

Equipment Specification Data Sheet

Equipment Name: Incubator

Document No.: DS-INC 02

Revision: 00

Project No.: 120310

Project Name: Integrated Vaccines Complex,
 Chengalpattu

Block Code	Block Name	Identification No.	Capacity (L)	Quantity
B4	Rabies Bulk	B4-INC 01	240 - 300	1
B4	Rabies Bulk	B4-INC 02	240 - 300	1
B4	Rabies Bulk	B4-INC 03	400- 500	1
G1	Animal House	G1-INC 01	240 - 300	1
G1	Animal House	G1-INC 02	240 - 300	1
Q1	Admin QA & QC	Q1-INC 01	240 - 300	1
Q1	Admin QA & QC	Q1-INC 02	240 - 300	1
Q1	Admin QA & QC	Q1-INC 03	240 - 300	1
Q1	Admin QA & QC	Q1-INC 04	240 - 300	1
Q1	Admin QA & QC	Q1-INC 05	240 - 300	1

NNE Pharmaplan India Limited

Name	Designation	Signature	Date
Prepared by			
Mr. Sandeep Kumar	Process Engineer	<i>Sandeep</i>	18/02/16
Checked by			
Mr. Yogesha M J	Process Engineer	<i>yogesha-mj</i>	18/02/2016
Approved by			
Dr. Harshad Mali	Lead Engineer - Process	<i>H</i>	19/02/16

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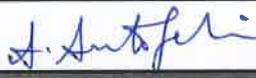
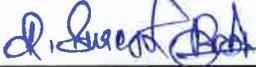
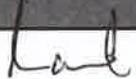
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Project Name: Integrated Vaccines Complex,
Chengalpattu

HLL Biotech Limited

Name	Designation	Signature	Date
Reviewed by			
User department: Rabies Bulk P. NAYAN KUMAR	DEPUTY MANAGER		03.03.16
User department: Animal House K. JASVANTH REDDY	Deputy Manager		02.03.16
User department: Quality Control SANTHOSH K. R.	MANAGER		29/02/16
Project / Engineering department A. ANO TEL K	Manager		29.02.16
Approved by			
Head of the department Rabies Bulk Dr. J. J. S. S. S.	Project head (VV)		03.03.16
Head of the department Animal House Dr. K. A. H. H. H.	MANAGER		03.03.16
Head of the department Quality Control V. S. S. S. S.	Manager		03.03.16
Head of the department (C) S. S. S. S. S.	DM		03.03.16
Authorized by			
Project Authority Raman K. R.	CEO		7.3.16

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HLL Biotech Limited, Chennai					
nne pharma plan*	INTEGRATED VACCINES COMPLEX, CHENGALPATTU				
	Equipment Name	Incubator			
	Document No.	DS-INC 02			
	Revision No.	00			
					
1	Process requirements				
1.1	The incubator shall be used for incubation of biological samples under controlled conditions				
2	Identification no	Volume in L	Table top/floor model	In built Data logging	Process requirements
2.1	B4-INC 01	240 - 300	Vendor to specify	NA	The incubator shall be used for incubation of biological samples under controlled conditions.
2.2	B4-INC 02	240 - 300	Vendor to specify	NA	
2.3	B4-INC 03	400- 500	Vendor to specify	Data logging with Thermal Printer Power Supply-provision to be provided to operate magnetic stirrers inside the incubator	
2.4	G1-INC 01	240 - 300	Vendor to specify	NA	
2.5	G1-INC 02	240 - 300	Vendor to specify	NA	
2.6	Q1-INC 01	240 - 300	Vendor to specify	NA	
2.7	Q1-INC 02	240 - 300	Vendor to specify	NA	
2.8	Q1-INC 03	240 - 300	Vendor to specify	NA	
2.9	Q1-INC 04	240 - 300	Vendor to specify	NA	
2.10	Q1-INC 05	240 - 300	Vendor to specify	NA	
3	Technical Specifications				
3.1	Model	cGMP Incubator			
3.2	Type	Standard			
3.3	Utility (Compressed air/gas)	Vendor to specify			
3.4	Shelves	4-5 Nos (adjustable); Perforated SS 304 shelves			
3.5	Temperature range	ambient +5 to 60°C			
3.6	Temperature Readability	0.1°C			
3.7	Temperature Uniformity	± 0.6 °C @37 °C			
3.8	Temperature Controller	PID controller			
3.9	Display Unit	LCD			
3.10	Interlocking	Electromagnetic door interlocking			
3.11	Dimension (Chamber size, external size)	As per the volume specified above			

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HBL HLL BIOTECH LIMITED A Division of HLL Group	INTEGRATED VACCINES COMPLEX, CHENGALPATTU	
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3.12	Quantity	10 nos.
3.14	Power Requirement	To be compatible to standard Indian power supply sockets
4 Material of Construction		
4.1	External body Construction	cGMP Compliant exterior
4.2	Internal body Construction	SS 304 (Electropolished)
4.3	Inner Door	Safety transparent door
4.4	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 c) All bolts, nuts on the exterior part of the equipment will be with cap head or cap nut
4.5	Gaskets, seals, O-ring	Food Grade/ nontoxic material;
4.6	Validation	Validation port to be provided to insert probes for temperature mapping
4.7	All welds shall be ground finish	
5 Specific Equipment Requirements		
5.1	Shelf shall be of perforated type	
5.2	Microprocessor controller unit with PID for system control	
5.3	Alarm : (Visual - Audio) 1. temperature over shoot of 2.5°C from set point 2. Alarm for prolonged door opening	
5.4	RS-232 Computer Interface allows remote data logging and monitoring of the system	
5.5	The heat given off by the unit must be stated (inside the room).	
5.6	Temperature mapping to be provided at the time of installation	
5.7	Temperature sensor (PT 100) should be provided.	
5.8	Equipment shall be compatible for cleaning with all standard disinfectants	
6 Other Requirements		
6.1	Training/Demo for the users on the operation and cleaning to be provided.	
6.2	Equipment should poses universal safety requirement.	
7 Regulatory Aspects		
7.1	DIN 12880 Class 3.1 (Temperature safety)	
7.2	IEC 61010-1 (Electrical safety)	
7.3	cGMP	
7.4	CE certification	

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8	Safety requirements			
	Following facilities must be provided to protect personnel and equipment:			
8.1	Noise level should be below 60 decible at a distance of 1m from the equipment			
8.2	Chamber shall be insulated properly to maintain inner environment			
8.3	Appropriate closure of all parts.			
8.4	Proper Earthing is necessary.			
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.			
9.1	IOQ Documents			
9.2	Operation and maintenance manuals shall be provided along with IOQ documents during installation at site			
9.3	Warranty Letter for 1 year from the date of installation.			
9.4	Calibration certificate of critical instruments with respect to the traceable national reference standard instrument and their calibration procedure.			
10	Timelines			
	Not Applicable			
11	Preferred list of make			
11.1	Esco, Thermo scientific, Binder, Memmert, Eppendorf.			
	NOTE: Accurate size and technical specification need to be mentioned by the vendor			

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HLL Biotech Limited, Chennai						
nne pharmaplan	INTEGRATED VACCINES COMPLEX, CHENGALPATTU					 <small>HLL BIOTECH LIMITED Address: 10, Sankaralingam Road, Chengalpattu, Tamil Nadu - 603001</small>
	Equipment Name	Incubator				
	Document No.	DS-INC 02				
	Revision No.	00				
Table-1: Equipment location						
Equipment ID	Block Name	Room Name	Room No	Room dimension in mm	Room height in mm	
B4-INC 01	Rabies Bulk	Cell Lab - 1	B4G038	5900 x 4850	2700	
B4-INC 02	Rabies Bulk	Virus Seed Lab	B4G048	4700 x 2950	2700	
B4-INC 03	Rabies Bulk	Virus Inactivation	B4G059	5700 x 3350	2700	
G1-INC 01	Animal House	Lab area - Testing	G1G055	4700 x 7300	2700	
G1-INC 02	Animal House	Lab Area (Challenge)	G1G078	4000 x 5000	2700	
Q1-INC 01	Admin QA & QC	Immuno chemistry lab	Q1S026	5300 x 5500	2400	
Q1-INC 02	Admin QA & QC	Virus Testing Labs	Q1S036	5450 x 2700	2400	
Q1-INC 03	Admin QA & QC	Cell culture area	Q1S069	2700 X 3760	2400	
Q1-INC 04	Admin QA & QC	Microbiology lab	Q1S045	3700 X 4600	2400	
Q1-INC 05	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						