DATASHEET		
HLL BIOTECH LIMITED, CHENNAI		
nne pharmaplan®	REVIVAL OF DPT VACCINE MANUFACTURING FACILITY	HBL HLL BIOTECH LIMITED
	Dry Fog Generator	
	PROJECT #: 110831	
	EQUIPMENT ID #: Refer Annexure:1	
	DOCUMENT # : DS/FOG 01	

1	**Process requirements**	
1.1	This equipment shall be used in clean rooms to reduce the bio-burden by creating the vapours / aerosols of suitable disinfectant solution.	
2	**Technical Specification**	
2.1	Model	cGMP for clean room application
2.2	Type	Mobile (portable)
2.3	Max. Room volume coverage required, m^3	Refer annexure-1 for total room volume (equipment should be designed to cover the entire room in single fogging cycle)
2.4	Disinfectant solution Tank capacity	Shall be suitable for all cycles of room decontamination mentioned in annexure-1
2.5	Aerosols generation type	Using compressed air or evaporator (electricity). Connectors for Air supply to be provided. Size: 8 mm PU Connector and 8mm to 12 mm PU expander connector
2.6	Droplet size	5 to 10 µm
2.7	Power connection requirement	To be compatible to standard Indian power supply socket
2.8	Power consumption, kW	Vendor to specify
2.9	Compressed air pressure requirement, bar	Vendor to specify
2.10	Compressed air consumption, CFM	Vendor to specify
2.11	Complete coverage of the room	Required
2.12	Operating temperature	15 to 40 deg.C
2.13	Operating Relative humidity	< 75% RH
2.14	Disinfectant type	Oil / Water based liquid
2.15	Disinfectant solution discharge rate	vendor to specify
2.16	External Dimensions	vendor to specify
2.17	Quantity	Five (Diphtheria block -1 no, Pertussis block -1 no., Tetanus block -1 no., Formulation Block -1 no., and Microbiology Block 1 no.)
2.18	Equipment id	1. B1-FOG -01 Diphtheria block 2. B1-FOG-02 Pertussis block 3. B2-FOG-01 Tetanus block 4. F1-FOG-01 Formulation Block 5. M1-FOG-01 Microbiology Block
2.19	No. of spray nozzles	Minimum 4 No.s
2.20	Type of control system	Vendor to specify
2.21	Remote control of the equipment	Required
2.22	Preferred disinfectant solution	Hydrogen Peroxide
2.23	Concentration of Hydrogen peroxide	Vendor to specify
3	**Material Of Construction**	
3.1	Spray Nozzle	SS 304 or Clean room Compliant (Vendor to specify)
3.2	Disinfectant solution tank	SS 304
3.3	Tank gasket	FDA approved
3.4	External surfaces	Poly Propylene or Clean room Compliant (Vendor to specify)
3.5	Wheels	Lockable castor wheels
4	**Specific Requirements**	
4.1	The equipment should be effective in decontaminating the rooms and equipment surfaces.	
4.2	The equipment shall have flow rate adjustable knob.	
4.3	The fog generated by equipment should not be condensed in the room.	
4.4	Fogger should provide maximum thrust, deeper penetration and wide spread of aerosols ensuring effective and uniform treatment of chemical being fogged.	
4.5	Vendor to demonstrate and validate the six log reduction of microbial with suitable indicators.	

4.6	Portable hydrogen peroxide sensors to be provided inside the room.
4.7	It should provide control on droplet size and is capable of generating ultrafine droplets as application demands.
4.8	Fogger should produce greater aerosol volume and fine diffusion of chemical being fogged in to space, obstructed surface ensuring uniform treatment of entire space.
4.9	There should not be leakage of disinfectants on the floor / surface.
4.10	It should be compatible with wide range of disinfectants (vendor to suggest the range of compatible disinfectants)
4.11	The equipment must have detachable solution tank for easy filling and cleaning.
4.12	Chocking of nozzles during the injection should be prevented.
4.13	The system should be equipped with fixed lockable castor wheels for easy movement of equipment from one place to other place.
4.14	**Special Note:** Equipment should be able to pass through pass box having the dimension of 900 mm x 900 mm x 1200 mm (W x D x H)
5	**Other requirements**
5.1	The equipment must have rugged design and made from corrosion resistant material.
5.2	It should be light weight, portable and extremely user friendly.
5.3	It should be designed for easy cleaning
6	**Regulatory aspects**
	Not applicable
7	**Safety requirements**
7.1	Equipment should not contain any sharp edges.
7.2	In the event of equipment / system malfunction or loss of utilities, the unit must contain all necessary protection devices to ensure that the equipment / system and the article remain in a safe condition.
7.3	Proper earthing of the equipment (if applicable)
8	**Documents**
8.1	IOQ Protocol
8.2	Operational and maintenance manual
8.3	Comprehensive 1 year warranty after the succesful installation and handing over to the client
8.4	MOC certificates
8.5	List of COMPONENTS -MAKES used in this equipment with certificate
9	**Timelines**
	NA
	NOTE: Accurate size and technical specification need to be mentioned by the vendor.

	AFI Approved for Enquiry		AFO Approved for Ordering			
		Yogesha M.S.	Pulm			
01	14-09-2015	MJY	PULM	☐	☐	
Rev	Date	Completed By	Checked By	AFI	AFO	

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Annexure-1: Table showing the volume of rooms for each cycle

Equipment ID	Cycle no.	ROOM NO.	ROOM TITLE	HYGIENE CLASS	Area m^2	ROOM DIMENSION		
						Slab Height m	False Ceiling Height m	Room Volume m^3
Diphtheria Ground Floor								
B1-FOG-01	1	B1G054	Sterile Filtration	Grade B	23.3	5.5	3.0	69.9
	1	B1G063	Change Room	Grade B	6.6	5.5	3.0	19.8
Pertussis Ground Floor								
B1-FOG-02	1	B1G014	Microfiltration and heat inactivation	Grade B	20.2	5.5	3.0	60.7
	1	B1G013	Change Room	Grade B	7.3	5.5	3.0	21.8
	2	B1G023	Blending	Grade B	17.6	5.5	4.0	70.4
	2	B1G022	Change Room	Grade B	7.3	5.5	3.0	21.8
Tetnus Ground Floor								
B2-FOG-01	1	B2G043	Sterile Filtration	Grade B	21.0	5.5	3.0	63.0
	1	B2G042	Change Room	Grade B	3.0	5.5	3.0	9.0
Formulation Ground Floor								
F1-FOG-01	1	F1G059	Insitu Sterilization	Grade B	9.0	5.5	3.0	27.0
	2	F1G057	Blending	Grade B	43.0	5.5	4.0	172.0
	3	F1G055	Vial filling capping and sealing	Grade B	44.0	5.5	4.0	176.0
Microbiology Ground Floor								
M1-FOG-01	1	M1G035	C/R 2	Grade B	4.1	5.5	2.4	9.7
	1	M1G036	C/R 4	Grade B	2.6	5.5	2.4	6.1
	1	M1G030	Corridor	Grade B	5.9	5.5	2.4	14.2
	1	M1G037	Sterility lab -1	Grade B	8.2	5.5	2.4	19.7
	1	M1G038	Sterility lab -2	Grade B	8.2	5.5	2.4	19.7

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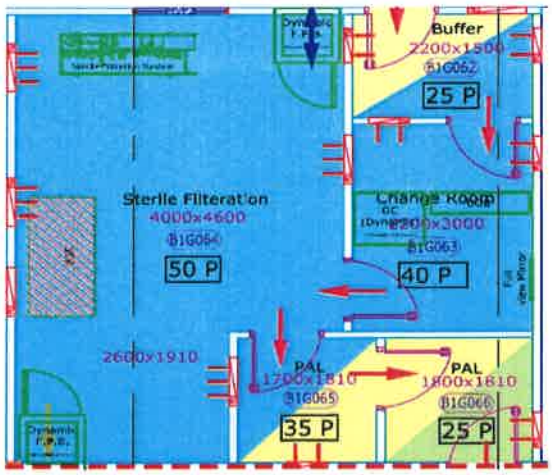
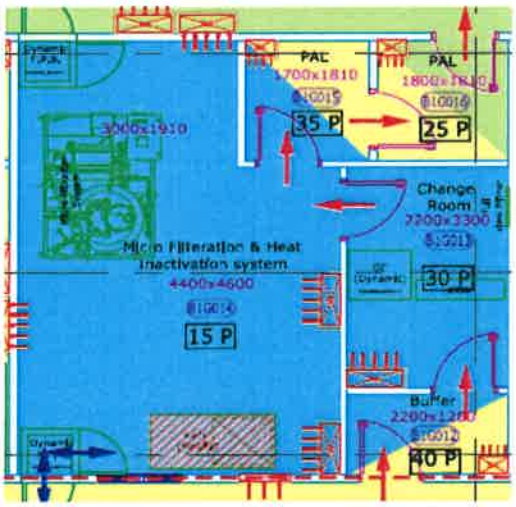
Annexure-2: Layout showing the shape of the rooms

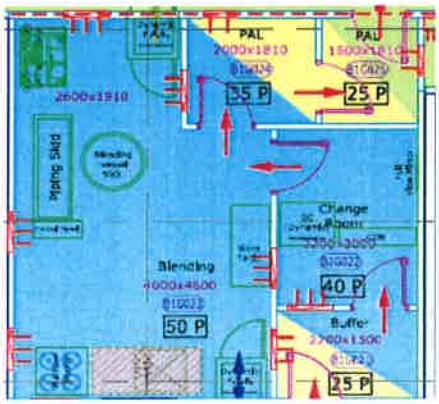
Diphtheria Block- Sterile Filteration



Pertussis Block -Microfiltration and heat inactivation



Pertussis Block- Blending



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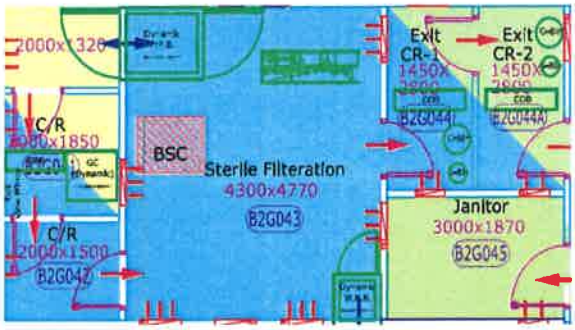
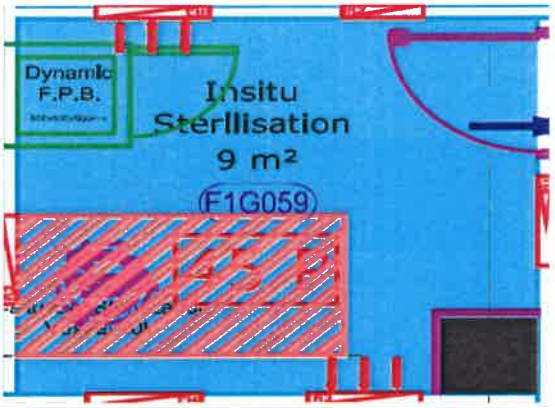
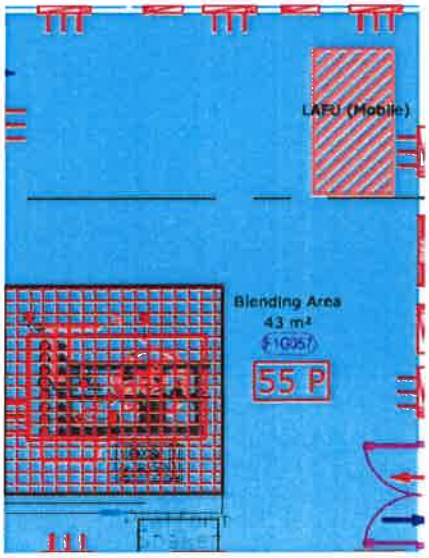
Tetanus Block- Sterile Filtration



Formulation block- In situ Sterilisation



Formulation block-Blending



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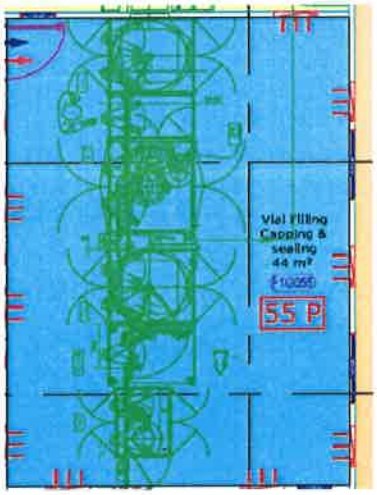
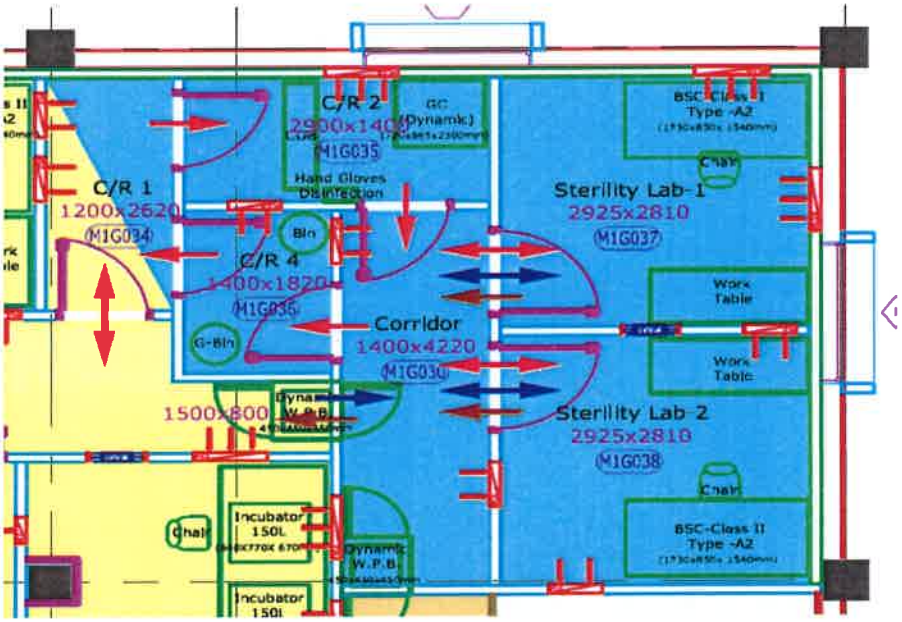
Formulation block-Vial Filling capping and sealing



Microbilogy block- Sterility Lab 1 & 2



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