User Requirement Specifications
Pressure vessel

Process Code	Area	Equipment code	Qty(Nos)	Capacity (W.V)
D	Diphtheria	D-PRV 01	1	500L
D	Diphtheria	D-PRV 03	1	100L
T	Tetanus	T-PRV 01	1	100L
T	Tetanus	T-PRV 02	1	500L
T	Tetanus	T-PRV 03	1	100L

URS Annexure List

URS Annex No.	Detail
1	A) Layout showing location of the Pressure vessel in the Diphtheria block
	B) Layout showing location of the Pressure vessel in the Tetanus block
2	P&ID as separate annexure
3	List of preferred MAKE of components

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	Identification	-	**Document**	URS/PRV 01
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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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Project Authority **Pasteur Institute of India**		

2.0 EQUIPMENT DESCRIPTION

The Pressure vessel shall be cylindrical having Torispherical top. The vessel shall be mounted on Stainless steel pipe legs and castor wheels. The mobile Pressure vessel shall be CIP/SIP able using mobile CIP trolley and SIP trolley.

The Equipment shall be made SS316L for product contact parts including vessel, inlet and out let nozzles, valves, piping interconnection.

Design, function and control of the unit have to be cGMP compliant.

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

S. No.	Description	Purpose	MOC
1.	Shell	Cylindrical to hold the product	SS316L
2.	Top closure	Torispherical dish	SS316L
3.	Bottom closure	Torispherical dish	SS316L
4.	Insulation	To avoid heat loss	Mineral wool
5.	Cladding	To cover the insulation and to avoid the heat dissipation onto outer surface of the vessel	SS304
6.	Height/Diameter Ratio	1.2:1 (vendor to specify ,if there is a change)	-

2.0.2 Design Specifications

S. No.	Area	Geometric volume	Maximum working volume	Quantity
1.	Diphtheria (D-PRV 01)	Vendor to specify	500L	1
2.	Diphtheria (D-PRV 02)	Vendor to specify	100L	1
3.	Tetanus (T-PRV 01)	Vendor to specify	100L	1
4.	Tetanus (T-PRV 02)	Vendor to specify	500L	1
5.	Tetanus (T-PRV 03)	Vendor to specify	100L	1

2.0.3 Vessel Specifications

SI.NO	Description	Specification
1.	Surface Finish	Internally Electro polished up to Ra ≤0.8microns(mirror finish) (All Valves Mechanically polished upto Ra ≤0.8microns)
		Internal finish of the interconnecting piping: Ra < 0.8 µm
		Externally Mechanically polished up to Ra≤1.2 microns(matte finish)

2.0.4 Vessels Application

S No	Description	Remarks
1	**D-PRV 01:** The Pressure vessel in the Diphtheria block shall be used to collect and transfer the media from media preparation vessel. The tank should be provided with sterile valve assembly for the addition of filtrate from the microfiltration system .The tank shall be provided with bottom mounted mixer.	
2	**D-PRV 02:** The Pressure vessel in the Diphtheria block shall be used to collect and transfer the saline to filtration system	
3	**T-PRV 01:** This Pressure vessel shall be used as a storage vessel	
4	**T-PRV 02** This Pressure vessel shall be used post micro filtration step for toxin collection and transfer. The tank should be provided with sterile valve assembly for the addition of filtrate from the microfiltration system. The tank shall be provided with bottom mounted mixer	
5	**T-PRV 03:** This Pressure vessel shall be used as a storage vessel	

2.0.5 General vessel specifications:

a) **Port for addition:** Port shall be provided for the intake of the process liquids

b) **Spray ball:** The port with fixed type Spray ball covering the entire area with 360^0 shall be provided on the top dish for the addition of WFI and pure steam.

c) **Pressure :** Pressure of the vessel during process and SIP shall be monitored by the following:

- Diaphragm Pressure Gauge
- FRL's
- Manual diaphragm valve in the exhaust line

d) **Mixer:** The vessel shall be designed with bottom mounted GMP mixer as per process requirement.

- 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

[**Only for D-PRV 01, T-PRV 01 & T-PRV 02**]

e) **Exhaust Line/Air inlet filter:** Pressure vessel vent line includes

- A single sterile vent filter (0.2/0.22 micron) with SS housing & a manual diaphragm valve.
- Compressed air inlet/vent filter
- Air PRV (with filter)

f) **A rupture disc:** It should be mounted on top of the pressure vessel to relieve excess pressure during operations.

g) **Tank Bottom Valve:** It is also Zero Dead Leg type valve [2-WAY], having a PTFE diaphragm.

h) **CIP (Cleaning– In – Place)**: The vessel should have a provision CIP using mobile CIP Trolley.

i) **SIP (Sterilization – In – Place)**: The Pressure vessel shall be designed for SIP using mobile SIP Trolley.

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

- The exhaust air filters to be sterilized along with the vessel.

2.0.6 Nozzle schedule

1. Top dish:

- Light/sight glass-1 No
- Spray ball-1 No
- Rupture disc - 1 No
- Spare port-1 No
- Inlet/Exhaust port with sterile filter(0.2/0.22µm PTFE)-1 no

2. Upper wall side:

- Port for addition-1 No
- Vertical view glass (with level marking)-1 No

3. Bottom dish:

- Tank bottom valve port – 1 No

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

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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 costs 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 vendors' 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 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/IRS01
12.	Refer tender document NPI/110831/EQP/TED/07

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User Requirement Specifications

Equipment/System	Pressure Vessel		
Identification	-	**Document**	URS/PRV 01
Effective Date	2014-10-17	**Revision**	06

Specifications	Remarks
3.0 PROCESS DESCRIPTION	
3.1 Input & Charging method	
3.1.1 The product shall be charged into the pressure vessel	
3.2 Brief Process Steps	
3.2.1 The product shall be transferred next process step.	
3.3 Output & Discharging method	
3.3.1 The product is transferred through the bottom valve of the pressure vessel	
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 monitor the following process parameters.	
6.1.1 Pressure of the vessel during process and SIP	
6.2 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):	
NA	
6.3 In – Process control	
6.4 Level of instrumentation	
Sufficient and suitable instrumentation for the process, safety and productivity control as indicated in the following table:	

Specifications	Remarks

Parameter	Purpose	Type of control and Instrumentation
Pressure	To monitor the pressure of the vessel during process	Diaphragm Pressure Gauge
Mixer	To control the RPM	VFD

6.5 Batch data display and record printing	
Not Applicable	
6.6 GMP requirements (Others)	
6.6.1 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.	
6.6.2 All nozzles shall be flushed to the wall on closure.	
6.6.3 Nozzle length shall be minimized (less than 2D) to avoid cold spot during steam sterilization.	
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 to ASME BPE compliant	
6.7.3. Mixer to be provided and Total motor drive assembly with SS304 cover	
6.7.4. The equipment shall be easily accessible for cleaning the non-product contact part at maintenance side of the equipment	
6.7.5. Vessel shall be on 3 legs MOC: SS 304 with double-roll lockable castor wheels for easy transportation.	
6.7.6. From user point to the equipment, food grade SIPable flexible hose (2m, 2Nos) 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. **Design Parameters:**	
6.7.8.1 Shell operating Pressure- FV to 2.0 bar(g) 6.7.8.2 Shell operating Temperature- 20-134°C 6.7.8.3 Shell sterilization Temperature- 121°C 6.7.8.4 Shell design Pressure- Vendor to specify 6.7.8.5 Shell design Temperature- Vendor to specify	

7.0 CONSTRAINTS

7.1 Equipment location and available space

a) This equipment shall be installed in the Diphtheria block of **Revival of DPT vaccine manufacturing facility** at PII, Coonoor as follows:

For D-PRV 01 and D-PRV 02

Floor: Ground floor

Room size: 5800(L) X 6150(W) mm, 1600(L) X 4610(W) mm,4300(L) x 4610(W) mm

False ceiling height: 4 m

Physical condition of the Fermentation room (B1G048) :

1. Room will be BSL 2
2. **Class:** EU Class "C"
3. **Differential Pressure:** 5 Pa
4. **Temperature maintained:** 22±2 ºC
5. **Relative Humidity:** <55% RH

For D-PRV 03

Floor: Ground floor

Room size: 4800 x 6510 mm, 1600 x 2710 mm (W x L)

False ceiling height:3 m

Physical condition of the Toxoid Concentration(B1G060)**:**

1. **Class:** EU Class "C"
2. **Differential Pressure: 3**5 Pa
3. **Temperature maintained:** 22±2 ºC
4. **Relative Humidity:** <55% RH

b) This equipment shall be installed in the **Tetanus block** of Revival of DPT vaccine manufacturing facility at PII, Coonoor as follows:

For T-PRV 01

Floor: Ground floor

Room size: 5300 x 2980 mm (W x L)

False ceiling height: 4000 mm

Physical condition of the Media Preparation Room (B2G033) :

1. Room will be Non BSL
2. **Class:** EU Class "C"
3. **Differential Pressure:** 15 Pa
4. **Temperature maintained:** 22±2 ºC
5. **Relative Humidity:** <55% RH

For T-PRV 02

This equipment shall be installed in the Tetanus block of **Revival of DPT vaccine manufacturing facility** at PII, Coonoor as follows:

Floor: Ground floor

Room size: 9500 x 6300 mm, 7400 x 3800 mm, 2000 x 3080 mm (W x L)

False ceiling height: 4 m

Physical condition of the Fermentation room (B2G027) :

1. Room will be BSL 2
2. **Class:** EU Class "C"
3. **Differential Pressure:** 15 Pa
4. **Temperature maintained:** 22±2 ºC
5. **Relative Humidity:** <55% RH

For T-PRV 03

This equipment shall be installed in the Tetanus block of **Revival of DPT vaccine manufacturing facility** at PII, Coonoor as follows:

Floor: Ground floor

Room size: 9500 x 6300 mm, 7400 x 3800 mm, 2000 x 3080 mm (W x L)

False ceiling height: 4 m

Physical condition of the Concentration +precipitation + Purification room (B2G027) :

1. Room will be Non BSL
2. **Class:** EU Class "C"
3. **Temperature maintained:** 22±2 ºC
4. **Relative Humidity:** <55% RH

The equipment location is indicated in the relevant block of the layout enclosed as **Annex 1.**

7.2 Avaialble Utility

7.2.1. Pure steam @2.4 bar (g) and 121^{0}C-130^{0}C----------(Report requirement)	
7.2.2. WFI (Hot loop) @2 bar(g) and 800-850C ----------(Report requirement)	
7.2.3. Compressed air @ 6.0– 8.0 bar (g) ----------(Report requirement)	
7.2.4. Electricity:1.5 kW ----------(Report requirement)	

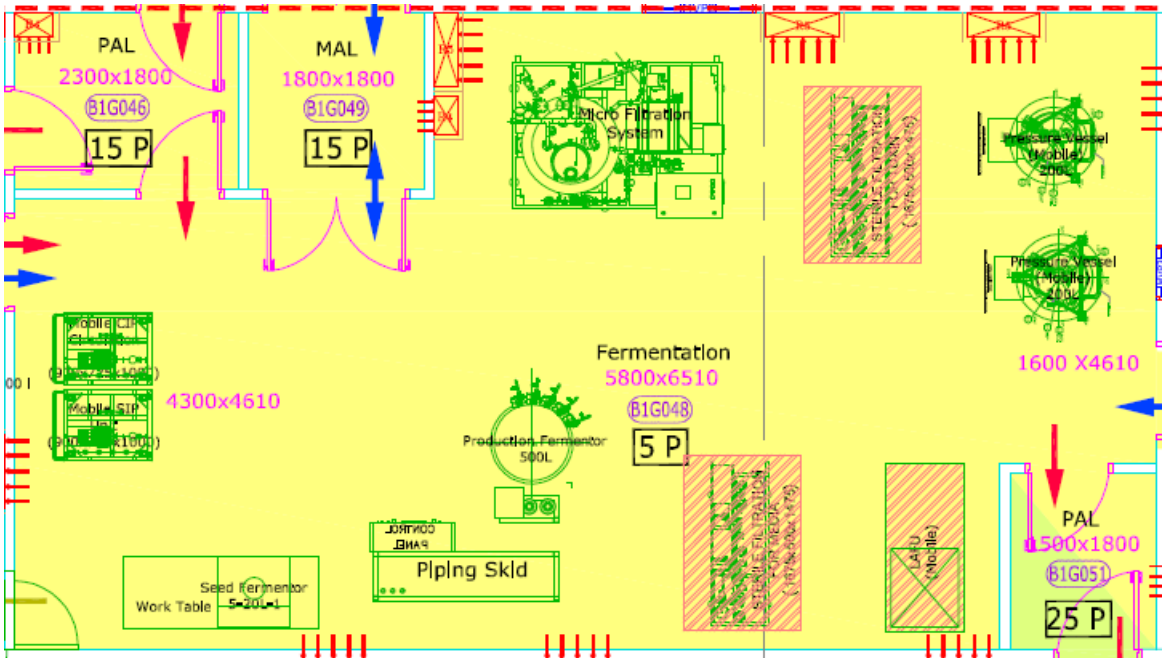
8.0 ABBREVIATION

Abbreviation	Definition
PII	Pasteur Institute Of India
PRV	Pressure Vessel
CIP	Clean In Place
SIP	Sterilization In Place
cGMP	current Good Manufacturing Practices
HLL	HLL Life care Limited
NPI	NNE Pharmaplan India Ltd
ISO	International Standards Organization

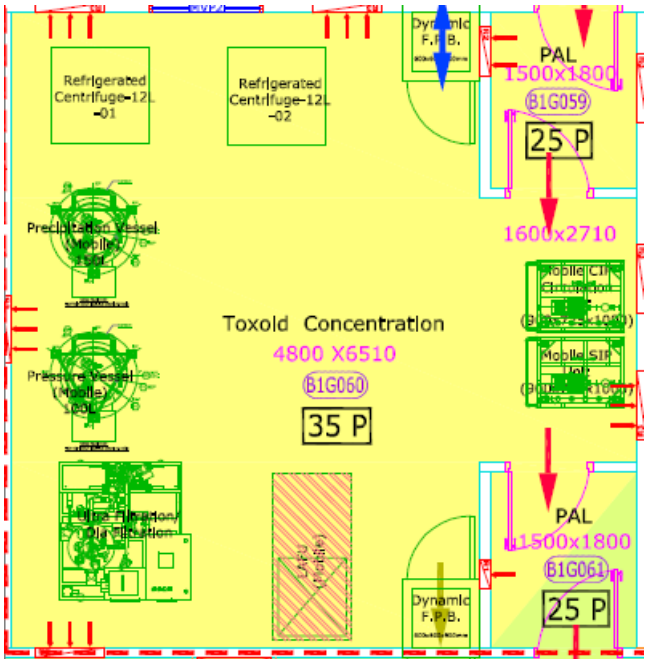
REVISION INDEX

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	2013-06-19	As per the MOM dated 2013-05-28 & 2013-05-29
03	2013-09-26	As per the discussion with HLL on Video Con on 2013-09-11 ,2013-09-12 and comments received on 2013-09-20
04	2014-01-22	Revised as per commented URS received on 2014.01.17
05	2014-01-28	URS's Consolidated as per telephonic confirmation between NNE and HLL
06	2014-07-07	Revised as per the discussion with HLL on 2014-06-19 and 2014-06-20

Annexure 1: LAYOUT A Room No: B1G048
For D-PRV 01 and D-PRV 02

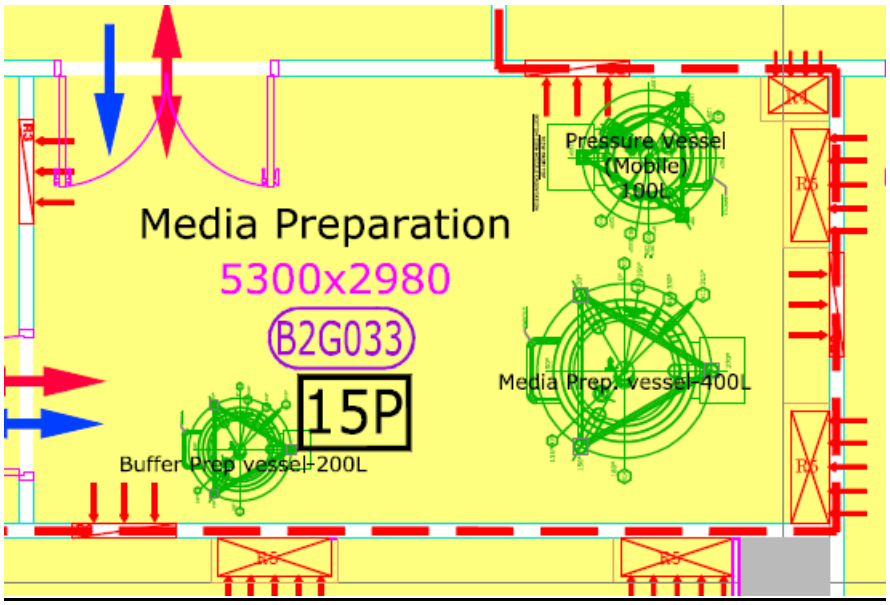


For D-PRV 03

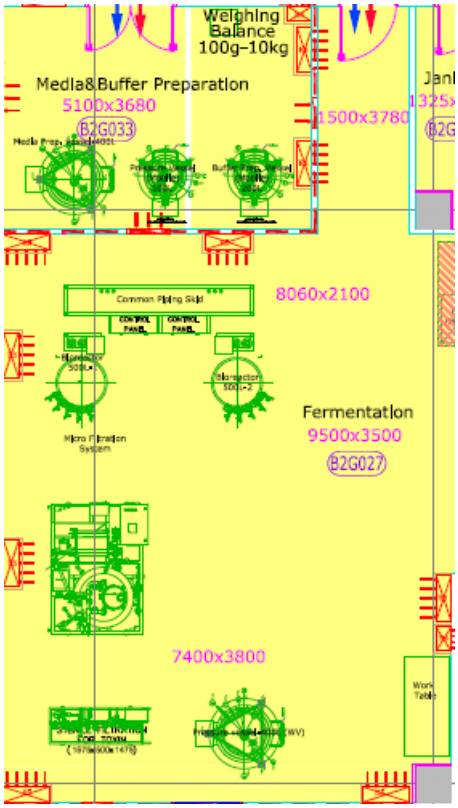


Annexure 1: LAYOUT C Room No: B1G033

For T-PRV 01



For T-PRV 02


Weighing
Balance
100g–10kg
Media&Buffer Preparation
5100x3680
B2G033
1500x3780
8060x2100
Fermentation
9500x3500
B2G027
7400x3800

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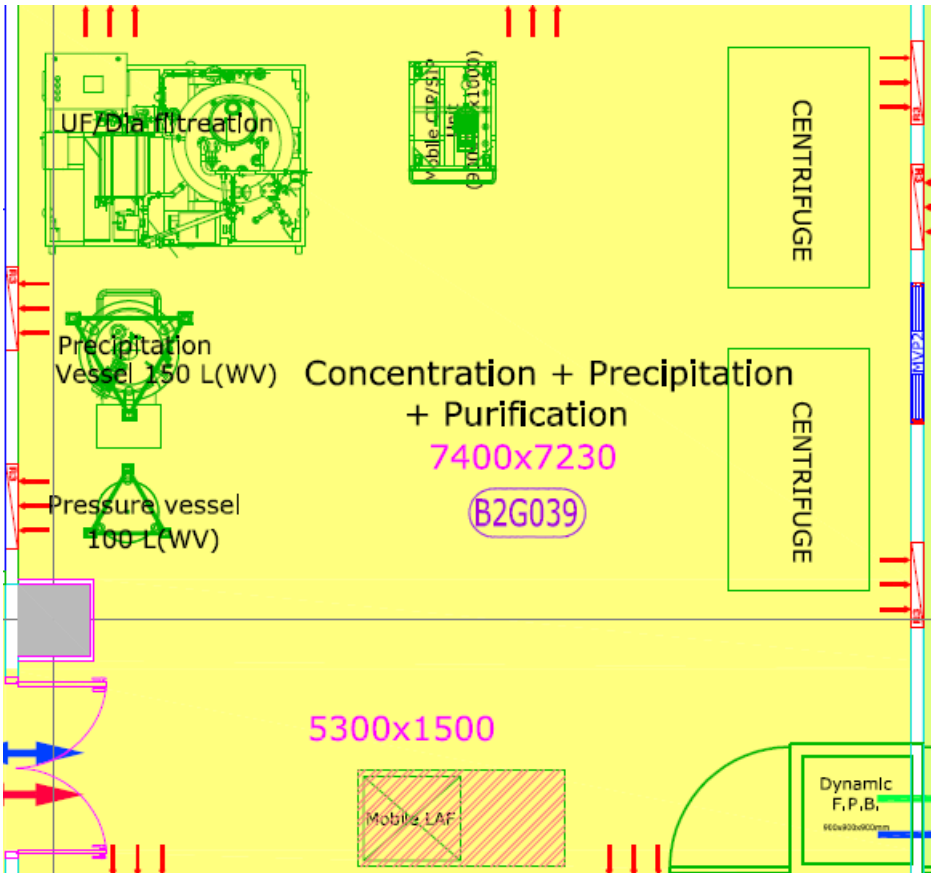
For T-PRV 03



URS Annexure 3: List of preferred make of components

	MECHANICAL	
1.	Pressure gauges	WIKA/Denver/Negele
2.	Air filter cartridge	Sartorius/PALL / Millipore
3.	Spray ball	HAKE
4.	Diaphragm valve(Manual)	GEMU/Burkert/ITT/SED/Saunders
5.	Ball valve(Manual)	Modentic/Saunders/Alfa laval
6.	Air- PRV	Festo/SMC
7.	Rupture disc	Zook/Elfab/FIKE