

DATA SHEET

HLL LIFECARE LIMITED, CHENNAI

nne pharmaplan®

REVIVAL OF BCG VACCINE LABORATORY, GUINDY, CHENNAI

INCUBATOR

PROJECT No: 110729

EQUIPMENT ID : BF-INC 05-06

DOCUMENT No : DS/BF-INC 05-06



1 Process requirements

1.1 The incubator shall be used for storage of samples under controlled conditions. 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	BF-INC 05 will be between 30-35 °C (Settable)		
		BF-INC 06 will be between 20-25 °C (Settable)		
2.8	Temperature Accuracy	±0.1°C		
2.9	Temperature Readability	0.1°C		
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°C	<10 min		
2.14	Interlocking	Electromagnetic door interlocking		
2.15	Capacity	S No.	Type	Specification
		BF-INC 05	Tubes - 54 Nos.	Ø10 mm, H:154 mm
		BF-INC 06	Tubes - 54 Nos.	Ø10 mm, H:154 mm
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		
2.17	Quantity	2 nos		
2.18	Electrical Requirement	Power Consumption: Vendor to specify		
		220-230 V, 50Hz, Single Phase		



3 Material Of Construction

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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°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 to be provided

5 Other requirement

5.1	The equipment must be easy to clean
5.2	Must ensure high safety of products
5.3	Vendor to give code no for each component
5.4	Cleaning should be done manually.

6 Regulatory guidelines / standards

NA

7 Safety

7.1	Emergency stop function on accessible area.
7.2	Doors interlocking alarm (visual/ audio).

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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	<input type="checkbox"/>	<input type="checkbox"/>	
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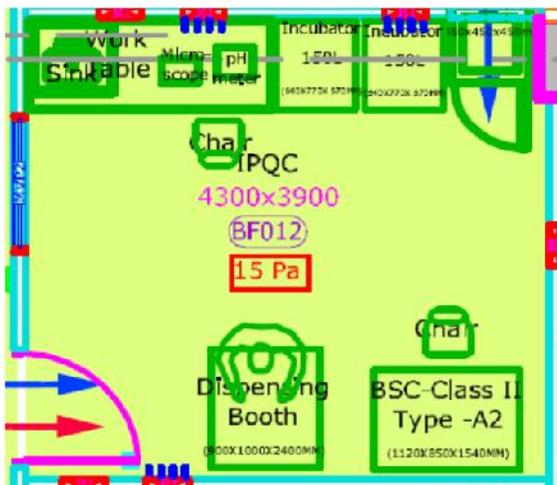
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ROOM LOCATION:	BF-INC 05-06
1	BF012 - FIRST FLOOR (BULK AREA)
2	ROOM DIMENSION: 4300mm x 3900mm
4	FALSE CEILING: 3000mm
5	ROOM PRESSURE: 15Pa



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