







| DATA SHEET | | | |
|--|---|---|---|
| HLL Biotech Limited, Chennai | | | |
|  | REVIVAL OF DPT VACCINE MANUFACTURING FACILITY, PII, COONOR | |  |
| | Anesthesia System | | |
| | PROJECT No : | 110831 | |
| | DOCUMENT No : | DS-ANS 01 | |
| 1 | Equipment ID and Process requirements | | |
| | Equipment ID | Process requirements | |
| 1.1 | A2-ANS 01 | It is used to anesthetize the animals like mice, guinea pigs in the animal experimental block | |
| 1.2 | A2-ANS 02 | | |
| 2 | Technical Specifications | | |
| 2.1 | Model | cGLP (Compact and versatile) | |
| 2.2 | Oxygen Flowmeter Volume | 0-4 liters per minute @ 55 psi | |
| 2.3 | Relative humidity | NMT 55 % | |
| 2.4 | Oxygen Flush Volume | 15-35 liters per mintue @ 55 psi. | |
| 2.5 | Gas Supply | Oxygen male DISS connector | |
| 2.6 | Gas Pressure Requirements | 50-55 psi. | |
| 2.7 | Flowmeter type | Single-turn metering valve | |
| 2.8 | Oxygen Flush | Plunger-actuated, springreturn valve | |
| 2.9 | Flex hose diameter | 20-22 mm or Vendor to specify | |
| 2.10 | Dimension, (W X D X H) | (280 X 220 X 360) mm or Vendor to specify | |
| 2.11 | Weight | 15 kg or Vendor to specify | |
| 2.12 | Number of animals to be handled | 15-20 nos. at a time | |
| 2.13 | Quantity | 2 nos. | |
| 3 | Material Of Construction | | |
| 3.1 | Body frame | cGLP Compliance | |
| 3.2 | Valves | cGLP Compliance | |
| 3.3 | bolts and screws | Stain-less steel | |
| 3.4 | Vaporizer | SS | |
| 4 | Specific requirments | | |
| 4.1 | Anesthesia system should be able to anasthetize the mice, guinea pigs at-least 15-20 numbers at a time. | | |
| 4.2 | It should use isoflurane as anesthetic. | | |
| 4.3 | Oxygen should flow from the pressurised tank to anesthesia machine through the DISS(Diameter Indix Safety System) connections. | | |
| 4.4 | Oxygen should pass through the vaporizer. (When oxygen flush valve closed) | | |
| 4.5 | Vaporizer should be fitted on non-skid feet. | | |
| 4.6 | When oxygen flush valve opened, oxygen should flow directly into patient circuit at a rate of approximately 15-35 LPM. | | |
| 4.7 | Amount of anesthetic agent vapor that will be added to oxygen flow should vary from 0-5 % of the total flow. | | |
| 4.8 | Lines from the vaporizer and the oxygen flush valve should merge through the common outlet and into the dual breathing circuit. | | |
| 4.9 | Dual breathing circuit should be bifurcated by a Y-fitting in to two branches. | | |
| 4.10 | Dual breathing circuit should be connected to the induction chamber and charcoal circuit. | | |
| 4.11 | A stopcock within each branch of the circuit should provide independent control of each branch. | | |
| 4.12 | Channels from the dual breathing circuit, one branch should go to the induction chamber and other channel should go to the patient breathing circuit. | | |
| 4.13 | There should be provision for two charcoal filters. | | |
| 4.14 | One charcoal filter should be connect to the induction chamber. Another charcoal filter should be connect to end of the patient breathing circuit. | | |

| DATA SHEET | | | | | | |
|--|--|--------------|------------|---|--------------------------|-----------|
| HLL Biotech Limited, Chennai | | | | | | |
|  | REVIVAL OF DPT VACCINE MANUFACTURING FACILITY, PII, COONOR | | |  | | |
| | Anesthesia System | | | | | |
| | PROJECT No : 110831 | | | | | |
| | DOCUMENT No : DS-ANS 01 | | | | | |
| 4.15 | Accessories required: <ul style="list-style-type: none"> ▪ Mouse and rat-sized nosecones ▪ Oxygen supply hose (Diameter Indix Safety System) ▪ Flex hose ▪ Blue connector (Black tubing) | | | | | |
| 5 | Other requirements | | | | | |
| 5.1 | Cleaning shall be done manually. | | | | | |
| 5.2 | All bolts, nuts on the exterior part of system will be with cap head or cap nut. | | | | | |
| 5.3 | Vendor to give code numbers for each component | | | | | |
| 5.4 | In general the equipment has to be designed in a way to get easy and quick access to all necessary maintenance points. Ex. dual breathing circiut, induction chamber, vaporizer, charcoal filters, DISS connections etc. | | | | | |
| 5.5 | The design shall be maintenance friendly for the ease of replacement of charcoal filters. | | | | | |
| 5.6 | All parts of the system exposed in classified area must be resistant to standard disinfectants or vendor shall provide the name of specific disinfectants | | | | | |
| 6 | Regulatory aspects | | | | | |
| 6.1 | cGLP compliances | | | | | |
| 6.2 | As per CPCSEA (Committee for the purpose of Control and Supervision On Experiments On Animals)guidelines | | | | | |
| 7 | Safety requirements | | | | | |
| 7.1 | All solid surfaces of anesthesia system must be impervious or painted, to facilitate cleaning and disinfection. | | | | | |
| 7.2 | Appropriate closure of all the parts. | | | | | |
| 8 | Documents | | | | | |
| | 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 | | | | | |
| 9 | Timelines | | | | | |
| | NA | | | | | |
| | NOTE: Accurate size and technical specification need to be mentioned by the vendor. | | | | | |
| | AFI Approved for Enquiry | | | AFO Approved for Ordering | | |
| 01 | 2015-10-01 | MNS | PULM | <input type="checkbox"/> | <input type="checkbox"/> | |
| Rev | Date | Completed By | Checked By | AFI | AFO | Sheet 1/2 |

| DATA SHEET | |
|------------|--|
|------------|--|

| | |
|------------------------------|--|
| HLL BIOTECH LIMITED, CHENNAI | |
|------------------------------|--|

| | | | |
|---|--|------------------|---|
|  | REVIVAL OF DPT VACCINE MANUFACTURING FACILITY, PII, COONOOR | |  |
| | Anesthesia System | | |
| | PROJECT No : | 110831 | |
| | DOCUMENT No : | DS-ANS 01 | |

| |
|-------------|
| TABLE NO: 1 |
|-------------|

| EQUIPMENT ID | Block Name | Room Name | Room No | Room dimension in mm | Room height in mm |
|--------------|-------------------|--------------------------------|---------|----------------------|-------------------|
| A2-ANS 01 | Animal Experiment | Euthenesia + Post morterm room | A2G021 | 4400 x 2550 | 3000 |
| A2-ANS 02 | Animal Experiment | Euthenesia + Post morterm room | A2G021 | 4400 x 2550 | 3000 |

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

| | | | | | | |
|-----|--------------------------|--------------|---------------------------|--------------------------|--------------------------|-----------|
| | AFI Approved for Enquiry | | AFO Approved for Ordering | | | |
| 01 | 2015-10-01 | MNS | PULM | <input type="checkbox"/> | <input type="checkbox"/> | |
| Rev | Date | Completed By | Checked By | AFI | AFO | Sheet 2/2 |