration Volume (L)	7-25	No concentration	0.2-2	4	15-30	0.5
No Of Diafiltration cycle	10-20	10-20	5	10	10-20	10-20
MWCO (KDa)	100	300	10	10	100	100

2.3 System Specifications

TABLE 3

S No.	Description	Purpose	MOC	Capacity/Size	Remarks
1.	System frame	To hold the process tank, cassette holder and Control panel	SS304	Vendor to specify	
2.	Cassette holder	To hold cassettes	SS316L with electro polishing and Ra < 0.5 µm	The holder should be designed to accommodate and operate with cassettes of other manufacturers with ½ inch sanitary flange.	
3.	Feed pump	To recirculate the feed and retentate	Sanitary type- SS316L	Vendor to specify the flow rate	
4.	Surface Finish	System should be Internally Electro polished and passivated. Ra ≤ 0.5 µm, according to ASME BPE guidelines			
		Externally Mechanically polished and passivated. Ra < 1.2 µm			
		Stainless steel piping interior Ra ≤ 0.5 µm, according to ASME BPE guidelines			

System should be provided with rotary lobe-feed pump made of SS316 L up to 6 bar pressure with variable frequency drive control and dry run protector.

All process piping, fittings and connectors within the system should be piped and connected via sanitary connections.

2.4 Vessel Specifications

TABLE 4

S. No.	Description	Purpose	MOC	Remarks
1.	Shell	Cylindrical	SS316L	
2.	Top closure	Flat Lid	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	

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8.	Addition port	For transfer of buffer	SS316L	
9.	Level sensor	Sense the fluid level	-	

2.5 Vessel design specification

TABLE 5

Parameters	B1-UFS-01	B1-UFS-02	B1-UFS-03	B1-UFS-04	B1-UFS-05	B1-UFS-06	Remarks
SS Vessel (L)	30L	30L	10L	20L	60L	10L	
MOC Vessel/Holder	SS 316L	SS 316L	SS 316L	SS 316L	SS 316L	SS 316L	
Vessel Minimum Working volume (L)	9L	9L	3L	6L	18L	3 L	
Vessel Maximum Working volume (L)	Vendor to specify	Vendor to specify	Vendor to specify	Vendor to specify	Vendor to specify	Vendor to specify	
Surface Finish	Internally Electro polished Ra ≤ 0.5 μm, according to ASME BPE guidelines						
	Externally Mechanically polished up to Ra <1.2μm matt finish for the jacket. Top and bottom dish - mirror finish.						
	Stainless steel piping interior Ra≤ 0.5μm, according to ASME BPE guidelines						

2.6 Design features

The Skid mounted Automatic Ultra Filtration system with integrated rotary lobe pump, cassette/s holder, process vessel and HMI with the following features;

Conditions	Remarks
<p>A. Temperature Control:</p> <p>The temperature during operation shall be controlled via the utilities (pure steam, Cooling water, Chilled water) in to the jacket. Temperature control during Concentration should be 2 °C - 40 °C (tolerance limit: ±2 °C) & during sterilization at 122°C (tolerance limit: ±1 °C). Pneumatically actuated valves for steam, Chilled water and cooling water should be provided.</p> <p>Provision for the supply of cooling water and chilled water into the system to be made to reduce the temperature of the feed inlet and for CIP.</p>	
<p>B. Vent Line/Exhaust Line:</p> <p>The feed Vessel should include a vent filter with SS housing. The hydrophobic vent filter shall be of sterilizing grade code 7 type. It shall be equipped with necessary drain arrangement. Integrity connector for in-situ integrity testing of filters shall be provided.</p>	

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<p>C. Pressure Control: Pressure of the vessel and CIP/SIP steps shall be controlled by Pressure Sensor and Transmitter for the Vessel</p>	
<p>D. Bottom valve with sampling Zero Dead Leg type valve directly welded to vessel bottom centrally, having a PTFE diaphragm with sampling diaphragm valve. It should be steam sterilizable type valve.</p>	
<p>E. Feed Line:</p> <ul style="list-style-type: none"> Rotary lobe pump Flow switch for pump protection Steam trap Pressure sensor transmitter – post pump 	
<p>F. Retentate Line: The following components/instruments to be provided,</p> <ul style="list-style-type: none"> Control valve - Pneumatically actuated diaphragm valve for ΔP and TMP control Pneumatically actuated diaphragm valve, steam trap Manual diaphragm valves for fluid flow path sample and drain. Diaphragm type pressure gauge, Temperature sensor, Conductivity sensor and pressure transmitter 	
<p>G. Permeate Line: The following components/instruments to be provided,</p> <ul style="list-style-type: none"> Mass Flow meter and transmitter[in l/min or l/hr and total volume] Manual diaphragm sampling valve Manual control of product flow in permeate must be possible Diaphragm type pressure gauge, Conductivity sensor ,Temperature sensor, pH sensor and pressure sensor with transmitter Pneumatically actuated diaphragm valve 	
<p>H. CIP (Clean in Place):</p> <ul style="list-style-type: none"> All Systems should able to perform Auto CIP by using inbuilt feed pump and spray ball. Manual CIP of the system must be possible 	
<p>I. SIP (Sterilization in Place): Steam will be injected through the pneumatically actuated diaphragm valve with spray ball and SIP has to be controlled with respect to the temperature and pressure of the system.</p> <ul style="list-style-type: none"> The complete system should be sterilized along with vent filter, addition port and process piping. Vent filter should be associated with manual diaphragm valve and steam trap. SIP of complete system should be able to perform with cassette holder and without cassette holder Steam traps to be provided wherever required. 	
<p>J. Additional requirements:</p> <ul style="list-style-type: none"> Calibration of measuring instruments according to international standards, full-loop calibration is required for GMP and quality relevant instruments. The Supplier has to provide calibration protocols and guidelines for writing SOPs for recalibration. Ultrafiltration system should be compatible with other manufacturers of UF cassettes. 	

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K. Nozzles Schedule :

I. Top Head Plate (design of shell to be provided by the vendor)

- GMP type Spray ball assembly with 360° spray (design of the same shall be submitted by the vendor)
- Port for Sterilizing grade hydrophobic inlet and vent filter – sterilization grade with SS housing and Pneumatic diaphragm valve with steam trap & connection to drain line
- Port for Rupture disc – NA connector with connection to the drain line
- Port for Sight glass with illumination lamp
- Port for Spare port- TC clamps with gasket
- Port for Pressure gauge & sensor

II. Upper wall side:

- “J” type nozzle Port for addition of feed/ buffer –TC end with necessary sterile valve assembly
- “J” type nozzle port for Retentate

III. Bottom Dish:

- Port for Product outlet

IV. Jacket:

- Bourdon pressure gauge
- Safety relief valve
- Pneumatic angle seat valve for chilled water inlet
- Pneumatic angle seat valve for chilled water outlet
- Pneumatic angle seat valve for steam inlet
- Pneumatic angle seat valve for condensate outlet with steam trap
- Pneumatic angle seat valve for jacket drain
- Valve for jacket vent

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I.	This Technical Specification is the basis for an inquiry to a vendor and therefore the basis for the vendor's proposal.
II.	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 an deviation a comment must be inserted or enclosed as a separate annexure by referring to the respective URS specification number.
III.	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.
IV.	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.
V.	The final version of this document including the vendor's comments will become basis of a potential purchase order or contract.
VI.	The Technical Specification serves to define a summary of all vendor's requirements concerning scope of delivery and services.
VII.	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.
VIII.	<p>Special Instruction</p> <ol style="list-style-type: none"> If no comments against any specification shall be considered as "NO" and 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.
IX.	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.
X.	The makes requested are standard international makes. In case of any deviation, vendor to seek clarification from HBL before submitting the offers.
XI.	Refer document Installation Requirement Specification and Specific Instructions with URS; NPI_120310_IRS_S1_01
XII.	Refer Tender document with URS; NPI_120310_EQP_S1_TD_17

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**
 - SI.NO 3 :FDA guidance for industry
 - SI.NO 5 CE Conformity, SI.NO 7 ANSI/NSF 49-2008,
 - SI.NO 8 ISO 14664, SI.NO 9 ISO 8362

File Name

NPI_120310_EQP_URS_UFS-02

Start Date

17-04-2015

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Specifications

Remarks

3.0 PROCESS DESCRIPTION

3.1 Input & Charging method

3.1.1 The feed will be fed into the feed tank of the filtration unit.

3.2 Brief Process Steps

3.2.1 The equipment will be used for concentration of antigen

The container containing purified component from previous process is fed to the feed vessel/PP Container.

- The flow-rate of the product into the system and the feed pump shall be controlled by a VFD.
- The required number of filtration modules shall be installed as per the required process in single or with multiple UF cassettes.
- Feed and retentate will be recirculated into the vessel until the equilibrium is achieved.
- The fluid from permeate line is discarded and the retentate fluid is collected in to the feed tank.
- Constant volume Diafiltration is performed, this process is continued until the required buffer exchange and concentration is achieved.
- Product Recovery- The concentrated product is recovered by passing the required volume of sterile buffer through the feed port and the product is collected through the retentate port in a sterile container placed in BSC.

3.3 Output & Discharging method

- After filtration the retentate shall be collected in the sterile container.

4.0 PRODUCTIVITY REQUIREMENT

4.1 Desired/ suggested capacity

- Feed Vessel: Minimum and maximum working volume of all equipment are mentioned in Table 5

4.2 Standard batch size

Not Applicable

4.3 Other Productivity Requirement

Not Applicable

5.0 CONTAINMENT

Ultrafiltration system should be validated as leak proof system to contain its integrity till the end of process

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6.0 GMP REQUIREMENTS

6.1 Process control

6.1.1 The Ultrafiltration unit should essentially have the necessary provisions for adjustment / control of the following critical process parameters:

6.1.2 Following parameters shall be controlled by the system

- Pressure (trans membrane pressure (TMP), differential pressure (ΔP))
- Retentate Flow
- Temperature of the product
- Flow of the feed
- NWP stabilization and measurement time
- Duration of the cycle
- The drain valve position and control.
- Parameters during CIP & SIP
- Variable frequency drive (Pump Speed)
- Level of the product
- Manual control of product flow in permeate and retentate line

6.1.3 Following conditions need only notification to operator for procedural control:

- Emergency stop activated.
- Power failure.
- Malfunction of sensors of temperature, pressure, flow and conductivity

6.2 Failure mode detection

6.2.1 Equipment shall be capable to detect the following failure, notify the operator with alarm and shutdown the process:

- High/Low feed temperature
- High/Low permeate conductivity
- High/Low permeate flow
- High/Low feed, Retentate and permeate pressure
- High/Low feed pump speed

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- Digital input alarms
- Step duration alarms

6.3 In -Process control

- 6.3.1 TMP, ΔP
- 6.3.2 Pressure monitoring at feed, retentate and permeate line.
- 6.3.3 Temperature measurement and control of the product.
- 6.3.4 Measurement and control of fluid level in the tank.
- 6.3.5 Flow measurement on the permeate line

6.4 Level of instrumentation

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

Parameters	Purpose	Type of Instrumentation	Remarks
Temperature	Monitor ,Indicate, Record and control the temperature of the product in the vessel	RTD sensor and temperature transmitter	
Pressure	Monitor, Indicate, Record and control the pressure(TMP& ΔP)	Pressure transmitter	
pH	To monitor, indicate and record the pH	pH Sensor	
Flow rate	Monitor the rate of permeate flow	Mass Flow meter with transmitter	
Conductivity	To monitor, indicate and record the conductivity during process	Conductivity sensor	
Level of the volume	To maintain the required volume	Level sensor with accuracy of +/-1% and the product foam/froth should not interfere with the level measurements	

6.5 Batch data display and record printing

Vendor have to provide the PLC based system and Batch data to be printed for all process values, all parameters including the volumes of permeate, retentate but not limited to these

6.5.1 HMI screen size shall be minimum of 10"

6.5.2 HMI should continuously display all parameters including volumes of retentate and permeate

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6.5.3 Human machine interface must be used to enter the process details, which should appear in the Batch data, print out.	
6.5.4 All critical alarms, critical parameters & interlocks	
6.5.5 All Recipes/ sequences (process, CIP, transfer etc.)	
6.5.6 P&ID of the UF system along with instrumentation details to be shown in the HMI	
6.5.7 Login details	
6.6 GMP requirements (Others)	
6.6.1 Equipment design must be designed for aseptic processing.	
6.6.2 All process relevant wiring has to be executed in fail safe manner.	
6.7 Specific requirements	
6.7.1 In general the equipment has to be designed in a way to get easy and quick access to all necessary maintenance points e. g. Motors, etc.	
6.7.2 All pipeline joints should be connected with sanitary type triclover clamps and flanges	
6.7.3 The configuration of the system should be that, the operator would be able to create any particular cycle like the regular process, sanitation cycle, CIP cycle, etc. The parameters of the cycle should be choose-able by the operator at any given point of time in a predetermined path	
6.7.4 High pressure/Low pressure cut off installed on the feed line after the pump.	
6.7.5 System should be programmable to process product feed inlet and concentration simultaneously.	
6.7.6 Auto Torque hardware for uniform cassette sealing should be provided	
6.7.7 All diaphragm valves must be of sanitary type	
6.7.8 All pressure gauge's should be sanitary type and diaphragm seal type rated from 0 to 6 bar(g) connected with a TC end	
6.7.9 Manual override provision should be provided, in case the Operator chooses to adjust any of the parameters manually for any reason	
6.7.10 Nozzle shell shall be seamless.	
6.7.11 Nozzle connection to be Triclover.	
6.7.12 Nozzles, adaptors, instrument shall comply to ASME BPE compliant.	
6.7.13 Total motor drive assembly with SS304 cover.	

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Specifications

Remarks

6.7.14 Lamp for illumination should be provided.

6.7.15 Pump specification: Sterile Sanitary design

Type: Rotary Lobe type

CIP able : Yes

SIP able: Yes

Surface finish: Ra <0.5 µm [EP]

MOC: SS316L

Pump rate: 2m³/hr @ 4 bar(g)

Speed: 50-600 RPM

Seal: Single mechanical seal[EP]

Elastomers: EPDM – FDA/ USP

6.7.16 SS Piping design should be ASME BPE 2012 compliant

6.7.17 All controls should be ergonomically located for operator convenience

6.7.18 The ultrafiltration system should have dry-run protection before the feed pump.

6.7.19 Cassette holder should be placed in a position that it should completely drainable

6.7.20 Design Considerations:

6.7.20.1 Vessel design Pressure: (vendor to specify)

6.7.20.2 Design pressure for safety release valve: (vendor to specify)

6.7.20.3 Jacket design pressure: (vendor to specify)

6.7.20.4 Vessel design Temperature: (vendor to specify)

6.7.20.5 Vessel working Temperature: 0°C to 134°C

6.7.20.6 Vessel working Pressure: -1 to 3 bar(g)

6.7.21 Performance Requirements: Vendor to demonstrate the following during FAT/SAT and not limited to below mentioned requirements:-

6.7.21.1 Sterility of the complete system during SAT

6.7.21.2 Flux- to be demonstrated with dummy cassettes during SAT

6.7.21.3 CIP- effectiveness to be demonstrated and spray ball coverage during FAT

6.7.21.4 Temperature Control along with the level accuracy to be demonstrated.

6.7.21.5 Containment of the whole system

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Specifications	Remarks
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7.0 CONSTRAINTS

7.1 Equipment location and available space

The equipment will be installed in Multi-Bacterial Block in IVC Chengalpattu.

Equipment Location:

Location	B1-UFS-01	B1-UFS-02	B1-UFS-03	B1-UFS-04	B1-UFS-05	B1-UFS-06
Floor	Ground Floor				Ground Floor	
Block	HiB	HiB	HiB	HiB	Hep B	Hep B
Location	Fermentation and Harvest	Polysaccharide Purification room	Conjugation Purification room	Conjugation Purification room	Diafiltration room	Chromatography room
Room Area	130m ²	58m ²	43 m ²	43m ²	39 m ²	50 m ²
False sealing height	3.0 m	3.0 m	3.0 m	3.0 m	3.0 m	3.0 m
Room Temperature	22±2 °C					
Relative Humidity	Not more than 55 %					

7.2 Available Utility

- Plant steam - 130 °C - 150°C at 3 – 3.5 bar (g) -----(Report requirement)
- Pure steam - 121 °C - 130 °C at 2.4 bar (g) -----(Report requirement)
- WFI (Hot loop) - 80-85°C at 2 bar (g) -----(Report requirement)
- Purified Water- 28 - 30°C at 2.5 bar (g) -----(Report requirement)
- Cooling water- 28°C -30°C at 3 bar (g) -----(Report requirement)
- Chilled water- 8°C to 12°C at 3 bar (g) -----(Report requirement)
- Electricity - Vendor to specify----- (Report requirement)
- Compressed air- 6.0– 8.0 bar (g) -----(Report requirement)

Note: Utility consumption to be specified by the vendor, in case if there is a deviation in the values mentioned above.

HLL BIOTECH LIMITED, CHENNAI

INTEGRATED VACCINES COMPLEX, CHENGALPATTU

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User Requirement Specifications

Equipment/System	Ultra Filtration System		
Identification #	-	Document No	URS/ UFS 02
Effective Date	18-04-2016	Revision#	01



8.0 ABBREVIATION

Abbreviation	Definition
ΔP	Differential Pressure
°C	Degree Centigrade
db	Decibel
HMI	Human Machine Interface
HBL	HLL Biotech Ltd
MOC	Material Of Construction
MWCO	Molecular Weight Cut Off
NNE	Novo Nordisk Engineering
NPI	NNE Phamaplan India Ltd
P&ID	Piping and Instrumentation Diagram
PRP	Polyribosylribitol Phosphate
NMT	Not more than
NWP	Nominal Water Permeability
PLC	Programmable Logic Controller
RPM	Revolutions Per Minute
SS	Stainless steel
TMP	Trans membrane Pressure
UFS	Ultra Filtration System

9.0 REVISION INDEX

Revision	Date	Reason for revision
00	25-06-2015	First Draft for Client's Review
01	16-03-2016	Updated as per comments given by HBL dated 03-02-2016

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User Requirement Specifications

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Annexure 1

List of Preferred Make of components

S.NO	DESCRIPTION	MAKE
A	INSTRUMENTATION	
1	PLC	Allen Bradley/ Siemens
2	Operator Interface/HMI	Allen Bradley/ Siemens
3	Temperature transmitter	Radix/ Yokogawa/Emerson
4	Temperature sensor	NEGELE/E&H/Radix
5	pH sensor	METTLER TOLEDO/E&H
6	Conductivity sensor	METTLER TOLEDO/E&H
7	Pressure transmitter	Wika /Dwyer/labom
8	Air pressure regulator	FESTO/Janatics
9	Level sensor	E&H / Mettler Toledo
10	Mass flow meter	E&H/Rosemount
B	MECHANICAL	
11	Steam trap	Spirax Marshall/STERIFLOW
12	Rupture Disc	Fike
13	Pressure gauges	WIKA/Denver/Negele
14	Vent filter cartridge	Sartorius/PALL/Millipore
15	Filter housing	Sartorius/ PALL/Millipore
16	Spray ball	HAKE/LECHLER
17	Diaphragm valve(Manual)	GEMU/Burkert/Saunders
18	Ball valve(Manual)	Modentic/Alfa laval
19	Flush bottom valve	Novaseptic/GEMU
20	Flow switch	E&H/ Wika/Emerson
C	PNEUMATIC	
21	Diaphragm valve(Automatic)	GEMU /Burkert/Saunders
22	Angle Seat valve	GEMU/Burkert/Saunders
D	ELECTRICAL	
23	Lamp	PAPENMEIER