

DATA SHEET

HLL Biotech Limited, Chennai

nne pharmaplan®

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

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.

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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)
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5	Other requirements
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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
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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
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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
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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
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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

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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.

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