

DATA SHEET

HLL BIOTECH LIMITED, CHENNAI

	REVIVAL OF DPT VACCINE MANUFACTURING FACILITY, PII, COONOOR		
	Bacterial Incubator		
	Project :	110831	
	EQUIPMENT ID :	See Annexure -1	
	Document :	DS-BIC 01	

1 Process requirements

1.1 The incubator shall be used for storage of samples under controlled conditions.

2 Equipment ID, Capacity and Temperature range

2.1	Equipment ID	Capacity (L) (Nearest to standard)	Temperature range (°C)	Quantity (No's)		
2.2	B1-BIC 01	150	35 ± 1	1		
2.3	B2-BIC 01	150	35 ± 1	1		
2.4	M1-BIC 01, 02	150	35 ± 1	2		
2.5	M1-BIC 03, 04	150	23 ± 1	2		

3 Technical Specification

3.1	Model	BOD Incubator.
3.2	Temperature control	Microprocessor with P.I.D
3.3	Temperature Readability(Resolution)	0.1 °C
3.4	Number of shelves	TBD; 3 or 4 adjustable and perforated SS shelves
3.5	Refrigerant	CFC Free
3.6	Display type	LED Display
3.7	Power supply	230 V, 50 Hz or Vendor to specify
3.8	Total quantity	6 no's
3.9	Dimensions (W x D x H) Internal Work area External dimensions	Vendor to specify

4 Material of Construction

4.1	External body Construction	cGMP compalint material
4.2	Internal body Construction	SS 304, electropolished.
4.3	Inner Door	Safety transparent door
4.4	Outer Door	Fully insulated SS door with lock and handle
4.5	Finishes	a) Rounded inner chamber corners for easy cleaning b) Design of the equipment should enhance cleaning by providing minimum sharp
4.6	Gaskets, seals, O-ring	Food Grade/ nontoxic material; Use of Asbestos is prohibited
4.7	Expected operational hours per day	24 hrs

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4.8	Validation	Validation port to be provided to insert probes for temperature mapping	
5	Specific Equipment requirement		
5.1	Temperature mapping to be provided at the time of installation		
5.2	The body construction shall provide temperature stability.		
5.3	The gap between the outer and the inner wall should be fitted with highgrade poly urethane foam		
5.4	It shall have forced air circulation to achieve uniformity of conditions.		
5.5	Incubator shall include a safety thermostat.		
5.6	Compressor shall have overload relay.		
5.7	It should have viewing window in the doors.		
5.8	There should be independent over-temperature safety protection.		
5.9	It should have lockable adjustable feet and stable casters for stability and easy repositioning incubator.		
5.10	Alarm : (Visual - Audio) for temperature deviation		
5.11	Equipment design must realize zero contamination.		
5.12	The heat/noise level given off by the unit shall be stated (inside the room).		
5.13	Vendor should provide four electrical sockets for accessories.		
6	Other requirement		
6.1	The equipment must be easy to clean and shall be compatible for cleaning with all standard disinfectants		
6.2	Training for the users must be provided.		
7	Regulatory aspects		
7.1	CE certification		
8	Safety requirements		
8.1	Doors interlocking alarm (visual/ audio).		
8.2	Noise level should be below 60 decible at a distance of 1m from the equipment		
9.3	Chamber shall be insulated properly to maintain inner environment		
9	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			

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9.1	IOQ Protocol.
9.2	Operation and maintenance manuals shall be provided along with IQ and OQ documents during installation at site
9.3	Calibration certificate of critical instruments with respect to the traceable national reference standard instrument and their calibration procedure.
9.4	All equipment warranty should be valid for one year from the date of completion.
9.5	Vendor should provide list of standard spare parts with ordering information.
9.6	Vendor should provide list of change parts (if applicable) with ordering information

10 Timelines

Not Applicable

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

	AFI Approved for Enquiry	AFO Approved for Ordering			
01	30-09-2015	MNS	PULM	<input type="checkbox"/>	<input type="checkbox"/>
Rev	Date	Completed By	Checked By	AFI	AFO

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TABLE NO: 1					
Equipment ID	Block Name	Room Name	Room No	Room dimension in mm	Room height in mm
B1-BIC 01	Pertussis Block	IPQC	B1G018	2200 x 3310	3000
B2-BIC 01	Tetanus Block	Seed preparation	B2G028	4600 x 5280	3000
M1-BIC 01, 02, 03 04	Microbiology and QC	Incubator room	M1G025	5825 x 2875	2400

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