

DATA SHEET

HLL LIFECARE LIMITED, CHENNAI

REVIVAL OF BCG VACCINE
LABORATORY, GUINDY, CHENNAI

Laminar Air Flow Bench

nne pharmaplan®

PROJECT #: 110729
EQ. ID #: FG-LAF 01
DOCUMENT # : DS/FG-LAF 01



1 Process requirements

1.1 This LAF bench will be used in IPQC room of formulation block (Ground floor).

2 Technical Specification

| | | | |
|------|------------------------|--|--|
| 2.1 | Model | cGMP LAF bench | |
| 2.2 | Type | Grade A (ISO 5) | |
| 2.3 | Overall Area (mm) | FG-LAF 01 | 1340 x 800 x 1850 (approx); vendor to specify exact dimension |
| 2.4 | Inner Area (mm) | vendor to specify exact dimension | |
| 2.5 | Type & Capacity | Vertical Laminar Air Flow type a) Uni-directional Laminar Air Flow type b) Double Stage filtration | |
| 2.6 | Pre- Filter | EU - 6 Efficiency > 95% Size: 5 µ | |
| 2.7 | HEPA Filter | H - 14 Efficiency > 99.997% Size: 0.3 µ | |
| 2.8 | UV light | a) UV light with Hour meter The light minimum hour life should be 5000 hr & light emitted shall be short-wave UV radiation with a peak at 253.7 nm (UV-C) for germicidal action. The hour meter should be able to be manually re-set. b) UV light with digital Hour Meter | |
| 2.9 | Air flow rate | 0.45 m/s ± 20% from 6" below the HEPA filter | |
| 2.10 | Quantity | 1 No | |
| 2.11 | Electrical Requirement | Power Consumption: Vendor to specify | |
| 2.12 | | 220-230 V, 50 Hz , Single phase | |




3 Material Of Construction



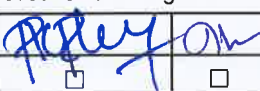
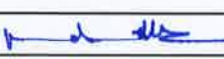
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|-----|-------------------|--|
| 3.1 | Body Construction | SS 304, min 240 grit |
| 3.2 | Support Stand | SS 304, min 240 grit |
| 3.3 | Coving | SS in built |
| 3.4 | Working Table | SS 316 |
| 3.5 | Side Panels | UV protected safety glass |
| 3.6 | Back Panels | SS 304 |
| 3.7 | MOC Fan | Aluminium or better |
| 3.8 | Safety Glass | UV protected safety glass |
| 3.9 | Wheels | Non shedding Teflon/Nylon with lockable castor wheels. |

4 All welds shall be ground finish

4 Specific requirment

- 4.1 Angled front bench shall be provide for the ease of the operator
- 4.2 Automatic front glass sash shall be provided with safe clear opening.
- 4.3 Blower System shall be balanced for vibration free operation and noise level.
- 4.4 The dead working table shall be SS 316 with zero vibration. One piece formed stainless steel work surface
- 4.5 1 no.- magnehelic guage to be provided to monitor the differential pressure across the HEPA filter
- 4.6 2no. Electrical switch/ sockets shall be provided with SS cladding flushed with cabinet walls.
- 4.7 Soft touch controls for blower, light, outlet and UV shall be provided along color coded indicator (different for each application)
- 4.8 UV light with hour meter shall be provided.
- 4.9 UV protected sheet shall be provided in the front

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| 4.10 | The UV lamp shall be interlocked with blower, sash, fluorescent lamp and UV lamp can be switched on only when the front sash is completely closed, otherwise it should give alarm | | |
| 4.11 | HEPA filter shall have an efficiency of 99.997 % when tested with DOP. | | |
| 4.12 | Pre-filters should be easily detachable for periodic cleaning. | | |
| 4.13 | LAF bench shall be provided with fluorescent lamp suitable to provide minimum 400 lux level. | | |
| 4.14 | Sleeving for accommodating the pre filters. | | |
| 4.15 | Side access panel for final filters and blowers. | | |
| 4.16 | LED display for motor operation. | | |
| 4.17 | Preferred make for Motor Blower assembly : Crompton Greaves/ ABB/ GE/ Siemens/EBM-PAPST/Nicotra | | |
| 4.18 | Approved make for filter: Camfil Farr/AAF/Freudenberg | | |
| 5 | Other requirements | | |
| 5.1 | Support stand shall be adjustable with manual lift on lockable caster wheels | | |
| 5.2 | Cleaning shall be done manually. | | |
| 5.3 | All bolts, nuts shall be of dome type of SS304 material | | |
| 5.4 | Vendor to give code numbers for each component | | |
| 5.5 | There shall be no crevices, so as to avoid dust accumulation | | |
| 5.6 | 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. | | |
| 5.7 | The design shall be maintenance friendly for the ease of replacement of filters | | |
| 5.8 | All parts of the machine exposed in A/B area must be resistant to standard disinfectants or vendor shall provide the name of specific disinfectants | | |
| 5.9 | The heat given off by the unit must be stated (inside the room). | | |
| 5.10 | Failure mode detection A. 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. c) LAF blower is stop. d) Alarm shall be triggered if the front door is raised more than safe clear opening during operation B. Following condition need only notification to operator for procedural control: a) Differential pressure across the HEPA filter not within the limit | | |
| 5.11 | Vendor to submit detailed fabrication drawing for approval before fabrication. | | |
| 5.12 | 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 | | |
| 6 | Regulatory guidelines / standards | | |
| 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 | | |
| 7 | Safety requirement | | |
| 7.1 | Following facilities must be provided to protect personnel and equipment: | | |
| 7.1.1 | Emergency stop function on accessible area. | | |
| 7.1.2 | Noise level below 75 decible. | | |
| 7.1.3 | Appropriate closure of all the rotating parts. | | |
| 8 | Documents | | |
| | Vendor to submit detailed fabrication drawing for approval before fabrication. | | |
| 8.1 | Phase 1: Post ordering and prefabrication stage of the equipment | | |
| 8.1.1 | Functional design specification containing: | | |

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| 8.1.2 | Equipment descriptions | | | | | |
| 8.1.3 | Equipment operation steps | | | | | |
| 8.1.4 | List of failure indications and interlocks (as applicable) | | | | | |
| 8.1.5 | Critical list of major component, devices and instruments with their specific functions, specs and data sheets. | | | | | |
| 8.1.6 | GA/ Schematic diagram of the equipment | | | | | |
| 8.1.7 | DQ Specification | | | | | |
| 8.1.8 | IOQ specification | | | | | |
| 8.2 | Phase - 2 | | | | | |
| 8.2.1 | Vendor shall provide the FAT protocol at least 1 month in advance of the date of FAT, for the approval by the user. | | | | | |
| 8.2.2 | System shall be inspected and tested (FAT) at the Vendor's site in the presence of user's representative before delivery. | | | | | |
| 8.3 | Phase - 3 | | | | | |
| 8.3.1 | 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. | | | | | |
| 8.3.2 | Shipping checklist. | | | | | |
| 8.3.3 | 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. | | | | | |
| 8.3.4 | Operation and maintenance manuals for the bought out items (as applicable). | | | | | |
| 8.3.5 | Drawings: Electrical, instrumentation, final GA drawing etc. | | | | | |
| 8.3.6 | Spare and/ or change parts list with ordering information. | | | | | |
| 8.3.7 | MOC certificates for all product contact surfaces. | | | | | |
| 8.3.8 | Calibration certificates of critical instruments with respect to the traceable national reference standard instrument and their calibration procedure. | | | | | |
| 8.3.9 | Comprehensive 1 year warranty from the date of completion. | | | | | |
| 8.3.10 | Types of Lubricant and Lubrication instructions. Food grade certificates. | | | | | |
| 8.3.11 | 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 | | | |
| | |  | K. Sricharhar |  |  | |
| 03' | 2014-02-17 | BKSH | SDBB | <input type="checkbox"/> | <input type="checkbox"/> | |
| Rev | Date | Completed By | Checked By | AFI | AFO | Sheet 1/2 |


 08/3/19

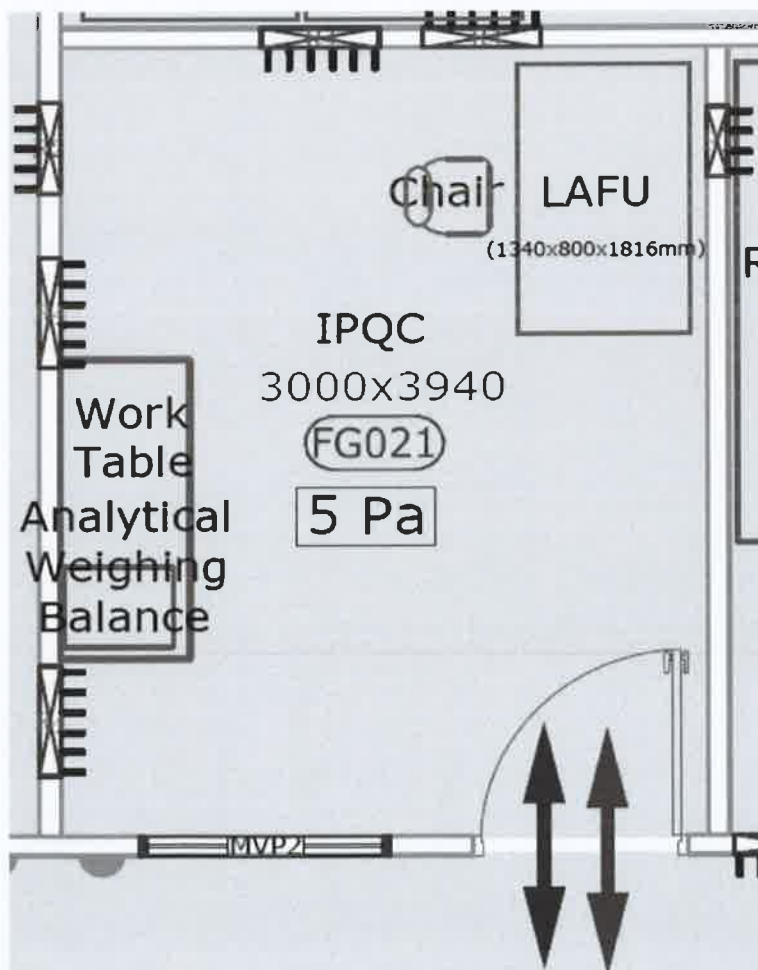
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| ROOM | GROUND FLOOR (FORMULATION AREA) |
|------|--|
| 1 | FG021: IPQC |
| 2 | ROOM DIMENSION: L(3000mm) X W(3940mm) |
| 3 | FALSE CEILING: 3000mm |
| 4 | ROOM PRESSURE : 5 Pa |



| | | | | | |
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