




| DATA SHEET | | | |
|-----------------------------------|---|--|--|
| HLL LIFECARE LIMITED, CHENNAI | | | |
| nne pharma ® plan | REVIVAL OF BCG VACCINE LABORATORY, GUINDY, CHENNAI | |  |
| | VHP Fumigation Unit | | |
| | PROJECT #: | 110729 | |
| | EQ. ID #: | BF-VHP 01 | |
| | DOCUMENT #: | DS/BF-VHP 01 | |
| 1 Process requirements | | | |
| 1.1 | The VHP fumigation unit is used for bio decontamination capable of 6-log sporicidal reduction of clean rooms, filling lines, manufacturing areas and Equipment Surfaces. (It is placed in Janitor room (FG023), BCGVL block, Ground floor) | | |
| 2 Technical Specifications | | | |
| 2.1 | Model | cGMP for clean room applications |  |
| 2.2 | Type | Mobile (Portable) | |
| 2.3 | Aerator type | Inbuilt / as accessory (Vendor to specify) | |
| 2.4 | Airflow rate (Gassing) | Vendor to specify | |
| 2.5 | Airflow rate (Air distribution) | Vendor to specify | |
| 2.6 | Airflow rate (Aeration) | Vendor to specify | |
| 2.7 | H ₂ O liquid injection rate | 10 g/min to 25 g/min or vendor to specify | |
| 2.8 | H ₂ O ₂ concentration | 30-40% (W / W) | |
| 2.9 | H ₂ O ₂ Tank capacity | The capacity should sufficient to carry one fumigation cycle based on maximum room volume indicated in the layout. | |
| 2.10 | Operating temperature | 15-40 °C | |
| 2.11 | Relative humidity | up to 75 % | |
| 2.12 | Filter | HEPA filter at exhaust of aerator | |
| 2.13 | Control system | Siemens/Allen Bradley | |
| 2.14 | Utility | Vendor to specify | |
| 2.15 | Power requirements | Vendor to specify | |
| 2.16 | Dimension | Vendor to specify Special Note: It should pass through dynamic pass box of size 1200 mm (D) X 1200 mm (W) X 1200 mm (H) | |
| 2.17 | Catalyst | Platinum based catalyst or vendor to specify | |
| 2.18 | Weight | Vendor to specify | |
| 2.19 | Accessories | H ₂ O ₂ solution, H ₂ O ₂ sensors (Portable), Chemical / Biological indicators, Adhesive tape, Housing for accessories | |
| 2.20 | Quantity | One no | |
| 3 Material Of Construction | | | |
| 3.1 | External surface | Polypropylene (PP) | |
| 3.2 | Wheels | Castor wheels or Vendor to specify | |
| 4 Specific requirments | | | |
| 4.1 | It should be suitable to fumigation of the room to kill the live mircobial organisms in clean rooms and on the surface of process equipments. | | |
| 4.2 | The equipment should be effective in decontaminating the rooms/ equipment against a wide range of micro-organisms. | | |
| 4.3 | Operation should be closed circuit. (it should not require any external vents during operation) | | |
| 4.4 | Fumigant should not react with the material / equipment to which it is exposed. | | |

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|  | | |
| 4.5 | It should have option for room pre-conditioning or dehumidification prior to fumigation. | |
| 4.6 | Equipment should be allowed to reach the saturated vapour conditions. | |
| 4.7 | The equipment should be compact and portable to carry to different rooms for fumigation. | |
| 4.8 | Equipment shall be able to quickly validate the bio decontamination cycles. | |
| 4.9 | There should be formation of micro-condensation to achieve rapid inactivation. | |
| 4.10 | Equipment should have a graphical display of bio-decontamination cycle progress tracking critical parameters during fumigation cycle. | |
| 4.11 | Equipment should have built in Hydrogen Peroxide gas sensor. | |
| 4.12 | It should measure and display concentration of Hydrogen peroxide vapour within the room throughout the cycle. | |
| 4.13 | Equipment should use refrigerant dryer which does not need to be regenerated or cartridge replaced. | |
| 4.14 | There should be system for room aeration to remove excess of H ₂ O ₂ to reduce it to less than 1ppm. | |
| 4.15 | Training for the technical persons to be included to handle and to operate the fumigation unit. | |
| 4.16 | Preferred Makes: a) Steris Life sciences b) Bioquell c) Sixlog | |
| 5 | Other requirements | |
| 5.1 | Control panel should have color touch screen, GAMP compliant software. | |
| 5.2 | It should have simple menu-driven user interface to set cycle parameters and access to bio-decontamination parameters. | |
| 5.3 | Communications port should allow integration to building management system (BMS) or related systems and equipment through volts free contact for external signals. | |
| 5.4 | There should be cycle edit and store facility for new applications. | |
| 5.5 | The equipment must be designed to retain the program in case of power loss and it should start from beginning and be able to recover with minimal operator actions. | |
| 5.6 | The equipment should be integrated with data logger recorder and printer. | |
| 5.7 | PLC control of the fumigation unit shall be outside the fumigation area. | |
| 5.8 | The control system should be PLC based along with touch screen and HMI screen size should be minimum of 12 inch. | |
| 5.9 | Data logging software to monitor and capture data like Cycle time, Temperature, Humidity, Concentration levels etc... | |
| 5.10 | The system should be equipped with fixed lockable castors for easy movement of equipment from one place to other place. | |
| 5.11 | The equipment should be designed for easy cleaning. | |
| 6 | Regulatory aspects | |
| | 21 CFR Part 11 Compliance: | |
| 6.1 | RS 232 interface is required to transfer the data as well as to take the print out. | |
| 6.2 | CE certification required | |
| 6.3 | UL certification required. | |
| 7 | Safety requirement | |
| 7.1 | The equipment should be integrated with audio or visual alarm in case of any failure. | |
| 7.2 | All fittings and stays must be chamfered against the plate on which they are mounted. | |
| 7.3 | No sharp edges/Corners, crevices, pin holes in the process wetted parts of the equipment. | |
| 7.4 | The operator should not be exposed to any moving parts during normal operation. | |
| 7.5 | Noise level below 75 decibel. | |

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- 7.6 There should be emergency stop function on both sides
- 7.7 If emergency button is pressed in between process, then door should not open until H₂O₂ concentration reaches less than 1ppm (i.e. exhaust should work accordingly)
- 7.8 All electrical wiring should be concealed for proper earthing.
- 7.9 In the event of equipment malfunction or loss of utilities, the unit must contain all necessary protection devices to ensure that the equipment remain in a safe condition.

8 Documents

- 8.1 IQ Protocol
- 8.2 OQ Protocol
- 8.3 MOC certificates
- 8.4 Operating manual
- 8.5 Vendor should provide one year warranty letter from date of supply

9 Timelines

NA

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

AFI Approved for Enquiry

AFO Approved for Ordering

| | | | | | | |
|-----|------------|--------------|------------|-------------------------------------|--------------------------|-----------|
| | | | | | | |
| 2 | 2013-12-18 | BKSH | SDBB | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| Rev | Date | Completed By | Checked By | AFI | AFO | Sheet 1/2 |

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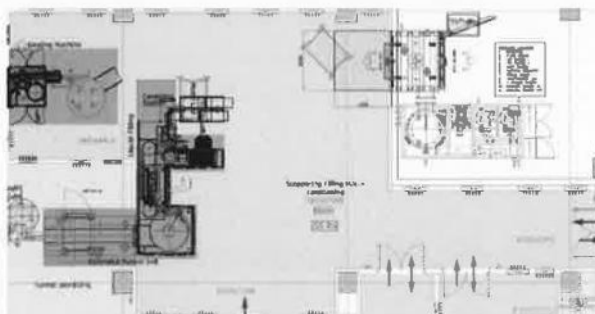
REVIVAL OF BCG VACCINE LABORATORY, GUINDY, CHENNAI

VHP Fumigation Unit

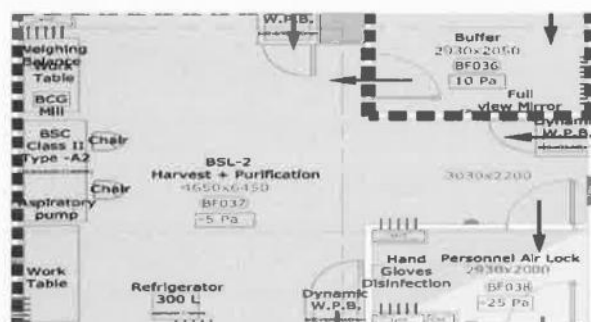
PROJECT #: 110729

EQ. ID #: BF-VHP 01

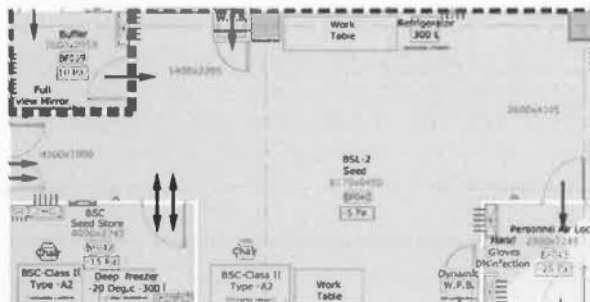
DOCUMENT #: DS/BF-VHP 01



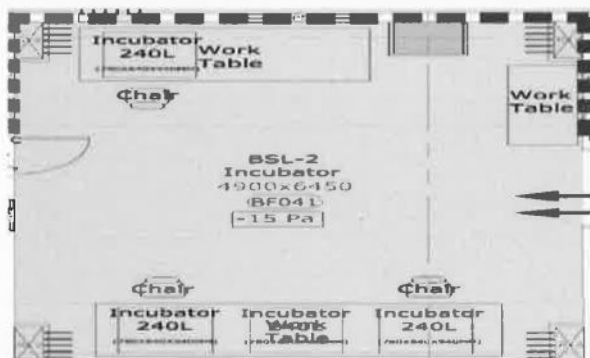
| | |
|-----------------------|----------------------------------|
| ROOM LOCATION: | FG034 |
| 1 | GROUND FLOOR |
| 2 | ROOM AREA: 102 m ² |
| 3 | FALSE CEILING: 3000 mm |
| 4 | ROOM PRESSURE : 55 Pa |
| 5 | Temperature: 22+/- 2°C |
| 6 | Relative humidity: < 55 % |





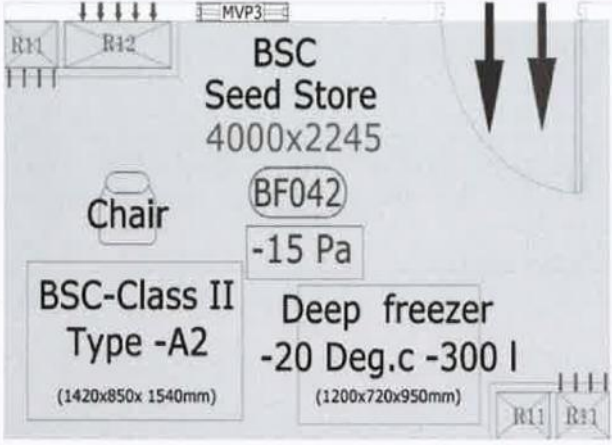
| | |
|-----------------------|---|
| ROOM LOCATION: | BF037 |
| 1 | FIRST FLOOR |
| 2 | ROOM DIMENSION: L X W: (4650X 6450) mm |
| 3 | FALSE CEILING: 3000mm |
| 4 | ROOM PRESSURE : - 5 Pa |
| 5 | Temperature: 22+/- 2°C |
| 6 | Relative humidity: < 55 % |



| | |
|-----------------------|------------------------------|
| ROOM LOCATION: | BF040 |
| 1 | FIRST FLOOR |
| 2 | ROOM AREA: 62 m ² |
| 3 | FALSE CEILING: 3000mm |
| 4 | ROOM PRESSURE : - 5 Pa |
| 5 | Temperature: 22+/- 2°C |
| 6 | Relative humidity: < 55 % |



| | |
|-----------------------|---|
| ROOM LOCATION: | BF041 |
| 1 | FIRST FLOOR |
| 2 | ROOM DIMENSION: L X W: (4900X 6450) mm |
| 3 | FALSE CEILING: 3000mm |
| 4 | ROOM PRESSURE : - 15 Pa |
| 5 | Temperature: 22+/- 2°C |
| 6 | Relative humidity: < 55 % |

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| 1 | FIRST FLOOR | | | | | | | | | | | | | | | | | | | | | |
| 2 | ROOM DIMENSION: | | | | | | | | | | | | | | | | | | | | | |
| 3 | L X W: (4000X 2250) mm | | | | | | | | | | | | | | | | | | | | | |
| 4 | FALSE CEILING: 3000mm | | | | | | | | | | | | | | | | | | | | | |
| 5 | ROOM PRESSURE : - 15 Pa | | | | | | | | | | | | | | | | | | | | | |
| 6 | Temperature: 22+/- 2°C | | | | | | | | | | | | | | | | | | | | | |
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| AFI Approved for Enquiry | | | AFO Approved for Ordering | | | | | | | | | | | | | | | | | | | |
| 2 | 2013-12-18 | BKSH | SDBB | <input checked="" type="checkbox"/> | <input type="checkbox"/> | | | | | | | | | | | | | | | | | |
| Rev | Date | Completed By | Checked By | AFI | AFO | Sheet 2/2 | | | | | | | | | | | | | | | | |