

DATA SHEET

HLL LIFECARE LIMITED, CHENNAI

nne pharmaplan™

REVIVAL OF BCG VACCINE LABORATORY, GUINDY, CHENNAI

DEEP FREEZER

PROJECT No:	110729
EQUIPMENT ID :	BF-DFG 01
DOCUMENT No :	DS/BF-DFG 01

**1 Process requirements**

1.1 It is used for maintaining ultra low temperature of samples.

2 Technical Specifications

2.1	Model	cGMP Deep Freezer with stainless steel/ powder coated door, Chest type
2.2	Freezer compartment	300L or the near standard
2.3	External dimension (W X D X H mm)	vendor to specify
2.4	Internal dimension (W X D X H mm)	vendor to specify
2.5	Shelves (W X D mm)	vendor to specify
2.6	Height between the shelves (mm)	vendor to specify
2.7	No. of Shelves	vendor to specify (Shelves shall be adjustable)
2.8	Purpose	For the storage of Master Seed or Culutre Seed Storage
2.9	Temperature Range	Reach up to (-86) °C
2.10	Refrigerant	R134a (HFC refrigerant) or vendor to specify
2.11	Temperature precision (setting resolution)	± 0.5 °C
2.12	Temperature stability	± 1 °C
2.13	Temperature uniformity	± 2 °C
2.14	Air circulation	Natural Circulation
2.15	Quantity	1 No.

**3 Material of construction**

3.1	Body Construction	Interior	SS 304
		Shelves	Perforated, SS304
		Exterior	Stainless steel/ powder coated
		Door	Stainless steel/ powder coated
3.2	Gaskets, seals, o-rings	Food Grade/ nontoxic material Use of Asbestos is prohibited	
3.3	Insulation	Heavy walled CFC Free	
3.4	All welds shall be ground finish		

4 Specific Requirements

4.1	Chamber should be rounded corners for easy cleaning.
4.2	Cleaning shall be done manually.
4.3	System shall be designed for 100% coverage of the internal surface areas.
4.4	The vendor shall provide the detail of cleaning agent based on compatibility of material.
4.5	The freezer shall be provided with adjustable shelves for flexible storage.
4.6	Freezer shall be fitted with double-roll lockable caster wheels for easy transportation.
4.7	The control shall be microprocessor based with digital display cum controller.
4.8	Key lock for Parameter change Protection to be provided
4.9	Temperature to be recorded, monitored and displayed. Temperature probe installed in freezer (Two nos).
4.10	Temperature controlling must be based on set point.
4.11	Interface port RS 232 to transfer data to be provided
4.12	One inkless Chart recorder / graphic recorder and printing for traceability of alarms

DATA SHEET

HLL LIFECARE LIMITED, CHENNAI

nne pharmaplan™

REVIVAL OF BCG VACCINE LABORATORY, GUINDY, CHENNAI

DEEP FREEZER

PROJECT No:	110729
EQUIPMENT ID :	BF-DFG 01
DOCUMENT No :	DS/BF-DFG 01



- 4.13 A complete batch record indicating the following important parameters, but not limited to these:
a) Date, Time
b) All failures and alarms
- 4.14 Internal clock to be maintained to retrieve data at setpoint interval i.e.; 24 hrs .
- 4.15 Temperature sensor for set temperature
- 4.16 Alarms for parameters like high temperature, low temperature shall be provided
- 4.17 Temperature set points should be adjustable
- 4.18 Alarm if door is open for >5 min.
- 4.19 It should have fully automatic defrost cycle.
- 4.20 key lock for Parameter change Protection to be provided
- 4.21 1 no. Door lock should be provided
- 4.22 Spring loaded, self closing door with 90° angle stay open feature should be provided with holder.
- 4.23 **Special note:** All deep freezers, refrigerators and incubators should have provision to connect centralized monitoring device with printer (common) -
Vendor scope
(Cable length between deep freezer to centralized monitoring device with printer (common) should be minimum of approx. 35m)
- 4.24 **Approved Makes:**
a) Thermo Scientific
b) Eppendorf
c) Telstar
d) Panasonic
- 5 Other requirements**
- 5.1 A CE declaration of conformity must be available. The CE Identification must comply with the current EC instructions.
- 5.2 Control lights and other display elements shall not be influenced by voltage failure
- 5.3 Installation of equipment with refrigerants has to be done by a certified cooling technician.
- 5.4 The control circuit has to be 24 Volt
- 5.5 Audio alarms have to be in the range of 2.3 — 2.9 kHz in order to avoid interference and confusion with evacuation alarms
- 6 Regulatory guidelines / standards**
NA
- 7 Safety requirements**
- 7.1 Emergency stop function on accessible area.
- 7.2 Noise level below 65 decible.
- 7.3 Proper earthing
- 7.4 No sharp edges/Corners, crevices, pin holes in the process wetted parts of the equipment.
- In the event of equipment malfunction or loss of utilities, the unit must contain all necessary protection devices to ensure that the equipment and the product remain in a safe condition.
- 8 Documents**
- 8.1 CE Certificate
- 8.2 Operation and maintenance manuals.
- 8.3 IQ protocol
- 8.4 List of alarms
- 8.5 Comprehensive 1 year warranty letter from 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 type="checkbox"/>
Rev	Date	Completed By	Checked By	AFI	AFO

Sheet 1/2

18/3/14
[ENGG DFG]
BCGVL

DATA SHEET

HLL LIFECARE LIMITED, CHENNAI

nne pharmaplan

REVIVAL OF BCG VACCINE LABORATORY, GUINDY,CHENNAI

DEEP FREEZER

PROJECT No:

110729

EQUIPMENT ID :

BF-DFG 01

DOCUMENT No :

DS/BF-DFG 01



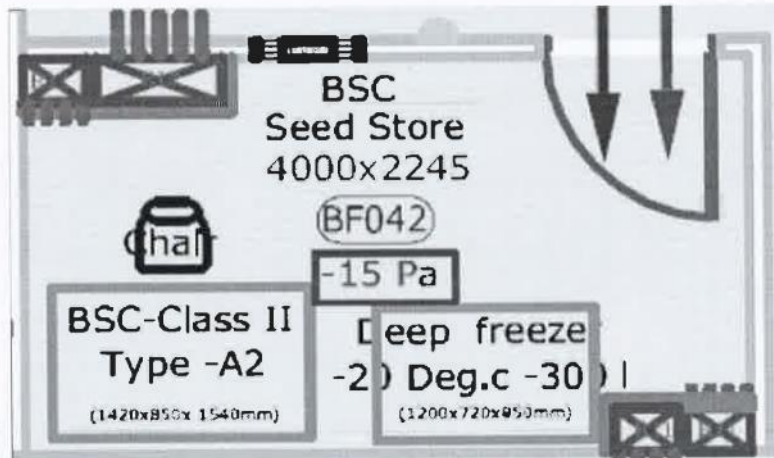
ROOM LOCATION: BF-DFG 01

1 BF042 - First floor

2 ROOM DIMENSION:
L(4000mm) X W(2245mm)

3 FALSE CEILING: 3000mm

4 ROOM PRESSURE: (-15) Pa



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

DATA SHEET

HLL LIFECARE LIMITED, CHENNAI

nne pharma plan™

REVIVAL OF BCG VACCINE LABORATORY, GUINDY, CHENNAI

DEEP FREEZER

PROJECT No:	110729
EQUIPMENT ID :	BF-DFG 02
DOCUMENT No :	DS/BF-DFG 02

**1 Process requirements**

1.1 It is used store formulated bulk vaccine at ultra low temperature.

2 Technical Specifications


2.1	Model	cGMP Deep Freezer with stainless steel/ powder coated double door, Chest type
2.2	Freezer compartment	300 L or the near standard
2.3	External dimension (W X D X H mm)	vendor to specify
2.4	Internal dimension (W X D X H mm)	vendor to specify
2.5	Shelves (W X D mm)	vendor to specify
2.6	Height between the shelves (mm)	vendor to specify
2.7	No. of adjustable Shelves	12 or Vendor to confirm (SS 304 Perforated shelves shall be adjustable)
2.8	Purpose	To store container having 10L (working volume) of formulated bulk vaccine. <u>Bulk vessel dimensions:</u> 12L gross volume H/D ratio- 1:1 Diameter: 24.81 cm Height: 24.81 cm
2.9	Door type	Double door
2.10	Temperature Range	Reach up to (-86) °C
2.11	Refrigerant	R134a (HFC refrigerant) or vendor to specify
2.12	Temperature precision (setting resolution)	± 0.5 °C
2.13	Temperature stability	± 1 °C
2.14	Temperature uniformity	± 2 °C
2.15	Air circulation	Natural Circulation
2.16	Quantity	1 No.






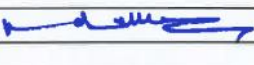

**3 Material of construction**

3.1	Body Construction	Interior	SS 304
		Shelves	Perforated, SS304
		Exterior	Stainless steel/ powder coated
		Door	Stainless steel/ powder coated
3.2	Gaskets, seals, o-rings	Food Grade/ nontoxic material Use of Asbestos is prohibited	
3.3	Insulation	Heavy walled CFC Free	
3.4	All welds shall be ground finish		

4 Specific requirements

4.1	Chamber should be rounded corners for easy cleaning
4.2	Cleaning shall be done manually
4.3	System shall be designed for 100% coverage of the internal surface areas
4.4	The vendor shall provide the detail of cleaning agent based on compatibility of material
4.5	The freezer shall be provided with adjustable shelves for flexible storage
4.6	Freezer shall be fitted with double-roll lockable caster wheels for easy transportation
4.7	The control shall be microprocessor based with digital display cum controller.

DATA SHEET			
HLL LIFECARE LIMITED, CHENNAI			
nne pharma plan	REVIVAL OF BCG VACCINE LABORATORY, GUINDY, CHENNAI		
	DEEP FREEZER		
	PROJECT No:	110729	
	EQUIPMENT ID :	BF-DFG 02	
	DOCUMENT No :	DS/BF-DFG 02	
4.8	Key lock for Parameter change Protection to be provided		
4.9	Temperature to be recorded, monitored and displayed. Temperature probe installed in freezer (Two nos).		
4.10	Temperature controlling must be based on set point.		
4.11	Interface port RS 232 to transfer data to be provided .		
4.12	One inkless Chart recorder / graphic recorder and printing for traceability of alarms		
4.13	A complete batch record indicating the following important parameters, but not limited to these: a) Date, Time b) All failures and alarms		
4.14	Internal clock to be maintained to retrieve data at setpoint interval i.e.; 24 hrs .		
4.15	Temperature sensor for set temperature.		
4.16	Alarms for parameters like high temperature, low temperature shall be provided.		
4.17	Temperature set points should be adjustable.		
4.18	Alarm if door is open for >5 min.		
4.19	It should have fully automatic defrost cycle.		
4.20	key lock for Parameter change Protection to be provided		
4.21	1 no. Door lock should be provided		
4.22	Spring loaded, self closing door with 90° angle stay open feature should be provided with holder.		
4.23	Special note: All deep freezers, refrigerators and incubators should have provision to connect centralized monitoring device with printer (common) - Vendor scope (Cable length between deep freezer to centralized monitoring device with printer (common) should be minimum of approx. 15m) Placement of centralized monitoring device with printer (common) shall be office room (BF011)		
4.24	Approved Makes: a) Thermo Scientific b) Eppendorf c) Telstar d) Panasonic		
5	Other requirements		
	A CE declaration of conformity must be available. The CE Identification must comply with the current EC instructions.		
5.2	Control lights and other display elements shall not be influenced by voltage failure.		
5.3	Installation of equipment with refrigerants has to be done by a certified cooling technician.		
5.4	The control circuit has to be 24 Volt.		
5.5	Audio alarms have to be in the range of 2.3 — 2.9 kHz in order to avoid interference and confusion with evacuation alarms.		
6	Regulatory guidelines / standards		
	NA		
7	Safety requirements		
7.1	Emergency stop function on accessible area.		
7.2	Noise level below 65 decible.		
7.3	Proper earthing		
7.4	No sharp edges/Corners, crevices, pin holes in the process wetted parts of the equipment.		
7.5	In the event of equipment malfunction or loss of utilities, the unit must contain all necessary protection devices to ensure that the equipment and the product remain in a safe condition.		
8	Documents		
8.1	CE Certificate		
8.2	IOQ protocol		
8.3	Operation and maintenance manuals.		
8.4	List of alarms		
8.5	Comprehensive 1 year warranty letter from date of completion.		

DATA SHEET						
HLL LIFECARE LIMITED, CHENNAI						
nne pharma plan	REVIVAL OF BCG VACCINE LABORATORY, GUINDY, CHENNAI					
	DEEP FREEZER					
	PROJECT No:	110729				
	EQUIPMENT ID :	BF-DFG 02				
	DOCUMENT No :	DS/BF-DFG 02				
9	Timelines					
	NA					
	NOTE: Accurate size and technical specification need to be mentioned by the vendor					
	AFI Approved for Enquiry			AFO Approved for Ordering		
						
4	2014-02-05	BKSH	VKKA		<input type="checkbox"/>	
Rev	Date	Completed By	Checked By	AFI	AFO	Sheet 1/2


 18/3/19
 [ENG G DEPT]
 OCGYL

DATA SHEET

HLL LIFECARE LIMITED, CHENNAI

nne pharmaplan®

REVIVAL OF BCG VACCINE LABORATORY, GUINDY, CHENNAI

DEEP FREEZER

PROJECT No:

110729

EQUIPMENT ID :

BF-DFG 02

DOCUMENT No :

DS/BF-DFG 02



ROOM LOCATION: BF-DFG 02

1 BF021 - First floor

2 ROOM DIMENSION:
L(2810 mm) X W(3700 mm)

3 FALSE CEILING: 3000 mm



AFI Approved for Enquiry

AFO Approved for Ordering

4

2014-02-05

BRSH

VKKA

☐

Rev

Date

Completed By

Checked By

AFI

AFO

Sheet 2/2