

**DATA SHEET**

**HLL LIFECARE LIMITED, CHENNAI**

**nne pharmaplan<sup>®</sup>**

**REVIVAL OF BCG VACCINE LABORATORY, GUINDY, CHENNAI**

**REFRIGERATOR**

|                       |                     |
|-----------------------|---------------------|
| <b>PROJECT No:</b>    | <b>110729</b>       |
| <b>EQUIPMENT ID :</b> | <b>BF-RFG 03_06</b> |
| <b>DOCUMENT No :</b>  | <b>DS/BF-RFG 02</b> |



|          |   |  |  |
|----------|---|--|--|
| <b>1</b> | <b>Process requirements</b>   |  |  |
| 1.1      | It is used to store the media chemicals and Buffer Storage required for the process.  |  |  |
| <b>2</b> | <b>Technical Specifications</b>   |  |  |
| 2.1      | Model   | cGMP Refrigerator with glass door in upper chamber and stainless steel door in lower compartment |  |
| 2.2      | Refrigerator compartment  | 300 L or near to standard  |  |
| 2.3      | External dimension (W X D X H mm)   | 600 x 750 x 2000 or near to standard   |  |
| 2.4      | Internal dimension (W X D X H mm)   | 500 x 550 x 1500 or near to standard   |  |
| 2.5      | Shelves (W X D mm)  | <b>vendor to specify</b>   |  |
| 2.6      | Height between the shelves (mm)   | <b>vendor to specify</b>   |  |
| 2.7      | No. of Shelves  | <b>vendor to specify</b> (SS 304 Perforated shelves shall be adjustable)                         |  |
| 2.8      | Purpose   | Media chemicals and Buffer Storage   |  |
| 2.9      | Temperature Range   | +1°C to +8°C   |  |
| 2.10     | Refrigrant  | R134a (HFC refrigerant) or <b>vendor to specify</b>  |  |
| 2.11     | Temperature precision   | ± 0.5 deg C  |  |
| 2.12     | Temperature precision (setting resolution)  | ± 1 deg C  |  |
| 2.13     | Temperature uniformity  | ± 2 deg C  |  |
| 2.14     | Air circulation   | Forced air circulation   |  |
| 2.15     | Quantity  | 4no.s  |  |
| <b>3</b> | <b>Material of construction</b>   |  |  |
| 3.1      | Body Construction   | Interior   | SS 304   |
|          |   | Shelves  | Perforated, SS304                                  |
|          |   | Exterior   | Powder coated GI sheet or <b>vendor to specify</b> |
| 3.2      | Gaskets, seals, o-rings   | Food Grade/ nontoxic material Use of Asbestos is prohibited                                      |  |
| 3.3      | Insulation  | Heavy walled CFC Free  |  |
| 3.4      | Door  | Double layer Borosilicate glass in upper chamber and Stainless steel door for lower chamber      |  |
| 3.5      | MOC Fan   | Aluminium  |  |
| 3.6      | All welds shall be ground finish  |  |  |
| <b>4</b> | <b>Specific requirements</b>  |  |  |
| 4.1      | Chamber should be rounded corners for easy cleaning.  |  |  |
| 4.2      | System shall be designed for 100% coverage of the internal surface areas for manual cleaning.   |  |  |
| 4.3      | The vendor shall provide the detail of cleaning agent based on compatibility of material.   |  |  |
| 4.4      | The refrigerators shall be provided with adjustable shelves for flexible storage.   |  |  |
| 4.5      | Refrigerator shall be fitted with double-roll lockable caster wheels for easy transportation.   |  |  |
| 4.6      | The control shall be microprocessor based with digital display cum controller.  |  |  |
| 4.7      | Key lock for Parameter change Protection to be provided.  |  |  |
| 4.8      | Temperature to be recorded, monitored and displayed. Temperature probe installed in freezer (Two nos).  |  |  |
| 4.9      | Temperature controlling must be based on set point.   |  |  |
| 4.10     | Provision/ device to be provided to monitor the equipment through Wireless device & to transfer the data from the equipment and also USB port to be provided for getting the batch data[Non editable] |  |  |
| 4.11     | Paper less data logger to be provided   |  |  |



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|-------------------------------|--|--------------|------------|---|--------------------------|-------------|
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| nne pharmaplan®               | REVIVAL OF BCG VACCINE LABORATORY, GUINDY, CHENNAI   |              |            |  |                          |             |
|                               | REFRIGERATOR   |              |            |   |                          |             |
|                               | PROJECT No:  | 110729       |            |   |                          |             |
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| 4.12                          | A complete batch record indicating the following important parameters, but not limited to these:<br>a) Date, Time<br>b) Infrared port (for optional data transmission)<br>c) All failures and alarms |              |            |   |                          |             |
| 4.13                          | Internal clock to be maintained to retrieve data at setpoint interval i.e.; 24 hrs .   |              |            |   |                          |             |
| 4.14                          | Positive air circulation by internal fans must be provided to ensure temperature uniformity and recovery   |              |            |   |                          |             |
| 4.15                          | Temperature sensor for set temperature   |              |            |   |                          |             |
| 4.16                          | Alarms for parameters like high temperature, low temperature shall be provided.  |              |            |   |                          |             |
| 4.17                          | Temperature set points should be adjustable.   |              |            |   |                          |             |
| 4.18                          | Alarm if door is open for >5 min.  |              |            |   |                          |             |
| 4.19                          | Light on/ off in case of glass door.   |              |            |   |                          |             |
| 4.20                          | Auto switch off of fan when door opens.  |              |            |   |                          |             |
| 4.21                          | Automatic defrost cycle and melt water evaporation in heated tray should be provided.  |              |            |   |                          |             |
| 4.22                          | Dry contact for remote alarm should be provided.   |              |            |   |                          |             |
| 4.23                          | 1 no. Door lock should be provided.  |              |            |   |                          |             |
| 4.24                          | Spring loaded, self closing door with 90° angle stay open feature should be provided with holder.  |              |            |   |                          |             |
| 4.25                          | Both the chambers shall have independent cooling system, controller, and power   |              |            |   |                          |             |
| 4.26                          | Ring back function if any alarm condition remains active   |              |            |   |                          |             |
| <b>5</b>                      | <b>Other requirements</b>  |              |            |   |                          |             |
| 5.1                           | A CE declaration of conformity must be available. The CE Identification must comply with the current EC instructions.  |              |            |   |                          |             |
| 5.2                           | Cleaning shall be done manually  |              |            |   |                          |             |
| 5.3                           | Control lights and other display elements shall not be influenced by voltage failure   |              |            |   |                          |             |
| 5.4                           | Installation of equipment with refrigerants has to be done by a certified cooling technician.  |              |            |   |                          |             |
| 5.5                           | The control circuit has to be 24 Volt  |              |            |   |                          |             |
| 5.6                           | Audio alarms have to be in the range of 2.3 — 2.9 kHz in order to avoid interference and confusion with evacuation alarms  |              |            |   |                          |             |
| <b>6</b>                      | <b>Regulatory guidelines / standards</b>   |              |            |   |                          |             |
|                               | NA   |              |            |   |                          |             |
| <b>7</b>                      | <b>Safety requirements</b>   |              |            |   |                          |             |
| 7.1                           | Emergency stop function on accessible area.  |              |            |   |                          |             |
| 7.2                           | Noise level below 75 decible.  |              |            |   |                          |             |
| 7.3                           | Proper earthing  |              |            |   |                          |             |
| 7.4                           | No sharp edges/Corners, crevices, pin holes in the process wetted parts of the equipment.  |              |            |   |                          |             |
| 7.5                           | In the event of equipment malfunction or loss of utilities, the unit must contain all necessary protection devices to ensure that the equipment and the product remain in a safe condition.          |              |            |   |                          |             |
| <b>8</b>                      | <b>Documents</b>   |              |            |   |                          |             |
| 8.1                           | FDS Document (If applicable)   |              |            |   |                          |             |
| 8.2                           | Technical Specifications   |              |            |   |                          |             |
| 8.3                           | MOC certificates   |              |            |   |                          |             |
| 8.4                           | IOQ protocol   |              |            |   |                          |             |
| 8.5                           | CE Certificate   |              |            |   |                          |             |
| 8.6                           | List of alarms   |              |            |   |                          |             |
| 8.7                           | Comprehensive 1 year warranty letter from date of supply.  |              |            |   |                          |             |
| <b>9</b>                      | <b>Timelines</b>   |              |            |   |                          |             |
|                               | NA   |              |            |   |                          |             |
|                               | <b>NOTE:</b> Accurate size and technical specification need to be mentioned by the vendor  |              |            |   |                          |             |
|                               | AFI Approved for Enquiry   |              |            | AFO Approved for Ordering   |                          |             |
| 5                             | 2013-12-18   | BKSH         | VKKA       | <input type="checkbox"/>  | <input type="checkbox"/> |             |
| Rev                           | Date   | Completed By | Checked By | AFI   | AFO                      | Sheet 1 / 2 |

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**DS/BF-RFG 02**



**ROOM LOCATION:**

**1**

**Room no:** BF016[1no.] ,BF037[3no.s]

**2**

**FALSE CEILING:** 3000mm

AFI Approved for Enquiry

AFO Approved for Ordering

5

2013-12-18

BKSH

VKKA



Rev

Date

Completed By

Checked By

AFI

AFO

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