

Equipment Specification Data Sheet

Equipment Name: BOD Incubator

Document No.: DS-BIC 02

Revision: 00

Project No.: 120310

Project Name: Integrated Vaccines Complex, Chengalpattu

Block Code	Block Name	Identification No.	Capacity	Quantity
Q1	Admin QA & QC	Q1-BIC 01	200L to 260L	1

NNE Pharmaplan India Limited

Name	Designation	Signature	Date
Prepared by			
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HLL Biotech Limited

Name	Designation	Signature	Date
Reviewed by			
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HLL Biotech Limited, CHENNAI

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INTEGRATED VACCINES COMPLEX, CHENGALPATTU



Equipment Name	BOD Incubator
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1	Process Requirement	
1.1	The incubator shall be used for storage of samples under controlled conditions.	
2	Equipment ID	
2.1	Q1-BIC 01	
3	Technical Specification	
3.1	Model	BOD Incubator.
3.2	Temperature control	Microprocessor with P.I.D
3.3	Temperature range	15 to 60 °C
3.4	Temperature Readability(Resolution)	0.1 °C
3.5	Number of shelves	3 or more adjustable and perforated SS304 shelves
3.6	Refrigerant	CFC Free
3.7	Display type	LED/LCD Display
3.8	Capacity	200L to 260L
3.9	Power supply	To be compatible to standard Indian Power supply socket
3.10	Quantity	1 No
3.11	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 epoxy coated material
4.2	Internal body Construction	SS 316L/SS 304, electropolished.
4.3	Inner Door	Safety transparent door
4.4	Outer Door	SS304/Powder coated
4.5	Finishes	a) Rounded inner chamber corners for easy cleaning b) Design of the equipment should enhance cleaning by providing minimum sharp corners, minimum crevices and smooth finished welds joints
4.6	Gaskets, seals, O-ring	Food Grade/ nontoxic material like neoprene or better. Use of Asbestos is prohibited
4.7	Expected operational hours per day	24 hrs
4.8	Validation	Validation port to be provided to insert probes for temperature mapping
5	Specific Equipment Requirements	
5.1	Temperature mapping to be provided at the time of installation	
5.2	The body construction shall provide tempearture stability.	
5.3	The gap between inner & outer walls of chamber should be fitted with high grade polyurathane foam (PUF), to ensure maximum temperature efficiency.	
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	There should be independent over-temperature safety protection.	
5.8	It should have lockable adjustable feet and stable casters for stability and easy repositioning incubator.	
5.9	Alarm : (Visual - Audio) for temperature deviation	

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5.10	Equipment design must realize zero contamination.		
5.11	The heat/noise level given off by the unit shall be stated (inside the room).		
5.12	The equipment shall be compatible for cleaning with all standard disinfectants		
6	Other Requirement		
6.1	Training/Demo for the users on operation and cleaning to be provided.		
7	Regulatory aspects		
7.1	CE certification		
8	Safety Requirements		
	Following facilities must be provided to protect personnel and equipment:		
8.1	Appropriate closure of all parts		
8.2	Proper earthing is necessary		
8.3	Doors interlocking alarm (visual/ audio).		
8.4	Noise level should be below 60 decible at a distance of 1m from the equipment		
8.5	Chamber shall be insulated properly to maintain inner environment		
9	Documents		
9.1	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		
9.2	IOQ document.		
9.3	Operation and maintenance manuals shall be provided along with IOQ documents during installation at site		
9.4	Calibration certificate of critical instruments with respect to the traceable national reference standard instrument and their calibration procedure.		
9.5	Warranty Letter for Minimum 1 year from the date of installation.		
9.6	Vendor should provide list of standard spare parts with ordering information.		
9.7	Vendor should provide list of change parts (if applicable) with ordering information		
10	Timelines		
10.1	Not Applicable		
11	Preferred list of Makes		
11.1	Binder, Memmert, Thermo Scientific, Eppendorf		
	NOTE: Accurate size and technical specification need to be mentioned by the vendor		

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Table-1: Equipment location

Equipment ID	Block Name	Room Name	Room No	Room dimension in mm	Room height in mm
Q1-BIC 01	Admin QA & QC	Microbiology Lab	Q1S045	3700 x 4600	2400

Table-2: Change Log

Date	Name	Revision	Section	Change/Comment
10-02-2016	Sandeep Kumar	00	-	New document

Table-3: Annexure

Not applicable