DATA SHEET

HLL LIFECARE LIMITED, CHENNAI

nne pharmaplan

REVIVAL OF BCG VACCINE LABORATORY,GUINDY,CHENNAI

INCUBATOR

PROJECT No:	**110729**
EQUIPMENT ID :	**BF-INC 01-04**
DOCUMENT No :	**DS/BF-INC 01-04**

1 Process requirements

1.1 The incubator shall be used for incubation of production of cell cultures. The incubator maintains optimal temperature, relative humidity.
Due to their design the incubator guarantee reproducible and clean incubation conditions plus adequate safety for operators, products and the direct room environment.

2 Technical Specification

2.1	Model	cGMP Incubator
2.2	Type	BOD incubator
2.3	Machine Compliance	EU GMP Guideline part 1 Annex 11,15 Code of Federal Regulations (CFR) 21, part 210:cGMP in manufacturing, processing, packing and holding of drugs: General 21 CFR part 211: Current Good Manufacturing Practice for Finished Pharmaceuticals CE Certification Schedule "M" of Drugs and Cosmetics Act, 1940 European Pharmacopoeia USP
2.4	Electrical	**Vendor to specify**
2.5	Compressed air/gas	**Vendor to specify**
2.6	Shelves	4-5 Nos (adjustable)
2.7	Operating temperature	37ºC
2.8	Temperature Accuracy	±0.1ºC
2.9	Temperature Readability	0.1ºC
2.10	Temperature Sensor	PT 100
2.11	Temperature Controller	***Vendor to specify***
2.12	Temperature Display Sensor	***Vendor to specify***
2.13	Recovery Time @ 37^{O}C	<10 min
2.14	Interlocking	Electromagnetic door interlocking

2.15 Capacity

S No.	Type	Specification
BF-INC 01	STAGE 1:Tubes - 48 Nos (12 batches, 4 Nos each)	Ø25mm, H:200mm
BF-INC 02	STAGE 2:Tubes - 96 Nos (12 batches, 8 Nos each)	Ø25mm, H:200mm
BF-INC 03	250 ml Conical flasks - 60Nos. (4batches, 15 Nos each)	Ø85mm, H:145mm
BF-INC 04	500 ml maximum Tuberculin flasks - 80Nos. (4 batches, 20 Nos each)	Ø105mm, H:170mm

2.16	Dimesion (cu.ft)(Chamber size,external size,volume of incubator chamber)	2*3*3 ft³ (Depth x Length x Height) ***or Vendors should specify as per requirement***

DATA SHEET			
HLL LIFECARE LIMITED, CHENNAI			
nne pharmaplan®	REVIVAL OF BCG VACCINE LABORATORY,GUINDY,CHENNAI		
	INCUBATOR		
	PROJECT No:	110729	
	EQUIPMENT ID :	BF-INC 01-04	
	DOCUMENT No :	DS/BF-INC 01-04	

2.17	Quantity	4 nos
2.18	Electrical Requirement	Power Consumption: ***Vendor to specify***
		220-230 V, 50Hz, Single Phase
3	**Material Of Construction**	
3.1	External body Construction	Powder coated
3.2	Internal body Construction	SS 316L
3.3	Inner Door	Safety glass door with validation sampling nozzle
3.4	Outer Door	Heavy Duty SS 304 or ***vendor to specify***
3.5	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 c) All bolts, nuts on the exterior part of the equipment will be with cap head or cap nut
3.6	Gaskets, seals, O-ring	Food Grade/ nontoxic material; **Use of Asbestos is prohibited**
3.7	All welds shall be ground finish	
4	**Specific Equipment requirement**	
	The design for the optimum simulation of the physiological environment for various cell cultures includes.	
4.1	Shelf shall be of perforated type	
4.2	Control parameters: temperature	
4.3	Microprocessor controller unit with PID for system control	
4.4	Provision for inserting temperature probes during temperature mapping (min. 8 nos. of probes).	
4.5	***Alarm : (Visual - Audio)*** 1. temperature exceeds > $1^{O}C$ at set point 2. Alarm for long period of door opening and record of time period during open door	
4.6	**Software to integrate all incubators with:** • Automatic statistical calculation of data i.e. minimum, maximum. • Automatic trend chart (Graph) generation.	
4.7	Provision/ device to be provided to monitor the equipment through Wireless device & to transfer the data from the equipment and also USB port to be provided for getting the batch data[Non editable]	
4.8	Inner door (glass) shall be provided to monitor the sample without hampering the sterility of the chamber	
4.9	Inner door and Heavy-Duty Door Gasket maintains a leak-free seal and temperature uniformity.	
4.10	Equipment design must realize zero contamination	
4.11	Lockable castor wheel shall be provided.	
4.12	The heat given off by the unit must be stated (inside the room).	
4.13	Paper less data logger	
5	**Other requirement**	
5.1	The equipment must be easy to clean	
5.2	Must ensure high safety of products	
5.3	Cleaning should be done manually.	
5.4	Vendor to give code no for each component	
6	**Regulatory guidelines / standrds**	
	NA	
7	**Safety**	

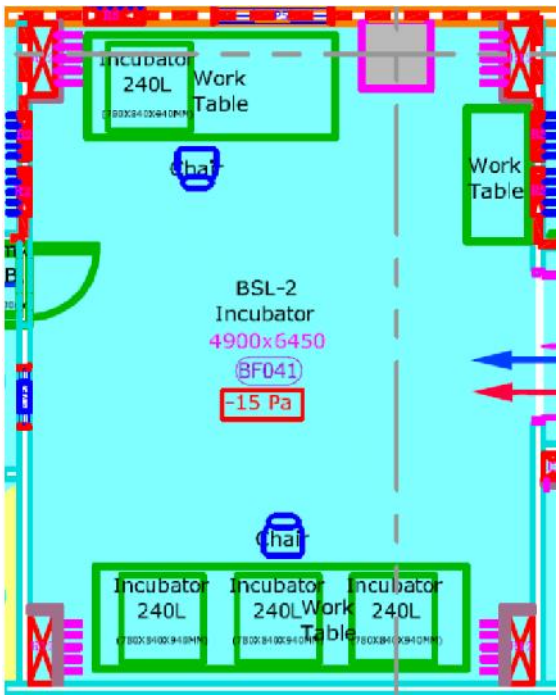
DATA SHEET						
HLL LIFECARE LIMITED, CHENNAI						
nne pharmaplan®	**REVIVAL OF BCG VACCINE LABORATORY,GUINDY,CHENNAI**					
	INCUBATOR					
	PROJECT No:	**110729**				
	EQUIPMENT ID :	**BF-INC 01-04**				
	DOCUMENT No :	**DS/BF-INC 01-04**				

7.1	Emergency stop function on accessible area.
7.2	Doors interlocking alarm (visual/ audio).
7.3	Noise level should be below 65 decible at a distance of 1m from the equipment
7.4	Appropriate failure detection and alarm notification
7.5	Chamber shall be insulated properly to maintain inner environment
7.6	Tightness of the gasket shall be maintained
8	**Documents**
8.1	IOQ Protocol
8.2	Operation and maintenance manuals
8.3	Calibration certificate of critical instruments with respect to the traceable national reference standard instrument and their calibration procedure.
8.4	List of standard spare parts with ordering information
8.5	Separate back-ups for software on CD/ Floppies
8.6	Comprehensive 1 year warranty letter from the date of completion.
9	**Timelines**
	NA
	NOTE: Accurate size and technical specification need to be mentioned by the vendor

	AFI Approved for Enquiry		AFO Approved for Ordering			
6	2014-02-05	MNS	SDBB	☐	☐	
Rev	Date	Completed By	Checked By	AFI	AFO	Sheet 1/2

DATA SHEET		
HLL LIFECARE LIMITED, CHENNAI		
nne pharmaplan®	REVIVAL OF BCG VACCINE LABORATORY,GUINDY,CHENNAI	
	INCUBATOR	
	PROJECT No:	110729
	EQUIPMENT ID :	BF-INC 01-04
	DOCUMENT No :	DS/BF-INC 01-04

ROOM LOCATION:	BF-INC 01-04
1	BF041 - FIRST FLOOR (BULK AREA)
2	**ROOM DIMENSION:** L(4900mm) X W(6450mm)
3	
4	**FALSE CEILING:** 3000mm
5	**ROOM PRESSURE: (**- 15Pa)



	AFI Approved for Enquiry		AFO Approved for Ordering			
6	2014-02-05	BKSH	VKKA	☐	☐	
Rev	Date	Completed By	Checked By	AFI	AFO	Sheet 2/2