

Revival of DPT Vaccine Manufacturing Facility, PII, Coonoor

nne pharmaplan®	User Requirement Specifications				
	Equipment/System	Micro Filtration System			
	Identification #	P-MFS 01	Document#	URS/P-MFS 01	
	Effective Date	2013-12-13	Revision#	08	

User Requirement Specifications Micro Filtration System & Heat Inactivation

PROCESS CODE	AREA	EQUIPMENT TAG	QUANTITY	CAPACITY/ VOLUME (G.V.)
P	PERTUSSIS	P-MFS 01	1no.	500L

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URS Annexure List

URS Annex No.	Detail
1.	Layout showing location of installation of the Microfiltration System in the Inactivation room
2.	Tentative P&ID for Microfiltration System

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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 “**Micro Filtration System (MFS) (with PVDF membrane)**” (Quantity- 1NO.). This system will be used for the clarification of the broth after the fermentation process.

2.1 Operating Conditions:

- Pressure bar:0-4 bar
- Flow range: vendor to specify
- Temperature range: 0-40 °C during process, 56.5 ± 0.5°C for inactivation of bacterial mass and 134 °C during SIP
- Surface area of the membrane: 10 m²in multiples of 1.7m² membrane cassettes of 0.45 µm pore size.
- Minimum working Volume: 1% of the total working volume, i.e.4L

2.2 System Specifications

TABLE 1

S. No.	Description	Purpose	MOC	Capacity/Size
1.	System frame	To hold cassette holder	SS304	Vendor to specify
2.	Cassette holder	To hold filter cassettes	SS316L	10 m ² of 0.45 µm pore size.
3.	Recirculation pump	To recirculate the retentate	Sanitary type-SS316L	Vendor to specify according to membrane area
4.	Flow path	For the circulation of feed, permeate and retentate	SS316L	Vendor to specify
5.	Pressure transmitter in the feed, permeate and retentate lines	To measure pressure differential (ΔP) and trans-membrane pressure(TMP)	Sanitary type with SS316L diaphragm	NA
6.	Surface Finish	Internally Electro polished and passivated Ra≤0.6µm, according to ASME BPE(2009)		
		Externally Mechanically polished and passivated up to Ra<1.2 µm		
		Stainless steel piping interior Ra≤ 0.6µm, , according to ASME BPE(2009)		

System should be designed to achieve high flux at low TMP and low cross flow rate.

All pressurized parts of the system should be hard piped and connected via sanitary connections

System should be provided with rotary lobe pump proven to handle shear sensitive cells with suitable flow rate and pressure with variable speed control and auto cut off pumpincase of dry condition in the tank.

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2.3 Vessel Specifications

TABLE 2

S. No.	Description	Purpose	MOC
1.	Shell	Cylindrical	SS316L
2.	Top closure	Flat Lid	SS316L
3.	Bottom closure	Torispherical dish	SS316L
4.	Spray Ball	For the cleaning of the interior of the vessel.	SS 316L
5.	Jacket	Hollow type; For temperature control	SS304
6.	Insulation	To avoid heat loss	Mineral wool
7.	Cladding	Cladding is welded to jacket around the insulation	SS304

2.4 Vessel design specification

TABLE 3

SI.NO	Description	Specification
1.	Geometric volume	500 L
2.	Maximum working volume	400L
3.	Quantity	1 No
4.	Working temperature range	25 °C-134°C
5.	Surface Finish	Internally Electro polished Ra ≤ 0.6 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≤ 0.6μm, according to ASME BPE guidelines
6.	Compliance	Design of the vessel shall compliance with ASME and ASME-BPE guidelines (current version)

2.4.a The Chassis mounted system (with lockable castor wheel with adjacent height adjustable leg paddle plate) comprising of One Microfiltration unit, Semi-automatic System and jacketed feed tank. The following are the main features:

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- A. Dosing unit for feed/buffer/saline:** Fermentor broth shall be transfer to feed tank of the system with the fixed piping with the help of sterile nitrogen/ sterile air through sterile valve assembly.
- B. The sterile valve assembly:** should have
- Steam Inlet Valve
 - Condensate drain valve
 - Temperature sensor/ transmitter
- C. Temperature Control:** Provision for the supply of chilled water/cooling water and plant steam to in the system to be made so as to reduce the temperature of the feed inlet and during CIP/SIP. Required set point (50-60°C) with a bandwidth of $\pm 0.5^{\circ}\text{C}$ for time period ranging from 0-60mins after successful completion of time period the temperature should automatically come down.
- Suitable inlet and outlet valves for temperature control
 - Suitable inlet and outlet valves with steam trap for SIP
 - Auto control Valve for jacket inlet
 - Auto control valve for outlet with steam trap for control of temperature ($56.5 \pm 0.5^{\circ}\text{C}$) with steam
 - Heat Exchanger for heating and cooling using chilled water and plant steam- A secondary heating cooling loop for precise control of temperature ($56.5 \pm 0.5^{\circ}\text{C}$) during inactivation.
- D. Air Filters:**
- Inlet Air filters:
 - Reusable and Sterilizable SS housing with 0.2/0.22 μm , sterile filter (code 7) with manual diaphragm valve, which is to be sterilized along with vessel.
 - Exhaust Air filters:
 - Exhaust filter with manual diaphragm valve
- E. Pressure Indication:**
- Pressure of the vessel
 - Compound Pressure gauge for vessel
 - Rupture disc, to release the excess pressure in the vessel
- F. Flush bottom valve:** It should be zero dead leg type valve attached directly bottom of the vessel. The diaphragm shall be of PTFE type.
- G. Feed Line:**
- Pressure Transmitter
- H. Permeate Line:**
- Pressure transmitter
 - Electromagnetic flow meter for measuring the flow of conductive fluids in process applications
 - Sampling valve
- I. Retentate Line:**
- Pressure transmitter

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- Electromagnetic flow meter for measuring the flow of conductive fluids in process applications
- Retentate Sampling
- Control Valve for ΔP and TMP
- Retentate collection : Flexible sterile hoses (GMP compliant) for aseptic transfer of inactivated bacterial mass

J. CIP(Clean in Place):

- CIP of the system to be carried out along with the tank and the associated pump
- CIP/ SIP of the system shall be done before MF process start-up

K. SIP (Sterilisation in Place): The stainless steel system and the associated piping shall be sterilized in place with clean steam. All sterilization processes are to be executed automatically from the PLC Control System. Sterilization temperatures are monitored by temperature sensors in the condensate lines. Inlet air filter and vent filter with associated manual diaphragm valve.

- Temperature indication at the lowest point before the drain point
- Steam traps to be provided as per process requirement and wherever necessary
- The exhaust filter is to be sterilized together with the vessel

L. General characteristics of the microfiltration membrane:

- Filter area of 10 m² in multiples of 1.7m² membrane cassettes
- Membrane pore Size- 0.45 μm,
- pH range operation pH 2-12.
- Hydrophilic in nature.
- PVDF Membrane
- Open Channel type
- SIPable membrane material suitable to handle toxin and fermentation broth shall be provided
- High velocity and high particulate level capability.
- Maximum containment of hazardous fluids.
- Low hold-up volume
- Low protein binding.
- Good compatibility with most of the cleaning, sanitizing, depyrogenation and storage agents

Note: membrane made up of equivalent polymer with above characteristics is optimal for use.

M. Additional requirements: 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.

N. Controller: PLC Based Controller with SCADA (21 CFR Part 11 Compliance) with a 10" industrial touch screen large HMI (Displaying data trends as Graphs, synoptic view of running parameters etc).

O. The HMI shall be touch screen type (Provision for manual operation also to be provided)

- HMI screen size shall be of 10 inches with resolution of 1200 x 800 pixels

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- Human machine interface must be used to enter the process details, which should appear in the print out.
- All critical alarms
- All Critical parameters & interlocks
- Addition of the buffer
- All Recipes/ sequences (Process, CIP , SIP, transfer etc)
- P&ID of the vessel along with instrumentation details
- Login details

P. Nozzles Schedule :

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

- GMP type Spray ball/s assembly- static type - 360°
- Sterilizing grade hydrophobic inlet and vent filter (0.2/0.22 µm)with SS housing and pneumatic diaphragm valve
- Rupture disc
- Hand hole - flushed flange with O-rings/caps
- Port for Light/Sight Glass –Bolted with gasket.
- Port for pressure gauge/ indicator
- Port for inlet of retentate
- Port for Spare port
- Port for level sensor with the accuracy of approx. 1%of the total range (4L)

Upper side wall:

The feed vessel upper cover / dish normally will have :

- Port for the addition of feed/ buffer/ saline with peristaltic pump
- Permeate recirculation port with “J” type nozzle

Lower side wall/ Bottom Connection:

The feed vessel shall have a lower cover, the following ports and elements shall be placed and fastened there:

- Port for temperature transmitter
- Port for pH transmitter

Jacket Connection

- **Jacket Bottom:** Jacket Inlet port with angle seat valve, jacket drain
- **Jacket Upper side:** Jacket outlet port, safety relief valve, jacket vent

Q. All points of the IRS except the below mentioned would be applicable for the equipment

- 4.1.10, 4.1.11, 4.1.13, 4.1.17
- FDA Guidance for industry for sterilization equipments,
- CE Certification,

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- ANSI/NSF 49-2008, ISO 14664, ISO 8362

Note:

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> <p>a. If no comments against any specification shall be considered as "NO" and</p> <p>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.</p>
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 HLL before submitting the quotes.
X.	The makes requested are standard international makes. In case of any deviation, vendor to seek clarification from HLL before submitting the offers.
XI.	Refer document Installation Requirement Specification and Specific Instructions with URS;NPI_110831_IRS_PII_01
XII.	Refer Tender document with URS; NPI/110831/EQP/TD/03

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Specifications	Remarks
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3.0 PROCESS DESCRIPTION	
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3.1 Input & Charging method	
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3.1.1 Then feed from fermentor shall be fed into the filtration unit (firstly in feed tank)by sterile compressed air..	
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3.2 Brief Process Steps	
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<p>3.2.1 The equipment will be used for cell mass recovery from fermentation broth</p> <ul style="list-style-type: none"> a) The broth (400L) from the fermenter shall be directly fed into the feed vessel of the system b) The required number of membrane modules shall be installed as per the required filtration area 10m²in multiples of 1.7m² membrane cassettes. c) The permeate and retentate will be recirculated into the vessel till the equilibrium is achieved. d) The clarified/concentrated cell mass shall be inactivated in the same vessel with hot media (Utility) at 56.5 ± 0.5°C for 30minutes followed by cooling to ambient temperature. The heat inactivation should be done after by-passing the membrane modules in recirculation mode using recirculation pump and heat exchanger. e) After achieving the equilibrium, retentate is collected and it shall be recirculated in the vessel. f) A separate provision to be made for product recovery to flush the module. 	
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3.3 Output & Discharging method	
--	--

a) The clarified/concentrated cell mass is then inactivated in the same vessel with hot utility media.	
b) The permeate is sent out in the drain and then sent to the kill tanks for further treatment	

4.0 PRODUCTIVITY REQUIREMENT	
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4.1 Desired/ suggested capacity	
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4.1.1 400 L Vessel (As working volume) / 500L (As Gross Volume)	
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4.2 Standard batch size	
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Feed: 400L broth from fermentor	
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4.3 Change over time	
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Not applicable	
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4.4 Other(if any)

Not applicable

5.0 CONTAINMENT

Not Applicable

6.0 GMP REQUIREMENTS

6.1 Process control

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

- a) Differential Pressure regulation parameters
- b) TMP regulation parameters
- c) Pressure indication
- d) Temperature control for inactivation of bacterial mass
- e) Volume in the vessel
- f) Pump start up speed(During Flush, NWP, Microfiltration, Washing, CIP,DP regulation)
- g) Duration of cycle(During Flush, NWP, Microfiltration, Washing, CIP,DP regulation, Depolarization)
- h) Volume (Flush, Microfiltration, washing etc)
- i) NWP stabilization and measurement time
- j) Depolarization
- k) Flux during microfiltration
- l) Pump recirculation speed during storage
- m) Tank Jacket cooling control parameters

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

- n) Emergency stop activated.
- o) Power failure.
- p) Malfunction of sensors of temperature, pressure, flow

6.2 Failure mode detection

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

- a) ΔP

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b) TMP control

c) SIP temperature and pressure of the vessel - Control

d) Temperature Control

e) pH indication

6.3 In –Process control

6.3.1 Temperature measurement and control.

6.3.2 Pressure control on the feed inlet, retentate and permeate lines

6.3.3 Measurement and control of fluid level in the tank.

6.4 Level of instrumentation

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

Type of control/test	Purpose	Instrumentation
Temperature	Monitor and control the temperature	RTD sensor and temperature indicator & controller on the tank and SIP drain
Pressure (TMP&Δ P)	Monitor and control the pressure of feed, Retentate and permeate	Pressure transmitter
Pressure	To monitor, indicate and control the tank pressure	Pressure sensor
Flow rate	Monitor the rate of flow of retentate	Electromagnetic flow meter
pH	To monitor and indicate of pH of the system	pH transmitter in tank
Level of the volume	To maintain the correct volume of the product	With the accuracy of 1% of the completed range.
Instrument air pressure	To maintain the flow and pressure of the instrument air	Regulator with pressure switch
Conductivity	To measure the conductivity during CIP	Conductivity Sensor

6.5 Batch data display and record printing

Refer IRS (Installation requirement Specification and specific Instruction).
 Non editable data shall be available / transferred to USB Drive for printing the batch report, alarm log.
 Realtime online printing shall be available for batch report

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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.
6.6.3	All parts of the machine exposed in A/C area must be resistant to standard disinfectants or vendor shall provide the name of specific disinfectants.
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	Pressure reducing valve for pure steam at the inlet air filter
6.7.3	All ports should be attached with Sanitary Tri clamps
6.7.4	Feed tank inlet shall have a sterile valve assembly with steam inlet and condensate drain valve.
6.7.5	All diaphragm valves to be sterile type
6.7.6	Automated Temperature control for the inactivation of the bacterial mass (tolerance limit: ±0.5° Celsius)
6.7.7	Automated pressure control during clarification process.
6.7.8	<u>Pump specificaion: Sterile Sanitary design</u> MOC: SS316L Seal: single mechanical seal Elastomers: EPDM - FDA/ USP CIP : Yes SIP: Yes Surface finish : Ra <0.6 µm (electropolished)
6.7.9	Nozzle shell shall be seamless.
6.7.10	Nozzle connection to beTriclover.
6.7.11	Nozzles, adaptors, instrument shall comply to ASME BPE compliant.
6.7.12	Total motor drive assembly with SS304 cover with TEFC eff 1.
6.7.13	Necessary sanitary TC end flexible hoses to be provided for all the utilities like pure steam, chilled water, cooling water, plant steam and for product recovery
6.7.14	Sterile inlet and vent filter and cartridge 0.45 µmhydrophobic of suitable size in SS316 L construction
6.7.15	All process Utility piping from header to the vessel skid: SS 316L. Ra < 0.6µm
6.7.16	Performance Requirements: Vendor to demonstrate the following during FAT/SAT <ul style="list-style-type: none"> • Sterility of the complete system

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- Flux- to be demonstrated with model solution
- CIP- effectiveness to be demonstrated and spray ball coverage.
- Temperature Control along with the level accuracy to be demonstrated.

- 6.7.17 Design Considerations:
- Vessel working Pressure: 0 to 3 Bar (g)
 - Vessel working Temperature: 0°C to 125°C.
 - Vessel design Pressure: 4 bar
 - Vessel design Temperature: 0-150⁰ C
 - Jacket working Pressure: 0 to 4 bar (g)
 - Jacket working Temperature: 0°C to 125°C.
 - Jacket design Pressure: 5 bar(g)
 - Jacket design Temperature: 0-150⁰ C
 - Design pressure for safety release valve: 4.9 bar
 - Vessel sterilization Temperature: 121°C(Design: 150°C)

6.7.18 Basic requirement shall be provided by the vendor to calculate the filter area

6.7.19 Module holder (process scale holder), all pipelines and connections, which come in contact with the product should be made SS 316 L and electro polished- To accommodate all mentioned makes of cassettes.

6.7.20 Vendor shall provide the FRL (Filter, regulator, lubricator), automatic valve assembly and air pressure switch for instrument air. Connections to automatic diaphragm valve shall be in vendor scope.

6.7.21 Online integrity test provision shall be provided for cassette and vent filter.

6.7.22 Software Design Specifications/Implementation Guidelines (SDS)

- 6.7.23 The development of the PLC Application Software will be done in accordance to the GAMP5 Guideline with the preparation of:
- Functional Specifications (FS)
 - Hardware Design Specifications (HDS)
 - It shall be 21CFR part 11 compliance for data acquisition

6.7.24 Dummy cassettes to carry out the validation activities.

7.0 CONSTRAINTS

7.1 Equipment location and available space

This equipment will be installed in the PertussisBlock of **Revival of D.P.T Vaccine Manufacturing Facility, PII, Coonoor.**

Microfiltration & Inactivation Room (B1G014)

Block: Pertussis Block
 Floor: Ground Floor
 Room Size:4400 mm x 4600 mm

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False Ceiling: 3000 mm

Physical condition of the rooms:

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

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

7.2 Available Utility

7.2.1 Electricity: 3 ph, 415V AC, 50Hz

7.2.2 Water for Injection: 80-85° C (point of use cooler provided)

7.2.3 Pure Steam: 3 bar

7.2.4 Plant steam: 3-3.5bar g

7.2.5 Chilled Water Supply: 6– 7°C,
Return: 11– 12°C (depends on process)

7.2.6 Compressed air: 8-10 bar g

Vendor need to take care the utility requirement as desired for the system. As per the system if changes required in the utility pressure vendor should consider within the package.

8.0 ABBREVIATION

Abbreviation	Definition
db	Decibel
DQ	Design Qualification
HMI	Human Machine Interface
MOC	Material Of Construction
MFS	Micro Filtration System
NPI	NNE Pharmaplan India Ltd
NPW	Nominal Water Permeability
PII	Pasteur Institute of India
PLC	Programmable Logic Controller
PID	Proportional Integral Derivative
QA	Quality Assurance

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RPM	Revolutions Per Minute
SS	Stainless steel

REVISION INDEX

Revision	Date	Reason for Revision
00	09.12.2011	First Draft
01	18.05.2012	Client's comments incorporated
02	2012-10-22	Format changed as per HLL requirement
03	2013-02-05	HLL Comments incorporated, received during the workshop dated 22nd and 23rd January, 2013
04	2013-02-28	PIIC comments incorporated, received on 26th February 2013
05	2013-02-21	PIIC comments incorporated, received on 18th March 2013
06	2013-05-14	Format internally revised
07	2013-11-11	Updated as per MOM dated 28.05.2013 & 29.05.2013 and Telecon dated 08.11.2013
08	2013-12-13	Updated as per commented URS received through E-Mail on 09.12.2013

HLL LIFECARE LIMITED, CHENNAI

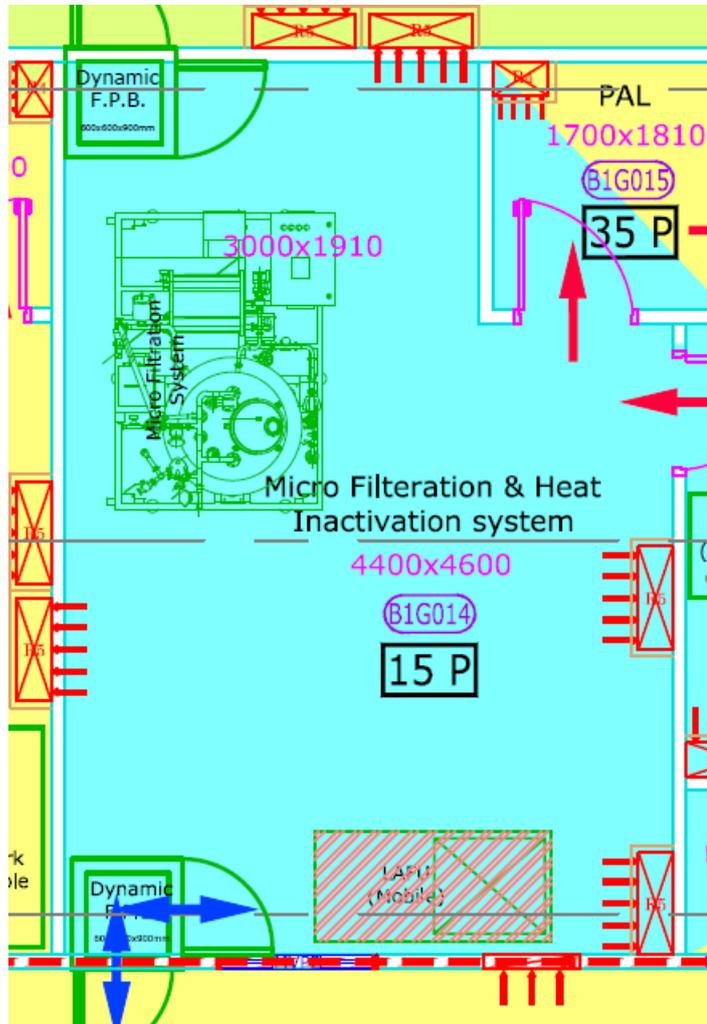
Revival of DPT Vaccine Manufacturing Facility, PII, Coonoor

nne pharmaplan®	User Requirement Specifications			
	Equipment/System	Micro Filtration System		
	Identification #	P-MFS 01	Document#	URS/P-MFS 01
	Effective Date	2013-12-13	Revision#	08



URS Annexure 1: LAYOUT POSITION

Room: (Pertussis Block): B1G014



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Revival of DPT Vaccine Manufacturing Facility, PII, Coonoor

	User Requirement Specifications				
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	Effective Date	2013-12-13	Revision#	08	

URS Annexure 3: List of Preferred Make of components

SL.NO	DESCRIPTION	MAKE
A	INSTRUMENTATION	
	PLC	Allen Bradley/ Siemens
	Operator Interface/HMI	Allen Bradley/ Siemens
	Temperature transmitter	Radix/ Yokogawa/Emerson
	Temperature sensor	NEGELE/E&H
	pH sensor	METTLER TOLEDO/E&H
	Pressure transmitter	Wika / Dwyer/ Labom
	Pressure regulator	FESTO
	Flow meter	E&H / Khrono Marshall/ Rosemount
	Steam trap	Spirax Marshall
	Rupture Disc	Fike
	Printer	Canon/Epsilon/HP
B	MECHANICAL	
	Pressure gauges	WIKA/Denver/Negele
	Vent filter cartridge	Sartorius/PALL/Millipore
	Filter housing	Sartorius/ PALL/Millipore
	Spray ball	HAKE/LECHLER
	Diaphragm valve(Manual)	GEMU /SED
	Ball valve(Manual)	Modentic/Alfa laval
	Flush bottom valve	Novaseptic/GEMU
	Sampling Valve	Novaseptic/GEMU
	Flow switch	E&H/ Wika/Emerson
	Recirculation Pump	Johnson/ Alfa Laval
C	PNEUMATIC	
	Diaphragm valve(Automatic)	GEMU/ SED
	Angle Seat valve	GEMU/Spirax/SED
D	ELECTRICAL	
	Lamp	PAPENMEIER