

# 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	37°C		
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	Humidity @37°C	50-60% rH		
2.15	Interlocking	Electromagnetic door interlocking		
2.16	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
2.17	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		
2.18	Quantity	4 nos		
2.19	Electrical Requirement	Power Consumption: Vendor to specify		
		220-230 V, 50Hz, Single Phase		
3	Material Of Construction			



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		INCUBATOR	
		PROJECT No:	110729
		EQUIPMENT ID :	BF-INC 01-04
		DOCUMENT No :	DS/BF-INC 01-04
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 <b>vendor to specify</b>	
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; <b>Use of Asbestos is prohibited</b>	
3.7	All welds shall be ground finish		
<b>Specific Equipment requirement</b>			
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).		
<b>Alarm : (Visual - Audio)</b>			
4.5	1. temperature exceeds $> 1^{\circ}\text{C}$ at set point 2. Alarm for long period of door opening and record of time period during open door		
<b>Software to integrate all incubators with:</b>			
4.6	• Automatic statistical calculation of data i.e. minimum, maximum. • Automatic trend chart (Graph) generation.		
4.7	RS-232 Computer Interface allows remote data logging and monitoring of the system		
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	<b>Special note:</b> All deep freezers, refrigerators and incubators should have provision to connect centralized monitoring device with printer (common) - <b>Vendor scope</b> (Cable length between incubator to centralized monitoring device with printer (common) should be minimum of approx. 35m) Placement of centralized monitoring device with printer (common) shall be office room, BF011		
<b>Approved makes:</b>			
4.14	a) Thermo b) Esco c) Panasonic d) Stable temp		
<b>5 Other requirement</b>			
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		
<b>6 Regulatory guidelines / standards</b>			
NA			

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INCUBATOR

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## 7 Safety

- 7.1 Emergency stop function on accessible area.
- 7.2 Doors interlocking alarm (visual/ audio).
- 7.3 Noise level should be below 65 decibel 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	BKSH	VKKA	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	
Rev	Date	Completed By	Checked By	AFI	AFO	Sheet 1/2

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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:

3

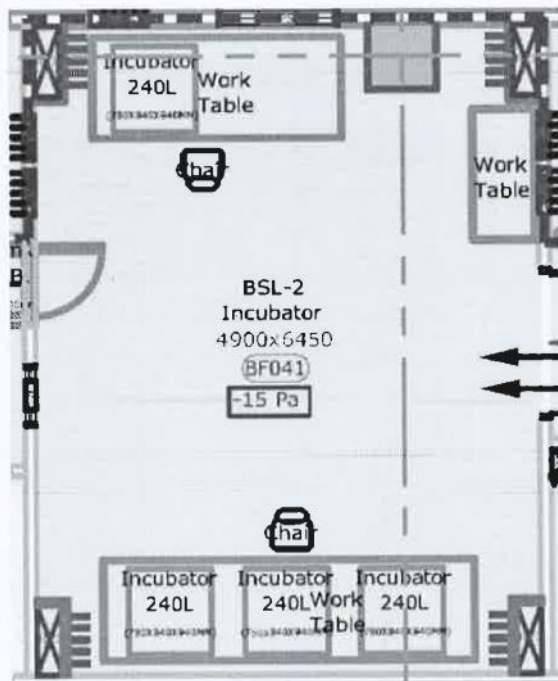
L(4900mm) X W(6450mm)

4

FALSE CEILING: 3000mm

5

ROOM PRESSURE: (- 15Pa)



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REVIVAL OF BCG VACCINE LABORATORY, GUINDY, CHENNAI

INCUBATOR

PROJECT No:

110729

EQUIPMENT ID :

BF-INC 05-06


DOCUMENT No :


DS/BF-INC 05-06

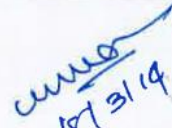


1	Process requirements			
1.1	The incubator shall be used for storage of samples under controlled conditions. Incubator maintains optimal temperature, relative humidity. Due to their design the incubator guarantee reproducible and clean incubation conditions plus adequate safety for operators, products and the direct room environment.			
2	Technical Specification			
2.1	Model	cGMP Incubator		
2.2	Type	Standard for IPQC		
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		
	Temperature Controller	Vendor to specify		
2.12	Temperature Display Sensor	Vendor to specify		
2.13	Recovery Time @37°C	<10 min		
2.14	Humidity @37°C	60-95% - Humidity control should be programmable		
2.15	Interlocking	Electromagnetic door interlocking		
2.16	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
2.17	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		
2.18	Quantity	2 nos		
2.19	Electrical Requirement	Power Consumption: Vendor to specify		
		220-230 V, 50Hz, Single Phase		
3	Material Of Construction			
3.1	External body Construction	Powder coated		



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	INCUBATOR		
	PROJECT No:	110729	
	EQUIPMENT ID :	BF-INC 05-06	
	DOCUMENT No :	DS/BF-INC 05-06	
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 <b>vendor to specify</b>	
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; <b>Use of Asbestos is prohibited</b>	
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4.5	1. temperature exceeds $> 1^{\circ}\text{C}$ at set point 2. Alarm for long period of door opening and record of time period during open door		
4.6	<b>Software to integrate all incubators with:</b> • Automatic statistical calculation of data i.e. minimum, maximum. • Automatic trend chart (Graph) generation.		
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	DOCUMENT No :		DS/BF-INC 05-06			
<b>7</b>	<b>Safety</b>					
7.1	Emergency stop function on accessible area.					
7.2	Doors interlocking alarm (visual/ audio).					
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7.5	Chamber shall be insulated properly to maintain inner environment					
7.6	Tightness of the gasket shall be maintained					
<b>8</b>	<b>Documents</b>					
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	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.					
<b>9</b>	<b>Timelines</b>					
	NA					
	NOTE: Accurate size and technical specification need to be mentioned by the vendor					
	AFI Approved for Enquiry		AFO Approved for Ordering			
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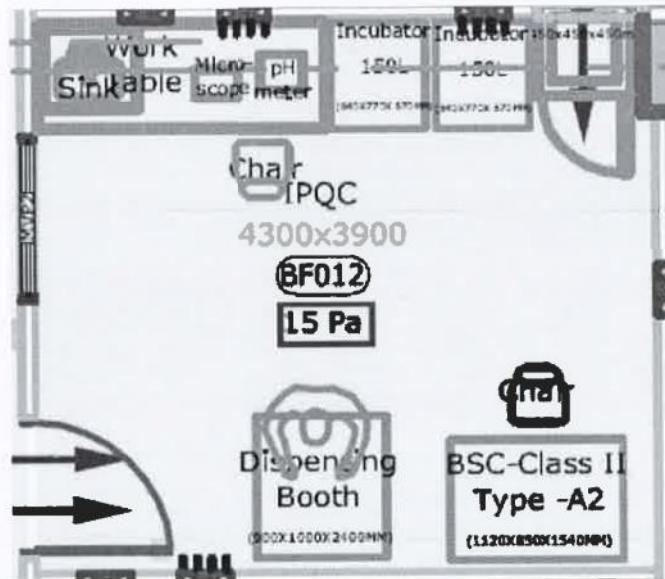
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INCUBATOR

PROJECT No:	110729
EQUIPMENT ID :	BF-INC 05-06
DOCUMENT No :	DS/BF-INC 05-06



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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