

**DATA SHEET**

**HLL LIFECARE LIMITED, CHENNAI**

**REVIVAL OF BCG VACCINE**

**LABORATORY, GUINDY, CHENNAI**

**Ceiling Suspended Laminar Air Flow**



**nne pharma plan®**

<b>PROJECT No:</b>	<b>110729</b>
<b>EQUIPMENT ID :</b>	<b>FG-CLF 01-08_BF-CLF 09-14</b>
<b>DOCUMENT No :</b>	<b>DS/FG-CLF 01-08_BF-CLF 09-14</b>

**1 Process requirements**

1.1 Ceiling Mounted Laminar Air Flow to be used for creating an aseptic environment that will ensure product protection and partial protection of the operator. The equipment to be used for clean sterile condition

**2 Technical Specification**

2.1	Model	cGMP ceiling suspended LAF
2.2	Type	Grade A (ISO 5)
2.3	Inner Area (mm)	<b>REFER SHEET -2</b>
2.4	Air flow pattern	Vertical downward Air Flow type a) Uni-directional Laminar Air Flow type b) Double Stage filtration
2.5	Pre- Filter	To trap large particle in the inflow air, protecting against damage and prolonging HEPA filter life. EU - 6 Efficiency >95% Size: 5 μ
2.6	HEPA Filter	H-14 Efficiency >99.997% <b>Size: 0.3 μ</b>
2.7	Air flow rate	0.45 m/s ±20% from 6" below the HEPA filter
2.8	Quantity	<del>13 nos.</del> 14 nos. <i>Raj</i>
2.9	Electrical Requirement	Power Consumption: <b>Vendor to specify</b> 220-230 V, 50 Hz, Single phase
<b>3 Material Of Construction</b>		
3.1	Body Construction	SS 304, min 240 Grit
3.2	Grills	SS 304, min 240 Grit
3.3	Coving	SS 304 in built
3.4	Curtains	Anti static PVC curtains (Except for filling and sealing line ceiling suspended LAFs)
3.5	All welds and weld beads shall be grounded and smoothened	



**4 Specific requirement**

4.1	Pre-filters should be easily accessible for periodic cleaning.
4.2	Sleeving for accommodating the pre filters.
4.3	Side access panel for final filters and blowers.
4.4	HEPA filter shall have an efficiency of 99.997 % when tested with POA
4.5	1 no Magnehelic gauge to be provided to monitor the differential pressure across the HEPA filter
4.6	Blower System shall be balanced for vibration free operation and noise level.
4.7	Blower shall be permanently lubricated
4.8	Individual blower motor shall be provided on each standard HEPA filter as per the LAF area
4.9	Motor and electrical devices designed for working in normal operating conditions.
4.10	Preferred make for Motor Blower assembly : Crompton Greaves/ ABB/ GE/ Siemens/EBM-PAPST/Nicotra
4.11	Light level shall be minimum 400 Lux. Lighting with tear drop light fitting installed in such a way as to generate no turbulence in air flow.
4.12	Soft touch controls for blower, light shall be provided along color coded indicator (different for each application). It shall be on accessible level (i.e. 1200-1500mm)
4.13	Easy access to electrical connections and instrumentation behind the control panel
4.14	PVC curtains shall be provided around the Ceiling suspended LAF to maintain the air flow pattern. Length of the curtains shall be till 500-600mm above the ground floor (Except for filling and sealing line ceiling suspended LAFs)

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4.15	Vendor shall specify the sizes and quantity of HEPA filter and pre filter in each Ceiling suspended LAF as per the sizes
4.16	Detailed Installation and fixing details shall be provided
4.17	Approved make for filter: Camfil Farr/AAF/Freudenberg
<b>5</b>	<b>Other requirements</b>
5.1	Cleaning shall be done manually.
5.2	All bolts, nuts shall be of dome type of SS304 material
5.3	Vendor to give code numbers for each component
5.4	There shall be no crevices, edges, cracks, pits so as to avoid dust accumulation
5.5	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, filters, etc.
5.6	The design shall be maintenance friendly for the ease of replacement of filters
5.7	All parts of the machine exposed in classified area must be resistant to standard disinfectants or vendor shall provide the name of specific disinfectants
5.8	The heat given off by the unit must be stated (inside the room).
5.9	Failure mode detection <b>A.</b> Equipment shall be capable to detect the following failure, notify the operator with alarm and shutdown the process: a) Blower motor overload. b) Emergency stop activated. <b>B.</b> Following condition need only notification to operator for procedural control: a) Differential pressure across HEPA filter should provide constant indication of pressure drops and a visual alarm signal of high and low pressure in the filter
5.10	The following test to be conducted at site during qualification 1. air velocity test 2. Filter Integrity Test 3. Flow Visualization Test (videography) 4. Non viable Particle Count 5. Recovery Test 6. Lux Level 7. Sound Level
<b>6</b>	<b>Regulatory guidelines / standards</b>
6.1	ISO 14644 – 1 (For Cleanliness Class)
6.2	ISO 14644 – 3 (For HEPA filter integrity testing & Velocity testing)
6.3	EU-GMP-Guideline Part 1, Annexes 1, 11 & 15
6.4	Schedule M of Indian Drugs and Cosmetics Act
6.5	Code of Federal Regulations (CFR) 21, Part 210: cGMP in Manufacturing, Processing, Packing and Holding of Drugs
<b>7</b>	<b>Safety requirement</b>
7.1	Emergency stop function on accessible area.
7.2	Noise level below 40 to 45 decible.
7.3	Appropriate closure of all the rotating parts.
<b>8</b>	<b>Documents</b>
8.1	Vendor to submit detailed fabrication drawing for approval before fabrication.
8.2	<b>Phase 1: Post ordering and prefabrication stage of the equipment</b>
8.2.1	Functional design specification
8.2.2	Equipment descriptions
8.2.3	Equipment operation steps
8.2.4	List of failure indications and interlocks (as applicable)
8.2.5	Critical list of major component, devices and instruments with their specific functions, specs and data sheets.
8.2.6	GA/ Schematic diagram of the equipment
8.2.7	DQ specification
8.2.8	IQ specification
8.2.9	OQ specification
8.3	<b>Phase - 2</b>
8.3.1	Vendor shall provide the FAT protocol at least 1 month in advance of the date of FAT, for the approval by the user.
8.3.2	System shall be inspected and tested (FAT) at the Vendor's site in the presence of user's representative before delivery.

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<b>8.4</b>	<b>Phase - 3</b>
<b>8.4.1</b>	Vendor shall provide the following documents in the delivery package in minimum 2 sets. The delivery package shall reach the site of user at least 15 days before the delivery equipments for the engineering check of the documents.
<b>8.4.2</b>	Shipping checklist.
<b>8.4.3</b>	Operation and maintenance manuals; preventive maintenance instruction & schedule for equipment major component as well as the operating system. Control system operation manual. Cleaning procedures to be provided.
<b>8.4.4</b>	Operation and maintenance manuals for the bought out items (as applicable).
<b>8.4.5</b>	Drawings: Electrical, instrumentation, final GA drawing etc.
<b>8.4.6</b>	Spare and/ or change parts list with ordering information.
<b>8.4.7</b>	MOC certificates
<b>8.4.8</b>	Calibration certificates of critical instruments with respect to the traceable national reference standard instrument and their calibration procedure.
<b>8.4.9</b>	Comprehensive 1 year warranty from the date of completion.
<b>8.4.10</b>	Types of Lubricant and Lubrication instructions. Food grade certificates.
<b>8.4.11</b>	The Vendor shall provide start-up services through successful completion of the site acceptance test. The site acceptance test will be a repeat of the factory integration test performed at the Vendor's facility.

**9 Timelines**

NA

**NOTE:** Accurate size and technical specification need to be mentioned by the vendor.

		AFI Approved for Enquiry		AFO Approved for Ordering		
03'	Date	Completed By	Checked By	AFI	AFO	Sheet 1/3
	2014-02-17	BKSH	SDBB	<input type="checkbox"/>	<input type="checkbox"/>	
		<i>[Signature]</i>	<i>K. Prishorbanu</i>	<i>[Signature]</i>	<i>[Signature]</i>	

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*18/3/14*

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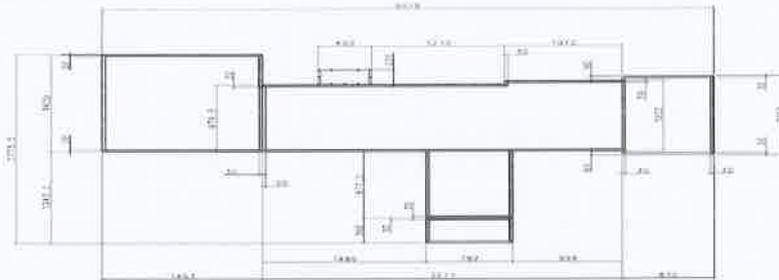
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S. NO.	ROOM NO.	ROOM TITLE	PURPOSE	INNER DIMENSION (L X W) In mm	
<b>GROUND FLOOR</b>					
FG-CLF 01	FG034	Stoppering Filling M/c.+Pcassttning	Above lyophiliser door	1800 X 1800	
FG-CLF 02	FG036	Receiving sterile material	Above dhs- unloading	1200 X 1200	
FG-CLF 03	FG036	Receiving sterile material	Above autoclave cum bung processor- unloading	1200 X 1200	
FG-CLF 04	FG026	Preparation & sterilisation	Above dhs- loading	1200 X 1200	
FG-CLF 05	FG026	Preparation & sterilisation	Above autoclave cum bung processor- loading	1200 X 1200	
FG-CLF 06	FG034	Stoppering Filling M/c.+cassttning	Extended C-LAF for Filling station vial cassetting	1350 X 1200	Vendor to specify actual dimensions
FG-CLF 07	FG034	Stoppering Filling M/c.+cassttning	Above filling machine	Refer drawing no 1	
FG-CLF 08	FG034	Stoppering Filling M/c.+cassttning	Above sealing machine	Refer drawing no 2	
<b>FIRST FLOOR</b>					
BF-CLF 09	BF016	Media preparation	Above autoclave- loading	1200 X 1200	
BF-CLF 10	BF033	Media bottle storage	Above autoclave- unloading	1200 X 1200	
BF-CLF 11	BF034	Sterilisation	Above autoclave- unloading	1200 X 1200	
BF-CLF 12	BF034	Sterilisation	Above dhs- unloading	1200 X 1200	
BF-CLF 13	BF050	Preparation	Above autoclave- loading	1200 X 1200	
BF-CLF 14	BF050	Preparation	Above dhs- loading	1200 X 1200	

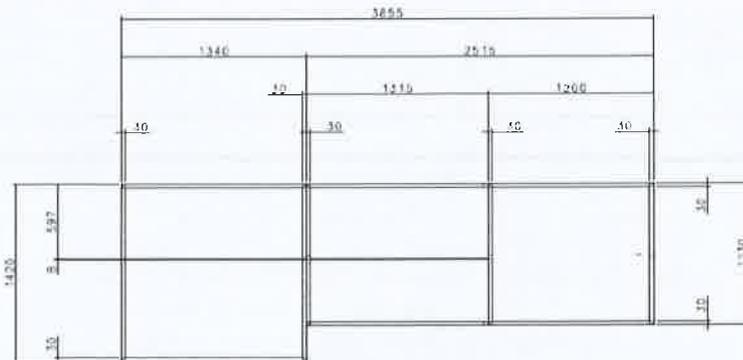
**Special note:** The C-LAF shall be sectionised into multiple parts as per the available filling ,Lyophilizer and sealing machine at site. Vendor will measure the actual dimensions onsite and fabricate the same for exact fit of the C- LAF on the machine to have a gapless fit and for extended C- LAF for Filling station vial cassetting.

1) Layout for Filling Machine



Drawing no 1

2) Layout for sealing Machine



Drawing no 2

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AFO Approved for Ordering

03'	2014-02-17	BKSH	SDBB	<input type="checkbox"/>	<input type="checkbox"/>	
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Handwritten signature and date: 14/7/14

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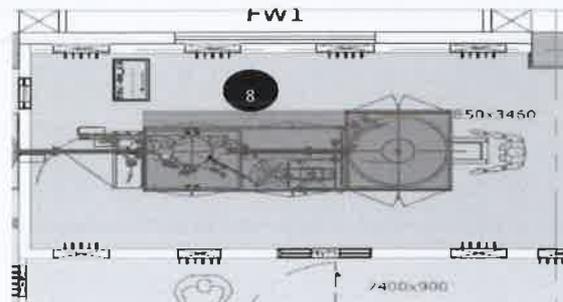
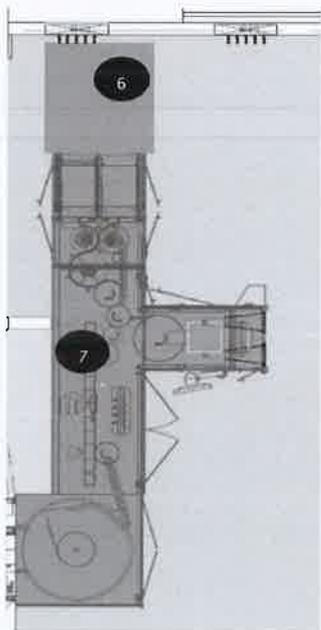
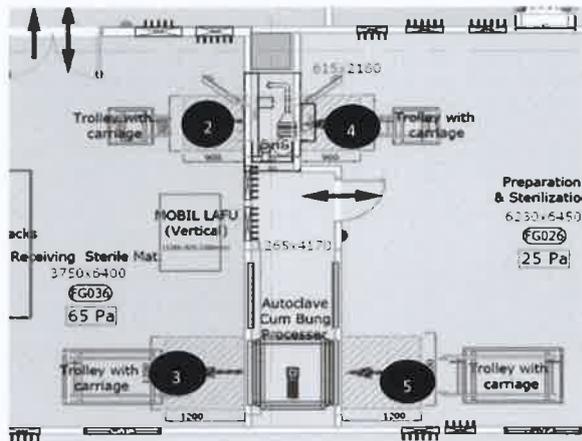
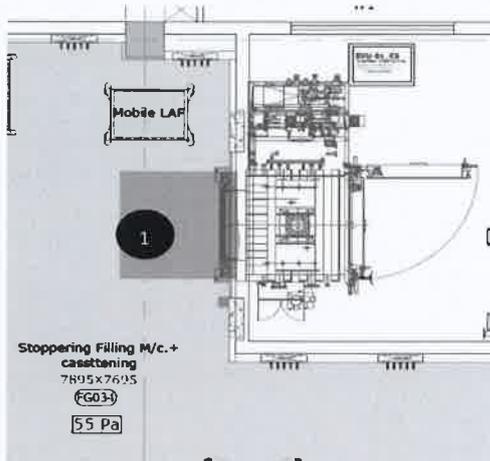
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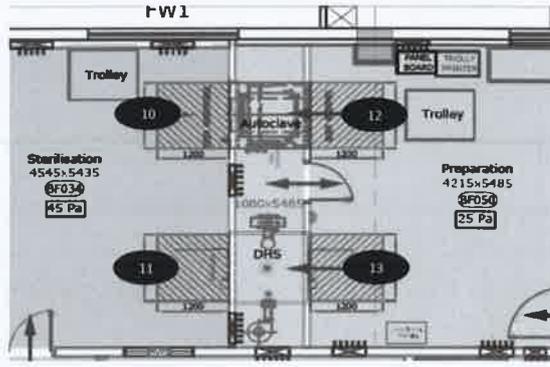
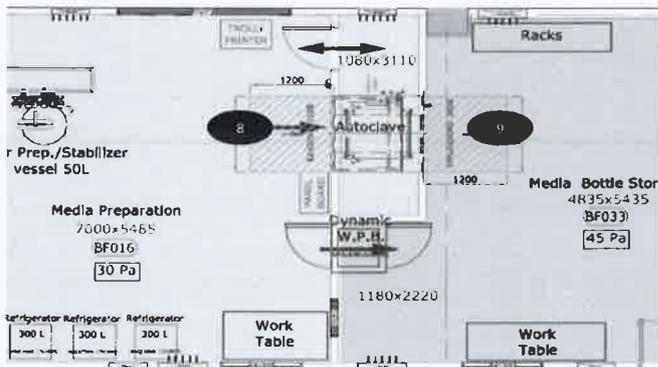


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GROUND FLOOR



FIRST FLOOR



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