

| DATA SHEET  |   |   |                               |   |
|---|---|---|-------------------------------|---|
| HLL Biotech Limited, Chennai  |   |   |                               |   |
|  | REVIVAL OF DPT VACCINE MANUFACTURING FACILITY, PII, COONOOR |   |                               |  |
|   | Refrigerator  |   |                               |   |
|   | Project #   | 110831  |                               |   |
|   | Document #  | DS-RFR 01   |                               |   |
| <b>1</b>  | <b>Process Requirements</b>                                 |   |                               |   |
| 1.1   | It is used to store materials at 2-8 °C                     |   |                               |   |
| <b>2</b>  | <b>Equipment ID, Capacity, and Quantity</b>                 |   |                               |   |
|   | <b>Equipment ID</b>   | <b>Minimum capacity (L) near to standard</b>                      | <b>Quantity (No.s)</b>        | <b>DoorType</b>   |
| 2.1   | B1-RFR 01   | 300   | 1 (Refer annexure 1)          | Vertical single door  |
| 2.2   | B1-RFR 02,03,04   | 300   | 3                             |   |
| 2.3   | B1-RFR 05   | 160   | 1                             |   |
| 2.4   | B2-RFR 01, 02   | 300   | 2                             |   |
| 2.5   | F1-RFR 01   | 300   | 1                             |   |
| 2.6   | M1-RFR 01,02  | 360   | 2                             | Vertical double door  |
| 2.7   | A2-RFR 01,02  | 300   | 2                             | Vertical single door  |
| 2.8   | A1-RFR 01,02  | 300   | 2                             |   |
| <b>3</b>  | <b>Technical Specification</b>                              |   |                               |   |
| 3.1   | Model   | cGMP  |                               |   |
| 3.2   | External dimension (W X D X H mm)                           | vendor to specify (based on the above mentioned capacity)         |                               |   |
| 3.3   | Internal dimension (W X D X H mm)                           | vendor to specify (As per the capacity)                           |                               |   |
| 3.4   | Shelves (W X D mm)  | vendor to specify (As per the capacity)                           |                               |   |
| 3.5   | Height between the shelves (mm)                             | vendor to specify   |                               |   |
| 3.6   | No. of Shelves  | vendor to specify (SS 304 Perforated shelves shall be adjustable) |                               |   |
| 3.7   | Temperature Range   | 2 °C to 8 °C  |                               |   |
| 3.8   | Refrigerant   | R 134a  |                               |   |
| 3.9   | Temperature precision                                       | ± 0.5 °C  |                               |   |
| 3.10  | Temperature stability                                       | ± 1 °C  |                               |   |
| 3.11  | Temperature Resolution                                      | ± 1 °C  |                               |   |
| 3.12  | Temperature uniformity                                      | ± 2 °C  |                               |   |
| 3.13  | Air circulation   | Forced air circulation  |                               |   |
| 3.14  | Quantity  | 300L- 11no.s  |                               |   |
|   |   | 160L-1 no.  |                               |   |
|   |   | 360L-2 no.s   |                               |   |
| 3.15  | Power requirement   | To be compatible to standard Indian Power supply socket.          |                               |   |
| <b>4</b>  | <b>Material of Construction</b>                             |   |                               |   |
| 4.1   |   | Interior  | SS 304                        |   |
| 4.2   | Body Construction   | Shelves   | Adjustable, Perforated, SS304 |   |

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| 4.3   |  | Exterior                      | cGMP compliant exterior   |
| 4.4   | Gaskets, seals, o-rings  | Food Grade/ nontoxic material |   |
| 4.5   | Insulation   | Polyurethane foam(PUF)        |   |
| 4.6   | Door   | Stainless steel door          |   |
| 4.7   | All welds shall be ground finish.  |                               |   |
| <b>5</b>  | <b>Specific Equipment Requirements</b>   |                               |   |
| 5.1   | The design of the equipment should facilitate efficient and easy cleaning  |                               |   |
| 5.2   | The equipment shall be compatible for cleaning with all standards disinfectants  |                               |   |
| 5.3   | Refrigerator shall be fitted with lockable caster wheels for easy transportation.  |                               |   |
| 5.4   | The control shall be microprocessor based with digital display cum controller.   |                               |   |
| 5.5   | Key lock for Parameter change Protection to be provided.   |                               |   |
| 5.6   | Temperature to be recorded, monitored and displayed. Circular chart recorder to be provided.(PT 100)   |                               |   |
| 5.7   | Interface port RS 232 to transfer data to be provided.   |                               |   |
| 5.8   | Positive air circulation by internal fans must be provided to ensure temperature uniformity and recovery   |                               |   |
| 5.9   | Audio visual alarms for parameters like high temperature, low temperature shall be provided and if door is open for > 5min.  |                               |   |
| 5.10  | Light on provision during door opening   |                               |   |
| 5.11  | Door lock should be provided.  |                               |   |
| 5.12  | Spring loaded, self closing door with 90° angle stay open feature should be provided with holder.  |                               |   |
| 5.13  | Validation Ports to be provided for inserting probes for temperature mapping.  |                               |   |
| 5.14  | Temperature mapping during installation is required.   |                               |   |
| 5.15  | Single compressor should be provided.  |                               |   |
| 5.16  | Equipment shall be compatible for cleaning with all standard disinfectant.   |                               |   |
| 5.17  | <b>Design Basis:</b> Refer Annexure 1 for specific design of B1-RFR 01   |                               |   |
| <b>6</b>  | <b>Other Requirements</b>  |                               |   |
| 6.1   | Training /Demo for the users on operation and cleaning to be provided.   |                               |   |
| <b>7</b>  | <b>Regulatory Aspects</b>  |                               |   |
| 7.1   | CE certification.  |                               |   |
| <b>8</b>  | <b>Safety Requirements</b>   |                               |   |
|   | <b>Following facilities must be provided to protect personnel and equipment:</b>   |                               |   |
| 8.1   | Proper earthing is necessary   |                               |   |
| 8.2   | No sharp edges/Corners in the equipment.   |                               |   |
| 8.3   | Appropriate closure of all parts.  |                               |   |
| <b>9</b>  | <b>Documents</b>   |                               |   |
|   | <b>Following documents, but not limited to these, are expected from the vendor as part of the supply package in hard copy as well as editable electronic file.</b> |                               |   |
| 9.1   | IOQ documents.   |                               |   |
| 9.2   | Operation and maintenance manuals shall be provided along with IOQ documents during installation at site.  |                               |   |
| 9.3   | Warranty letter for 1 year from the date of completion.  |                               |   |

| DATA SHEET                   |  |              |            |                           |  |             |
|------------------------------|--|--------------|------------|---------------------------|--|-------------|
| HLL Biotech Limited, Chennai |  |              |            |                           |  |             |
| nne pharmaplan®              | REVIVAL OF DPT VACCINE MANUFACTURING FACILITY, PII,<br>COONOOR   |              |            |                           | <br><small>HLL BIOTECH LIMITED<br/>(Subsidiary of HLL (India) Limited)<br/>(A Government of India Enterprise)</small> |             |
|                              | Refrigerator   |              |            |                           |  |             |
|                              | Project #  | 110831       |            |                           |  |             |
|                              | Document #   | DS-RFR 01    |            |                           |  |             |
| 9.4                          | Calibration certificate of critical instrument with respect to the traceable national reference standard instrument and their calibration procedure. |              |            |                           |  |             |
| 9.5                          | List of standard spare parts with ordering information   |              |            |                           |  |             |
| <b>10</b>                    | <b>Timelines</b>   |              |            |                           |  |             |
| 10.1                         | Not Applicable   |              |            |                           |  |             |
|                              | <b>NOTE:</b> Accurate size and technical specification need to be mentioned by the vendor  |              |            |                           |  |             |
|                              | AFI Approved for Enquiry   |              |            | AFO Approved for Ordering |  |             |
| 01                           | 24-09-2015   | MNS          | PULM       | <input type="checkbox"/>  | <input type="checkbox"/>   |             |
| Rev                          | Date   | Completed By | Checked By | AFI                       | AFO  | Sheet 1 / 3 |

**DATA SHEET**

**HLL Biotech Limited, Chennai**

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**REVIVAL OF DPT VACCINE MANUFACTURING FACILITY, PII, COONOOR**



**Refrigerator**

**Project #**

**110831**

**Document #**

**DS-RFR 01**

**TABLE NO: 1**

| EQUIPMENT ID | Block Name                                   | Room Name                          | Quantity(No's) | Capacity(L) | Room No | Room dimension in mm       | Room height in mm |             |      |
|--------------|--|------------------------------------|----------------|-------------|---------|----------------------------|-------------------|-------------|------|
| B1-RFR 01    | Diphtheria Bulk                              | Seed Preparation                   | 11             | 300         | B1G047  | 3500 x 6510                | 3000              |             |      |
| B1-RFR 02    | Diphtheria Bulk                              | IPQC                               |                |             | B1G057  | 2200 x 3310                | 3000              |             |      |
| B1-RFR 03    | Diphtheria Bulk                              | Media and buffer room              |                |             | B1G069  | 4900 x 3610<br>2000 x 2900 | 4000              |             |      |
| B1-RFR 04    | Pertussis Bulk                               | Seed preparation                   |                |             | B1G008  | 3500 x 6510                | 3000              |             |      |
| B2-RFR 01    | Tetanus Bulk                                 | IPQC                               |                |             | B2G026  | 3200 x 7435                | 3000              |             |      |
| B2-RFR 02    | Tetanus Bulk                                 | Seed preparation                   |                |             | B2G028  | 4600 x 3500<br>3675 x 2110 | 3000              |             |      |
| F1-RFR 01    | Formulation Block                            | Blending area                      |                |             | F1G057  | 5515 x 7730                | 4000              |             |      |
| A2-RFR 01    | Animal Experiment                            | Histopathology + Microbiology room |                |             | A2G019  | 6250 x 3250                | 3000              |             |      |
| A2-RFR 02    | Animal Experiment                            | Euthenesia + Post mortem room      |                |             | A2G021  | 4400 x 2550                | 3000              |             |      |
| A1-RFR 01    | Animal Breeding                              | Animal health monitor              |                |             | A1G012  | 2300 x 6350                | 2700              |             |      |
| A1-RFR 02    | Animal Breeding                              | Animal health monitor              |                |             | A1F014  | 2650 x 5215                | 2700              |             |      |
| M1-RFR 01-02 | Sterility Media Preparation and Microbiology | Lab                                |                |             | 2       | 360                        | M1G039            | 3020 x 5050 | 3000 |
| B1-RFR 05    | Pertussis Bulk                               | IPQC                               |                |             | 1       | 100                        | B1G018            | 2200 x 3310 | 3000 |

AFI Approved for Enquiry

AFO Approved for Ordering

| AFI Approved for Enquiry |            |              | AFO Approved for Ordering |            |      |                          |                          |
|--------------------------|------------|--------------|---------------------------|------------|------|--------------------------|--------------------------|
| 01                       | 24-09-2015 | MNS          |                           |            | PULM | <input type="checkbox"/> | <input type="checkbox"/> |
| Rev                      | Date       | Completed By |                           | Checked By | AFI  | AFO                      | Sheet 2/3                |

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| <b>nne pharmaplan®</b> | <b>REVIVAL OF DPT VACCINE MANUFACTURING FACILITY, PII,<br/>COONOOR</b> |                  | <br><small>HLL BIOTECH LIMITED<br/>(A Subsidiary of HLL Lifecare Limited)<br/>(A Government of India Enterprise)</small> |
|                        | <b>Refrigerator</b>  |                  |   |
|                        | <b>Project #</b>   | <b>110831</b>    |   |
|                        | <b>Document #</b>  | <b>DS-RFR 01</b> |   |

**Annexure 1 can contain specific equipment details**

| Table no. | Door type | Design Basis   |
|-----------|-----------|--|
| B1-RFR 01 | Vertical  | To store container having 6L (working volume) of 4 no.s seed flask<br>Glass bottle dimensions:<br>Diameter: 220 mm<br>Height: 360 mm |

|     |            | AFI Approved for Enquiry |            |                          | AFO Approved for Ordering |           |
|-----|------------|--------------------------|------------|--------------------------|---------------------------|-----------|
| 01  | 24-09-2015 | MNS                      | PULM       | <input type="checkbox"/> | <input type="checkbox"/>  |           |
| Rev | Date       | Completed By             | Checked By | AFI                      | AFO                       | Sheet 3/3 |