

## DATA SHEET

HLL BIOTECH LIMITED, CHENNAI

nne pharmanplan

REVIVAL OF DPT VACCINE MANUFACTURING FACILITY, PII, COONOR

ELISA Reader

Project No : 110831

Equipment ID : ELR 01


Document No : DS/ELR 01



|      |  |  |
|------|--|--|
| 1    | <b>Process requirements</b>  |  |
| 1.1  | ELISA readers are designed to detect biological samples in microliters, used in drug discovery, clinical trials, manufacturing processes in pharmaceutical industries. |  |
| 2    | <b>Technical Specifications</b>  |  |
| 2.1  | Microplate type  | 6 to 1536 well plates (Client to confirm)    |
| 2.2  | Filters  | Standard filtration system                   |
| 2.3  | Filter size  | 405 nm, 450 nm, 620 nm                       |
| 2.4  | Shaking  | linear shaking, 3 speeds (Vendor to confirm) |
| 2.5  | Measurement speed  | vendor to specify                            |
| 2.6  | Read out range   | 0 to 6 Abs                                   |
| 2.7  | Resolution   | 0.001 Abs                                    |
| 2.8  | Accuracy   | ± 1 %  |
| 2.9  | Temperature control  | 4 °C to 50 °C                                |
| 2.10 | Wavelength range   | 200 nm to 1000 nm                            |
| 2.11 | Wavelength accuracy  | ± 1 nm                                       |
| 2.12 | Bandwidth  | 2 nm   |
| 2.13 | Light source   | vendor to specify                            |
| 2.14 | Electrical requirement   | vendor to specify                            |
| 2.15 | Detectors  | vendor to specify                            |
| 2.16 | Quantity   | 1 no.  |
| 3    | <b>Material of Construction</b>  |  |
| 3.1  | Main body  | vendor to specify                            |
| 4    | <b>Specific requirements</b>   |  |
| 4.1  | Suitable ELISA reader software shall be provided   |  |
| 4.2  | Fully automatic functioning  |  |
| 4.3  | Printed test plate comparison data sheet should be provided to compare the data obtained by microplate reader at specific wavelength for accuracy.                     |  |
| 4.4  | Three broad spectrum light source to accommodate a wide variety of assays  |  |
| 5    | <b>Other requirements</b>  |  |
| 5.1  | Automatic shut off shall be provided   |  |
| 5.2  | Appropriate training to be given for our employees to operate the equipment  |  |
| 5.3  | Vendor shall provide the option to record the data.  |  |
| 6    | <b>Regulatory aspects</b>  |  |
| 6.1  | NA   |  |

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|--|---|-----------------|---|---------------------------|--------------------------|-----------|
| nne pharmaplan   | REVIVAL OF DPT VACCINE MANUFACTURING FACILITY, PII, COONOOR   |                 |  <b>HLL BIOTECH LIMITED</b><br><small>(Subsidiary of HLL Lifecare Limited)<br/>         (A Government of India Enterprise)</small> |                           |                          |           |
|  | ELISA Reader  |                 |   |                           |                          |           |
|  | Project No :  | 110831          |   |                           |                          |           |
|  | Equipment ID :  | ELR 01          |   |                           |                          |           |
|  | Document No :   | DS/ELR 01       |   |                           |                          |           |
| <b>7</b>   | <b>Safety requirements</b>  |                 |   |                           |                          |           |
| 7.1  | Proper earthing of the equipment  |                 |   |                           |                          |           |
| <b>8</b>   | <b>Documents</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 |   |                 |   |                           |                          |           |
| 8.1  | IOQ Protocol.   |                 |   |                           |                          |           |
| 8.2  | Operation and maintenance manuals shall be provided along with IQ and OQ documents during installation at site  |                 |   |                           |                          |           |
| 8.3  | Calibration certificate of critical instruments with respect to the traceable national reference standard instrument and their calibration procedure. |                 |   |                           |                          |           |
| 8.4  | All equipment warranty should be valid for one year from the date of completion.  |                 |   |                           |                          |           |
| 8.5  | Vendor should provide list of standard spare parts with ordering information.   |                 |   |                           |                          |           |
| 8.6  | Vendor should provide list of change parts (if applicable) with ordering information  |                 |   |                           |                          |           |
| <b>9</b>   | <b>Timelines</b>  |                 |   |                           |                          |           |
| Not Applicable   |   |                 |   |                           |                          |           |
|  | AFI Approved for Enquiry  |                 |   | AFO Approved for Ordering |                          |           |
|  |   | <i>D. Kumar</i> | <i>Pulm</i>   |                           |                          |           |
| 01   | 09-09-2015  | NRU             | PULM  | <input type="checkbox"/>  | <input type="checkbox"/> |           |
| Rev  | Date  | Completed By    | Checked By  | AFI                       | AFO                      | Sheet 1/2 |

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| <br>HLL BIOTECH LIMITED<br>(Subsidiary of HLL Lifescare Limited)<br>(A Government of India Enterprise) | REVIVAL OF DPT VACCINE MANUFACTURING FACILITY, PII,<br>COONOR |           |
|   | ELISA Reader  |           |
|   | Project No :  | 110831    |
|   | Equipment ID :  | ELR 01    |
|   | Document No :   | DS/ELR 01 |

TABLE NO: 1

| Equipment Id | Block Name      | Room Name             | Room No | Quantity |
|--------------|-----------------|-----------------------|---------|----------|
| A1-ELR-01    | Animal Breeding | Animal health monitor | A1G012  | 1        |

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