

HLL LIFECARE LIMITED, CHENNAI

Revival of DPT Vaccine Manufacturing Facility, PII, Coonoor

nne pharmaplan®

User Requirement Specifications

Equipment/System

Media Preparation Tank

Identification

D-MPT 01
P-MPT 01
T-MPT 01

Document

URS/MPT 01

Effective Date

2014-06-24

Revision

09



User Requirement Specifications Media Preparation Tank

Process Code	Area	Equipment code	Qty(Nos)	Capacity (W.V)
D	Diphtheria	D-MPT 01	1	400 L
P	Pertussis	P-MPT 01	1	400 L
T	Tetanus	T-MPT 01	1	400 L

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URS Annexure List

URS Annex No.	Detail
1	A) Layout showing location of the Media Preparation Tank in the Diphtheria block
	B) Layout showing location of the Media Preparation Tank in the Pertussis block
	C) Layout showing location of the Media Preparation Tank in the Tetanus block
2	P&ID as separate URS annexure
3	List of Preferred MAKE of components

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1.0 APPROVAL SIGNATURE

This document is prepared by the Process, Validation and GMP Compliance team of "NNE Pharmaplan India" for the project "Revival of DPT Vaccines manufacturing Facility" (**Project number:-110831**) of Pasteur Institute of India, Coonoor under the authority of their Project Manager. Hence, this document before being effective shall be approved by the QA team of Pasteur Institute of India, 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 TANK" which will be located in the Media preparation room of each block. The Equipment shall be fixed type and should have legs fitted on flange.

The tank shall be suitable to take water for injection (WFI) of 85°C for CIP and plant steam @121°C for SIP and other pre-weighed materials.

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

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

S. No.	Description	Purpose	MOC
1.	Shell	Cylindrical, For media preparation	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	To cover the jacket and to avoid the heat dissipation onto outer surface of the vessel	SS304
7.	GMP Mixer (Bottom driven)	Magnetic mixer, To mix up the media	SS316L
8.	Height/Diameter Ratio	1.2: 1	-

2.0.2. Vessel Specifications

SI.NO	Area	Geometric volume	Maximum working volume	Quantity
1.	Diphtheria	500 L	400 L	1 no
2.	Pertussis	500 L	400 L	1 no
3.	Tetanus	500 L	400 L	1 no

2.0.3. General Vessel Specifications

Min mixing volume	<i>Vendor to specify</i>
Surface Finish	Internally Electro polished up to Ra ≤0.8 µm (mirror finish) (For valves- Mechanically polished up to Ra ≤0.8 µm)
	Internal finish of the interconnecting piping: Ra < 0.8 µm
	Externally Mechanically polished up to Ra ≤1.2 µm (matt finish)

2.0.4. The general design must be hygienic, with no dead legs and no air pockets. This vessel must be a floor-standing type with mounting legs on pad plates. Following are the general requirements for a vessel.

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Description	Vendor Remarks
<p>a. Addition of powder material: All powder raw materials are added into the vessel through a hand hole</p>	
<p>b. Spray ball: The port with fixed type spray ball covering the entire area with 360° shall be provided on the top dish for the addition of WFI.</p>	
<p>c. Inlet /Exhaust line: The inlet /exhaust line shall be provided with</p> <ul style="list-style-type: none"> A sterile filter (0.2/0.22 µm) with SS housing for both inlet and exhaust. Compressed air inlet for vent filter Air PRV (with filter) 	
<p>d. Rupture disc: It should be mounted on top of the media preparation vessel to relieve excess pressure during operations.</p>	
<p>e. Temperature Control: The temperature during media preparation shall be controlled via circulation of utilities (plant steam, Cooling water, Chilled water, etc) in the jacket Temperature control during media preparation (tolerance limit: ±2.0 °C) & during sterilization(ESIP) (tolerance limit: 122 °C ± 1 °C)</p> <ul style="list-style-type: none"> Safety relief valve Bourdon type pressure gauge for jacket utility Pneumatically operated valves for steam and cooling water/ chilled water 	
<p>f. Pressure: Pressure of the media preparation vessel during process and SIP shall be monitored by the following :</p> <ul style="list-style-type: none"> Diaphragm pressure gauge 	
<p>g. Mixer: The vessel shall be designed with bottom mounted GMP mixer as per process requirement.</p> <ul style="list-style-type: none"> Variable speed 40-500 rpm motor with magnetic drive. Open end of the motor shaft have a flange fitted with a circular magnet. Bottom mounted, magnetically coupled. Magnetic mixer, suitable for liquids up to pH 1-14, Temp 134°C. On/ off switch shall be provided 	
<p>h. Sampling valve: It should be flush welded zero dead lag valve without steaming provision.</p>	
<p>i. pH: The vessel shall be provided with a sterilizable pH probe with display</p>	
<p>j. Tank bottom valve: It is Zero Dead Leg type valve. It shall be directly welded to vessel bottom centrally, having a PTFE diaphragm.</p>	
<p>k. CIP (Cleaning – In – Place): The vessel shall be cleaned by using a mobile CIP trolley.</p> <ul style="list-style-type: none"> SS 316L spray ball shall be provided for cleaning of the interior of the vessel and all the nozzles on the top dish and nozzles, ports on the vessel. 	

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I. SIP (Sterilization – In – Place):

For T-MPT 01- The Media preparation vessel shall be designed for SIP through SIP trolley

For D-MPT 01 and P-MPT 01- The media preparation vessel should be designed for inbuilt SIP

The following principles will be applied for SIP of the system:

- The exhaust air filters to be sterilized along with the vessel.
- The sensors should be reusable and sterilizable type.

m. Controller: - Relay based Controller shall be provided

n. SS Ladder: SS 304 ladder to access the top of the vessel

- It can be either integrated with the vessel or separate (Vendor to Specify)
- Supply of SS ladder in the scope of vendor
- Total Quantity- 4 nos (1 for each block)

2.0.5. Nozzle schedule:

1. Top dish

The media preparation vessel top dish will have:

- Light/ Sight Glass-1 no
- Hand hole - 1 no
- Port for pressure gauge-1 no
- Rupture disc-1 no
- Spray ball port - 1 no
- Spare port - 1 no
- Inlet/Exhaust port with sterile vent filter-1 no

2. Upper wall side

- Vertical view glass(with level marking)-1 no
- Jacket outlet-1 no

3. Lower wall side

- Port for temperature sensor/ transmitter-1 no
- Jacket inlet-1 no
- Port for Sampling valve-1 no
- Port for pH probe with display

4. Bottom dish

- Port for Tank bottom valve- 1 no
- Port for magnetic mixer-1 no

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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 5 CE Conformity,
- SI.NO 7 ANSI/NSF 49-2008, ISO 14664, ISO 8362
- SI.NO 8 ISO 14664
- SI.NO 9 ISO 8362
- Sec 5.4.1

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 an 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 <ol style="list-style-type: none"> 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 HLL before submitting the quotes.
10.	The makes requested are standard international makes. In case of any deviation, vendor to seek clarification from HLL before submitting the offers.
11.	Refer document "Installation Requirement Specifications and Specific Instructions" with URS NPI/110831/EQP/IRS 01
12.	Refer tender document NPI/110831/EQP/TED/07

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Specifications	Remarks
3.0 PROCESS DESCRIPTION	
3.1 Input & Charging method	
3.1.1 WFI is added into the vessel	
3.1.2 The powder materials for the media preparation shall be added into the vessel.	
3.2 Brief Process Steps	
A) The tanks have to be designed to prepare media solution in sufficient quantity and quality.	
3.2.1 After dissolving the ingredients, the solution is cooled down by using chilled water circulation in the tank jacket.	
3.2.2 Samples can be drawn through sampling valve	
3.3 Output & Discharging method	
3.3.1 The media is transferred through the bottom valve for further processing.	
4.0 PRODUCTIVITY REQUIREMENT	
4.1 Desired/ suggested capacity	
See Table 2.0.2	
4.2 Standard batch size	
See Table 2.0.2	
4.3 Change Over Time	
Not Applicable	
4.4 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 media preparation	
6.1.2 Speed of the Mixer during media preparation	

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Specifications	Remarks
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6.1.3 CIP/SIP process parameters	
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6.2 Failure mode detection	
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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):

6.2.1 Mixing speed is out of set range	
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6.2.2 Abrupt change in temperature in a particular time	
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6.3 In – Process control	
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NA	
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6.4 Level of instrumentation	
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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 of the product	To monitor, indicate and control the product temperature	Temperature sensor/Transmitter
Pressure	To monitor the pressure of the vessel during process/SIP	Diaphragm pressure gauge
Speed	To control magnetic mixer speed	Variable frequency drive with indicator
pH	To monitor the pH of the solution	pH probe with display

6.5 Batch data display and record printing	
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Batch Data to be printed by using real time printer	
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6.6 GMP requirements (Others)	
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6.6.1 The vent filter housings in the vessel shall be provided with sterilizing grade hydrophobic filter.	
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6.6.2 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.	
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6.6.3 All nozzles shall be flushed to the wall on closure.	
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6.6.4 Steam traps shall be provided where ever required at the system.	
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6.6.5 All valves in the sterile part of the vessel should be of sanitary Diaphragm valves	
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Specifications	Remarks
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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 shall be seamless.

6.7.2 Nozzles, adaptors, instrument shall comply with ASME BPE compliant.

6.7.3 Total motor drive assembly with SS304 cover

6.7.4 Vendor shall provide the FRL's (Filters, regulators, lubricators)

6.7.5 Design Parameters:

- 6.7.5.1. Shell working Pressure- FV to 2.5 bar(g)
- 6.7.5.2. Shell working Temperature- 20-134°C
- 6.7.5.3. Shell sterilization Temperature- 121°C
- 6.7.5.4. Shell design Pressure- Vendor to specify
- 6.7.5.5. Shell design Temperature- Vendor to specify
- 6.7.5.6. Jacket working Pressure- FV to 4 bar(g)
- 6.7.5.7. Jacket working Temperature- 135°C
- 6.7.5.8. Jacket design Pressure- Vendor to specify
- 6.7.5.9. Jacket design temperature-Vendor to specify

6.7.6 From user point to the equipment, food grade SIPable flexible hose (2 m, 2 Nos) with TC end to be provided.

6.7.7 From the equipment to the drain, food grade SIPable flexible hose with TC end of minimum 3 m length to be provided- 2 nos

6.7.8 Non sterile flexible hoses (2 m, 2 Nos) for black utility to be part of equipment supply

6.7.9 The equipment shall be easily accessible for cleaning the product non-contact part at maintenance side of the equipment.

6.7.10 Vessel shall be on 3 legs with pad plates MOC: SS 304

6.7.11 Performance criteria during FAT/SAT:

- a. Thermal Mapping
- b. Spray ball coverage test during FAT
- c. All FAT/SAT IQ, OQ as per IRS

7.0 CONSTRAINTS

7.1 Equipment location and available space

a) This equipment will be installed in the **Diphtheria block** of the Revival of DPT Vaccine manufacturing facility, PII, Coonoor as follows.

Floor: Diphtheria Ground floor; Room No: B1G069

Room size: 4.9 m x 3.61 m, 2.0 m x 2.9 m

False ceiling height: 4 m

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Specifications	Remarks
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<p>Physical condition of the room:</p> <ol style="list-style-type: none"> 1. Room will be NON-BSL 2 2. Class: EU Class "C" 3. Differential Pressure: 25 Pa 4. Temperature maintained: 22±2 °C 5. Relative Humidity: < 55% RH <p>b) This equipment will be installed in the Pertussis block of the Revival of DPT vaccine manufacturing facility at PII, Coonoor as follows</p> <p>Floor: <u>Ground floor-Pertussis bulk; Room No: B1G028</u> Room dimension : <u>4.7 m x 3.61 m , 1.8 m x 2.9 m</u> False ceiling height: <u>4 m</u></p> <p>Physical condition of the room:</p> <ol style="list-style-type: none"> 1. Room will be NON-BSL 2 2. Class: EU Class "C" 3. Differential Pressure: 25 Pa 4. Temperature maintained: 22±2 °C 5. Relative Humidity: <55% RH <p>c) This equipment will be installed in the Tetanus block of the Revival of DPT vaccine manufacturing facility at PII, Coonoor as follows</p> <p>Floor: <u>Ground floor-Tetanus block ; Room No: B2G033</u> Room dimension : <u>5.3 m x 2.98 m,</u> False ceiling height: <u>4 m</u></p> <p>Physical condition of the room:</p> <ol style="list-style-type: none"> 1. Room will be NON-BSL 2 2. Class: EU Class "C" 3. Differential Pressure: 15 Pa 4. Temperature maintained: 22±2 °C Relative Humidity: <55% RH <p>The equipment location is indicated in the layout enclosed as URS Annex 1.</p>	
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7.2 Available Utility

7.2.1 Cooling Water @3 bar _____ (Report requirement)	
7.2.2 Compressed Air @ 8 bar _____ (Report requirement)	

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Specifications	Remarks
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
PII	Pasteur Institute Of India
MPT	Media Preparation tank
CIP	Clean In Place
SIP	Sterilization In Place
cGMP	current Good Manufacturing Practices
HLL	HLL Life care Limited
NPI	NNE Pharmaplan India Ltd

REVISION INDEX

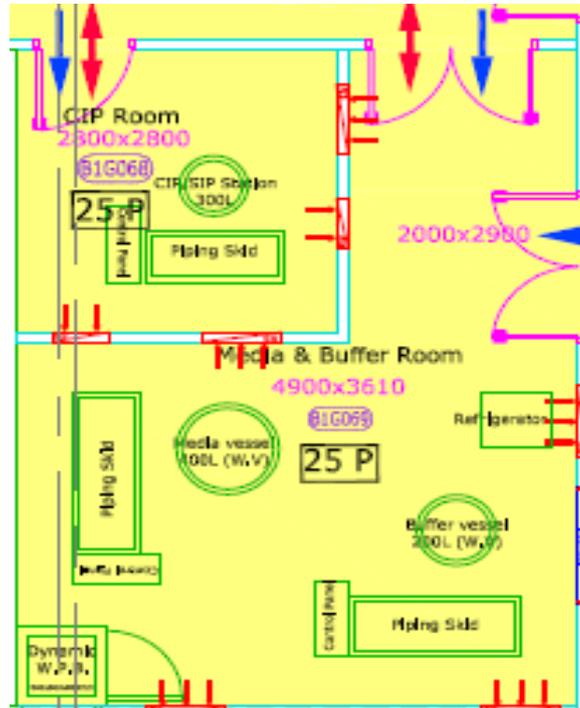
Revision	Date	Reason for Revision
00	2012-06-01	First Draft for Client's Review
01	2012-12-10	Format changed as per HLL requirement
02	2013-06-27	AS per the discussion with HLL/PIIC on 2013-05-28 and 2013-05-29
03	2013-09-23	As per the discussion with HLL on Video Con on 2013-09-11 ,2013-09-12 and comments received on 2013-09-20
04	2013-10-28	Revised as per comments received on URS by email on 2013-10-23
05	2013-11-20	Revised as per comments received on URS by email on 2013-11-12 and Telecon on 2013-11-15
06	2014-01-02	Revised as per the discussion with HLL on Video Con on 2014-01-02
07	2014-01-20	Revised as per comments received on URS by email on 2014-01-20
08	2014-01-28	URS's Consolidated as per telephonic confirmation between NNE and HLL
09	2014-06-24	Revised as per the discussion with HLL on 2014-06-19 and 2014-06-20

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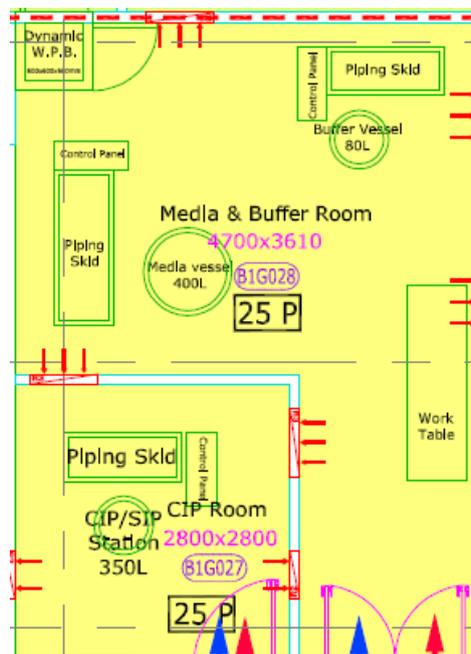
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URS Annexure 1: LAYOUT A; Room No: B1G069



URS Annexure 1: LAYOUT B; Room No: B1G028

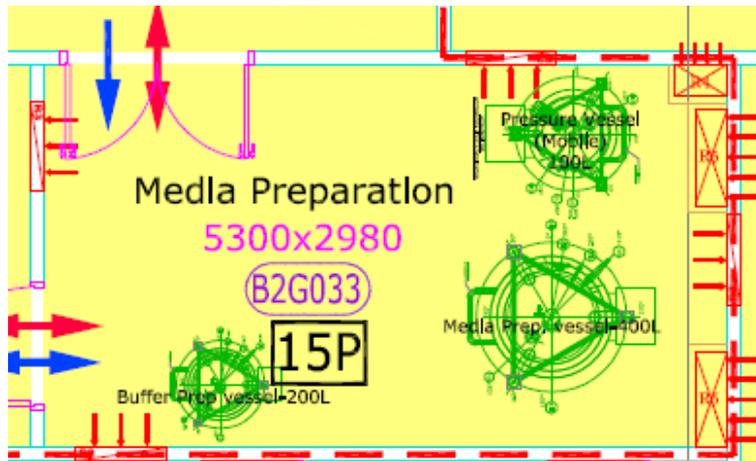


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URS Annexure 1: LAYOUT; Room No: B2G033



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URS Annexure 3: List of preferred make of components

SI.NO	COMPONENTS	MAKE
	INSTRUMENTATION	
1.	Temperature Sensor/transmitter	Radix/ NEGELE
2.	Steam trap	STERIFLOW/ITT/Spirax
	MECHANICAL	
3.	Pressure gauges	WIKA/Denver/Negele
4.	Air filter cartridge	Sartorius/PALL / Millipore
5.	Spray ball	HAKE
6.	Diaphragm valve(Manual)	GEMU/Burkert/ITT/SED/saunders
7.	Ball valve(Manual)	Modentic/Saunders/Alfa laval
8.	Sampling valve	GEMU/Burkert/ITT/SED/saunders
9.	Tank bottom valve	GEMU/Burkert/ITT/SED/saunders
10.	Rupture disc	Zook/Elfab/fike
11.	Air-PRV	Festo/SMC
12.	Magnetic mixer	Alfa Laval/Novaseptic/Roplan
13.	Flexible hose	AB Synthetic/ AMI Polymer/Venair
	PNEUMATIC	
14.	Diaphragm valve(Automatic)	GEMU/Burkert/ITT/SED/saunders
15.	Angle seat valve(Automatic)	GEMU/Burkert/ITT/SED/saunders
	ELECTRICAL	
16.	Lamp	PAPENMEIER