

# DATA SHEET

## HLL LIFECARE LIMITED, CHENNAI

nne pharmaplan\*

REVIVAL OF BCG VACCINE LABORATORY, GUINDY, CHENNAI

### REFRIGERATOR

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



### 1 Process requirements

1.1 It is used to store the media samples required for the process.

### 2 Technical Specifications

2.1	Model	cGMP Refrigerator with glass door, Upright type
2.2	Refrigerator compartment	2500 L or near to standard
2.3	External dimension (W X D X H mm)	2200 x 900 x 2000 or near to standard
2.4	Internal dimension (W X D X H mm)	2000 x 700 x 1500 or near to standard
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 (SS 304 Perforated shelves shall be adjustable)
2.8	Purpose	For the storage of samples in: Tuberlin flask-450 ml - 120 nos (D-120mm, H-100mm)
2.9	Temperature Range	+1°C to +8°C
2.10	Refrigerant	R134a (HFC refrigerant) or vendor to specify
2.11	Temperature precision (Setting resolution)	± 0.5 deg C
2.12	Temperature stability	± 1 deg C
2.13	Temperature uniformity	± 2 deg C
2.14	Air circulation	Forced air circulation
2.15	Quantity	1 No.




### 3 Material of construction

3.1	Body Construction	Interior	SS 304
		Shelves	Perforated, SS304
		Exterior	Powder coated GI sheet or vendor to specify
3.2	Gaskets, seals, o-rings	Food Grade/ nontoxic material Use of Asbestos is prohibited	
3.3	Insulation	Heavy walled CFC Free	
3.4	Door	Double layer Borosilicate glass	
3.5	MOC Fan	Aluminium	
3.6	All welds shall be ground finish		

### 4 Specific requirements

- 4.1 Chamber should have rounded corners for easy cleaning.
- 4.2 System shall be designed for 100% coverage of the internal surface areas
- 4.3 The vendor shall provide the detail of cleaning agent based on compatibility of material
- 4.4 The refrigerators shall be provided with adjustable shelves for flexible storage
- 4.5 Refrigerator shall be fitted with double-roll lockable caster wheels for easy transportation
- 4.6 The control shall be microprocessor based with digital display cum controller.
- 4.7 Set point security or Key lock for Parameter change Protection to be provided
- 4.8 Temperature to be recorded, monitored and displayed. Temperature probe should be installed (Two nos).

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nne pharmaplan	REVIVAL OF BCG VACCINE LABORATORY, GUINDY, CHENNAI		
	REFRIGERATOR		
	PROJECT No:	110729	
	EQUIPMENT ID :	BF-RFG 01	
	DOCUMENT No :	DS/BF-RFG 01	
4.9	Temperature controlling must be based on set point		
4.10	Interface port RS 232 to transfer data to be provided		
4.11	Inkless Chart recorder / graphic recorder		
4.12	A complete batch record indicating the following important parameters, but not limited to these: a) Date, Time b) Infrared port (for optional data transmission) c) All failures and alarms		
4.13	Internal clock to be maintained to retrieve data at setpoint interval i.e.; 24 hrs .		
4.14	Positive air circulation by internal fans must be provided to ensure temperature uniformity and recovery		
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	Light on/ off in case of glass door		
4.20	Auto switch off of fan when door opens		
4.21	Automatic defrost cycle and melt water evaporation in heated tray should be provided		
4.22	Dry contact for remote alarm should be provided		
4.23	1 no. Door lock should be provided		
4.26	Spring loaded, self closing door with 90° angle stay open feature should be provided with holder.		
4.27	Ring back function if any alarm condition remains active		
4.28	<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 refrigerator to centralized monitoring device with printer (common) should be minimum of approx. 50m) Placement of centralized monitoring device with printer (common) shall be office room (BF011)		
4.29	<b>Approved makes:</b> a) Telstar b) Panasonic c) Thermo scientific d) Voltas		
5	<b>Other requirements</b>		
5.1	A CE declaration of conformity must be available. The CE Identification must comply with the current EC instructions.		
5.2	Cleaning shall be done manually		
5.3	Control lights and other display elements shall not be influenced by voltage failure		
5.4	Installation of equipment with refrigerants has to be done by a certified cooling technician.		
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		
5.6	The control circuit has to be 24 Volt		
6	<b>Regulatory guidelines / standards</b>		
	NA		
7	<b>Safety requirements</b>		
7.1	Emergency stop function on accessible area.		
7.2	Noise level should be below 75 decible.		
7.3	Proper earthing should be provided		
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.		

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REVIVAL OF BCG VACCINE LABORATORY, GUINDY, CHENNAI

REFRIGERATOR

PROJECT No: 110729

EQUIPMENT ID : BF-RFG 01

DOCUMENT No : DS/BF-RFG 01



## 8 Documents

- 8.1 FDS Document (If applicable)
- 8.2 Technical Specifications
- 8.3 MOC Certificate
- 8.4 CE certificate
- 8.5 IOQ protocol
- 8.6 List of alarms
- 8.7 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

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5 2013-12-18

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18/12/18  
[ENGG DEPT  
BCGVL]

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REVIVAL OF BCG VACCINE LABORATORY, GUINDY, CHENNAI

REFRIGERATOR

PROJECT No:

110729

EQUIPMENT ID :

BF-RFG 01

DOCUMENT No :

DS/BF-RFG 01



ROOM  
LOCATION:

BSL-2 Seed, Bulk first floor

1

Room No: BF040

2

ROOM DIMENSION:

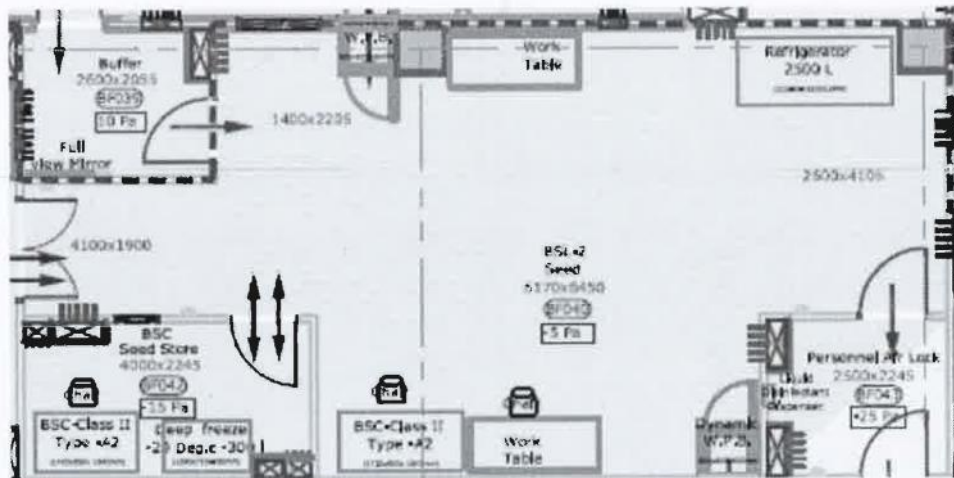
(2600 x 4105), (6170 x 6450), (1400 x 2205), (4100 x 1900)

3

FALSE CEILING HEIGHT: 3000 mm

4

ROOM PRESSURE: -5 Pa



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# DATA SHEET

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REVIVAL OF BCG VACCINE LABORATORY, GUINDY, CHENNAI

## REFRIGERATOR

PROJECT No: 110729

EQUIPMENT ID : BF-RFG 02

DOCUMENT No : DS/BF-RFG 02



### 1 Process requirements

1.1 It is used to store the buffer in conical flasks required for the process.

### 2 Technical Specifications

2.1	Model	cGMP Refrigerator with glass door, Upright type
2.2	Refrigerator compartment	300 L or near to standard
2.3	External dimension (W X D X H) mm	600 x 750 x 2000 or near to standard
2.4	Internal dimension (W X D X H) mm	500 x 550 x 1500 or near to standard
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 (SS 304 Perforated shelves shall be adjustable)
2.8	Purpose	For the storage of buffer in 15 nos Conical flasks (2 ltr)
2.9	Temperature Range	+1°C to +8°C
2.10	Refrigrant	R134a (HFC refrigerant) or vendor to specify
2.11	Temperature precision (Setting resolution)	± 0.5 deg C
2.12	Temperature stability	± 1 deg C
2.13	Temperature uniformity	± 2 deg C
2.14	Air circulation	Forced air circulation
2.15	Quantity	1 No




### 3 Material of construction

3.1	Body Construction	Interior	SS 304
		Shelves	Perforated, SS304
		Exterior	Powder coated GI sheet or vendor to specify
3.2	Gaskets, seals, o-rings	Food Grade/ nontoxic material Use of Asbestos is prohibited	
3.3	Insulation	Heavy walled CFC Free	
3.4	Door	Double layer Borosilicate glass	
3.5	MOC Fan	Aluminium	
3.6	All welds shall be ground finish		

### 4 Specific requirements

4.1	Chamber should be rounded corners for easy cleaning.
4.2	Ring back function if any alarm condition remains active
4.3	System shall be designed for 100% coverage of the internal surface areas for manual cleaning.
4.4	The vendor shall provide the detail of cleaning agent based on compatibility of material
4.5	The refrigerators shall be provided with adjustable shelves for flexible storage
4.6	Refrigerator 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 should be installed (Two nos).
4.10	Temperature controlling must be based on set point
4.11	Interface port RS 232 to transfer data to be provided

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	REFRIGERATOR		
	PROJECT No:	110729	
	EQUIPMENT ID :	BF-RFG 02	
	DOCUMENT No :	DS/BF-RFG 02	
4.12	Inkless Chart recorder / graphic recorder.		
4.13	A complete batch record indicating the following important parameters, but not limited to these: a) Date, Time b) Infrared port (for optional data transmission) c) All failures and alarms		
4.14	Internal clock to be maintained to retrieve data at setpoint interval i.e.; 24 hrs .		
4.15	Positive air circulation by internal fans must be provided to ensure temperature uniformity and recovery		
4.16	Temperature sensor for set temperature		
4.17	Alarms for parameters like high temperature, low temperature shall be provided		
4.18	Temperature set points should be adjustable		
4.19	Alarm if door is open for >5 min.		
4.20	Light on/ off in case of glass door		
4.21	Auto switch off of fan when door opens		
4.22	Automatic defrost cycle and melt water evaporation in heated tray should be provided		
4.23	Dry contact for remote alarm should be provided		
4.24	1 no. Door lock should be provided		
4.25	Spring loaded, self closing door with 90° angle stay open feature should be provided with holder.		
4.26	<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 refrigerator to centralized monitoring device with printer (common) should be minimum of approx. 25m) Placement of centralized monitoring device with printer (common) shall be office room (BF011)		
4.27	<b>Approved makes:</b> a) Thermo scientific b) Panasonic c) Telstar d) Voltas		
5	<b>Other requirements</b>		
5.1	A CE declaration of conformity must be available. The CE Identification must comply with the current EC instructions.		
5.2	Cleaning shall be done manually		
5.3	Control lights and other display elements shall not be influenced by voltage failure		
5.4	Installation of equipment with refrigerants has to be done by a certified cooling technician.		
5.5	The control circuit has to be 24 Volt		
5.6	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	<b>Regulatory guidelines / standards</b>		
	NA		
7	<b>Safety requirements</b>		
7.1	Emergency stop function on accessible area.		
7.2	Noise level below 75 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.		
7.6	For the safety of the operator the external surfaces (equipment doors, chamber etc.) should not have temperature more than 45°C by proper insulation, etc.		

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## REFRIGERATOR

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EQUIPMENT ID : BF-RFG 02

DOCUMENT No : DS/BF-RFG 02



8	Documents					
8.1	FDS Document (If applicable)					
8.2	Technical Specifications					
8.3	MOC certificates					
8.4	IOQ protocol					
8.5	CE Certificate					
8.6	List of alarms					
8.7	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			
						
5	2013-12-18	BKSH	VKKA	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
Rev	Date	Completed By	Checked By	AFI	AFO	Sheet 1 / 2

  
 18/12/19  
 [ENGG DEPT]  
 DCG VL

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REFRIGERATOR

PROJECT No: 110729

EQUIPMENT ID : BF-RFG 02

DOCUMENT No : DS/BF-RFG 02



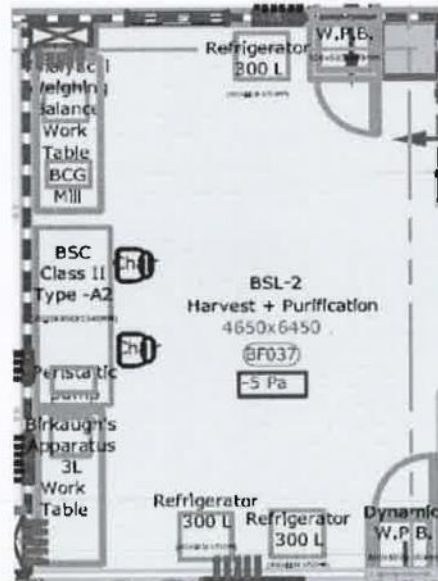
ROOM LOCATION: BSL-2 Harvest and purification

1 Room no: BF037

2 ROOM DIMENSION:  
4650 mm X 6450 mm

3 FALSE CEILING: 3000 mm

4 ROOM PRESSURE: (-5) Pa



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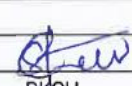

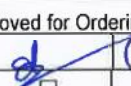
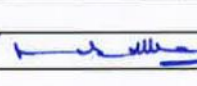
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nne pharmaplan™		REVIVAL OF BCG VACCINE LABORATORY, GUINDY, CHENNAI	
		REFRIGERATOR	
		PROJECT No:	110729
		EQUIPMENT ID :	BF-RFG 03
		DOCUMENT No :	DS/BF-RFG 03 ✓
<b>1 Process requirements</b>			
1.1	It is used to store 1.5% Sodium glutamate-Stabilizer in 5L round bottom conical flasks (7 nos) of concentrated Bulk.		
<b>2 Technical Specifications</b>			
2.1	Model	cGMP Refrigerator with glass door, Upright type	
2.2	Refrigerator compartment	300 L or near to standard	
2.3	External dimension (W X D X H mm)	600 x 750 x 2000 or near to standard	
2.4	Internal dimension (W X D X H mm)	500 x 550 x 1500 or near to standard	
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 (SS 304 Perforated shelves shall be adjustable)	
2.8	Purpose	To store 1.5% Sodium glutamate-Stabilizer in 5L round bottom conical flasks (7 nos) of concentrated Bulk	
2.9	Temperature Range	+1°C to +8°C	
2.10	Refrigerant	R134a (HFC refrigerant) or vendor to specify	
2.11	Temperature precision	± 0.5 deg C	
2.12	Temperature precision (setting resolution)	± 1 deg C	
2.13	Temperature uniformity	± 2 deg C	
2.14	Air circulation	Forced air circulation	
2.16	Quantity	1 No.	
<b>3 Material of construction</b>			
3.1	Body Construction	Interior	SS 304
		Shelves	Perforated, SS304
		Exterior	Powder coated GI sheet or vendor to specify
3.2	Gaskets, seals, o-rings	Food Grade/ nontoxic material Use of Asbestos is prohibited	
3.3	Insulation	Heavy walled CFC Free	
3.4	Door	Double layer Borosilicate glass	
3.5	MOC Fan	Aluminium	
3.6	All welds shall be ground finish		
<b>4 Specific requirements</b>			
4.1	Chamber should be rounded corners for easy cleaning.		
4.2	System shall be designed for 100% coverage of the internal surface areas for manual cleaning.		
4.3	The vendor shall provide the detail of cleaning agent based on compatibility of material		
4.4	The refrigerators shall be provided with adjustable shelves for flexible storage		
4.5	Refrigerator shall be fitted with double-roll lockable caster wheels for easy transportation		



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nne pharmaplan™	REVIVAL OF BCG VACCINE LABORATORY, GUINDY, CHENNAI		
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	DOCUMENT No :	DS/BF-RFG 03	
4.6	The control shall be microprocessor based with digital display cum controller.		
4.7	Key lock for Parameter change Protection to be provided		
4.8	Temperature to be recorded, monitored and displayed. Temperature probe shall be installed (Two nos).		
4.9	Temperature controlling must be based on set point		
4.10	Interface port RS 232 to transfer data to be provided		
4.11	Inkless Chart recorder / graphic recorder		
4.12	A complete batch record indicating the following important parameters, but not limited to these: a) Date, Time b) Infrared port (for optional data transmission) c) All failures and alarms		
4.13	Internal clock to be maintained to retrieve data at setpoint interval i.e.; 24 hrs .		
4.14	Positive air circulation by internal fans must be provided to ensure temperature uniformity and recovery		
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	Light on/ off in case of glass door		
4.20	Auto switch off of fan when door opens		
4.21	Automatic defrost cycle and melt water evaporation in heated tray should be provided		
4.22	Dry contact for remote alarm should be provided		
4.23	1 no. Door lock should be provided		
4.24	Spring loaded, self closing door with 90° angle stay open feature should be provided with holder.		
4.25	Ring back function if any alarm condition remains active		
4.26	<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 refrigerator to centralized monitoring device with printer (common) should be minimum of approx. 25m) Placement of centralized monitoring device with printer (common) shall be office room (BF011)		
	<b>Approved makes:</b> a) Telstar b) Panasonic c) Thermo scientific d) Voltas		
<b>5</b>	<b>Other requirements</b>		
5.1	A CE declaration of conformity must be available. The CE Identification must comply with the current EC instructions.		
5.2	Cleaning shall be done manually.		
5.3	Control lights and other display elements shall not be influenced by voltage failure		
5.4	Installation of equipment with refrigerants has to be done by a certified cooling technician.		
5.5	The control circuit has to be 24 Volt		
5.6	Audio alarms have to be in the range of 2.3 — 2.9 kHz in order to avoid interference and confusion with evacuation alarms		
<b>6</b>	<b>Regulatory guidelines / standards</b>		
	NA		

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	REFRIGERATOR					
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	DOCUMENT No :	DS/BF-RFG 03				
<b>7</b>	<b>Safety requirements</b>					
7.1	Emergency stop function on accessible area.					
7.2	Noise level below 75 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.					
<b>8</b>	<b>Documents</b>					
8.1	FDS Document (If applicable)					
8.2	Technical Specifications					
8.3	MOC certificates					
8.4	IOQ protocol					
8.5	CE Certificate					
8.6	List of alarms					
8.7	Comprehensive 1 year warranty letter from date of completion.					
<b>9</b>	<b>Timelines</b>					
	NA					
	<b>NOTE:</b> Accurate size and technical specification need to be mentioned by the vendor					
	AFI Approved for Enquiry		AFO Approved for Ordering			
						
5	2013-12-18	BKSH	VKKA	<input type="checkbox"/>	<input type="checkbox"/>	
Rev	Date	Completed By	Checked By	AFI	AFO	Sheet 1 / 2

  
 18/13/14  
 (ENGG DEPT)  
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REFRIGERATOR

PROJECT No: 110729  
EQUIPMENT ID : BF-RFG 03  
DOCUMENT No : DS/BF-RFG 03



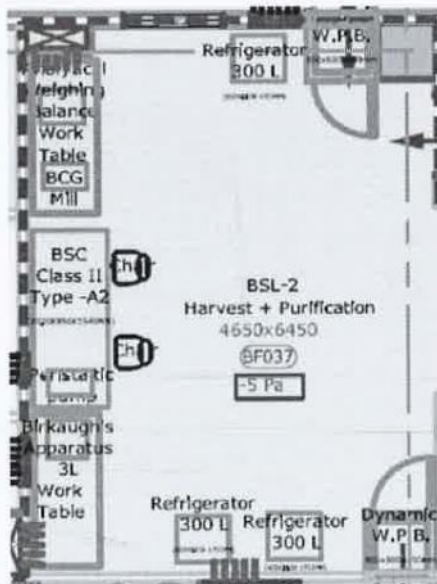
ROOM LOCATION: BSL 2 Harvest + Purification, Bulk first floor

1 Room No: BF037

2 ROOM DIMENSION:  
(4650 x 6450)

3 FALSE CEILING HEIGHT: 3000 mm

4 ROOM PRESSURE: -5 Pa



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REVIVAL OF BCG VACCINE LABORATORY, GUINDY, CHENNAI

## REFRIGERATOR

PROJECT No: 110729  
EQUIPMENT ID: BF-RFG 04  
DOCUMENT No: DS/BF-RFG 04



### 1 Process requirements

1.1 It is used to store suspension in conical flasks.

### 2 Technical Specifications

2.1	Model	cGMP Refrigerator with glass door, Upright type
2.2	Refrigerator compartment	300 L or near to standard
2.3	External dimension (W X D X H mm)	600 x 750 x 2000 or near to standard
2.4	Internal dimension (W X D X H mm)	500 x 550 x 1500 or near to standard
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 (SS 304 Perforated shelves shall be adjustable)
2.8	Purpose	To store suspension in 24 nos- 1 L conical flask
2.9	Temperature Range	+1°C to +8°C
2.10	Refrigrant	R134a (HFC refrigerant) or vendor to specify
2.11	Temperature precision (Setting resolution)	± 0.5 deg C
2.12	Temperature stability	± 1 deg C
2.13	Temperature uniformity	± 2 deg C
2.14	Air circulation	Forced air circulation
2.15	Quantity	1 No.




### 3 Material of construction

3.1	Body Construction	Interior	SS 304
		Shelves	Perforated, SS 304
		Exterior	Powder coated GI sheet or vendor to specify
3.2	Gaskets, seals, o-rings	Food Grade/ nontoxic material Use of Asbestos is prohibited	
3.3	Insulation	Heavy walled CFC Free	
3.4	Door	Double layer Borosilicate glass	
3.5	MOC Fan	Aluminium	
3.6	All welds shall be ground finish		

### 4 Specific requirements

4.1	Chamber should be rounded corners for easy cleaning.
4.2	Ring back function if any alarm condition remains active
4.3	System shall be designed for 100% coverage of the internal surface areas for manual cleaning.
4.4	The vendor shall provide the detail of cleaning agent based on compatibility of material
4.5	The refrigerators shall be provided with adjustable shelves for flexible storage
4.6	Refrigerator 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 should be installed (Two nos).
4.10	Temperature controlling must be based on set point
4.11	Interface port RS 232 to transfer data to be provided

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	REFRIGERATOR		
	PROJECT No:	110729	
	EQUIPMENT ID :	BF-RFG 04	
	DOCUMENT No :	DS/BF-RFG 04	
4.12	Inkless Chart recorder / graphic recorder.		
4.13	A complete batch record indicating the following important parameters, but not limited to these: a) Date, Time b) Infrared port (for optional data transmission) c) All failures and alarms		
4.14	Internal clock to be maintained to retrieve data at setpoint interval i.e.; 24 hrs .		
4.15	Positive air circulation by internal fans must be provided to ensure temperature uniformity and recovery		
4.16	Temperature sensor for set temperature		
4.17	Alarms for parameters like high temperature, low temperature shall be provided		
4.18	Temperature set points should be adjustable		
4.19	Alarm if door is open for >5 min.		
4.20	Light on/ off in case of glass door		
4.21	Auto switch off of fan when door opens		
4.22	Automatic defrost cycle and melt water evaporation in heated tray should be provided		
4.23	Dry contact for remote alarm should be provided		
4.24	1 no. Door lock should be provided		
4.25	Spring loaded, self closing door with 90° angle stay open feature should be provided with holder.		
4.26	<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 refrigerator to centralized monitoring device with printer (common) should be minimum of approx. 25m) Placement of centralized monitoring device with printer (common) shall be office room (BF011)		
4.27	<b>Approved makes:</b> a) Telstar b) Panasonic c) Thermo scientific d) Voltas		
5	<b>Other requirements</b>		
5.1	A CE declaration of conformity must be available. The CE Identification must comply with the current EC instructions.		
5.2	Cleaning shall be done manually		
5.3	Control lights and other display elements shall not be influenced by voltage failure		
5.4	Installation of equipment with refrigerants has to be done by a certified cooling technician.		
5.5	The control circuit has to be 24 Volt		
5.6	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	<b>Regulatory guidelines / standards</b>		
	NA		
7	<b>Safety requirements</b>		
7.1	Emergency stop function on accessible area.		
7.2	Noise level below 75 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.		
7.6	For the safety of the operator the external surfaces (equipment doors, chamber etc.) should not have temperature more than 45°C by proper insulation, etc.		
8	<b>Documents</b>		
8.1	FDS Document (If applicable)		
8.2	Technical Specifications		

## DATA SHEET

HLL LIFECARE LIMITED, CHENNAI

nne pharmaplan

REVIVAL OF BCG VACCINE LABORATORY, GUINDY, CHENNAI

## REFRIGERATOR

PROJECT No:	110729
EQUIPMENT ID :	BF-RFG 04
DOCUMENT No :	DS/BF-RFG 04



8.3	MOC certificates				
8.4	IOQ protocol				
8.5	CE Certificate				
8.6	List of alarms				
8.7	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		
5	2013-12-18	BKSH	VKKA	<input type="checkbox"/>	<input type="checkbox"/>
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REVIVAL OF BCG VACCINE LABORATORY, GUINDY, CHENNAI

## REFRIGERATOR

PROJECT No:	110729
EQUIPMENT ID :	BF-RFG 05
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## 1 Process requirements

- 1.1 It is used to store the media chemicals and Buffer Storage required for the process.

## 2 Technical Specifications

2.1	Model	cGMP Refrigerator with glass door in upper chamber and stainless steel door in lower compartment
2.2	Refrigerator compartment	300 L or near to standard
2.3	External dimension (W X D X H mm)	600 x 750 x 2000 or near to standard
2.4	Internal dimension (W X D X H mm)	500 x 550 x 1500 or near to standard
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 (SS 304 Perforated shelves shall be adjustable)
2.8	Purpose	Media chemicals and Buffer Storage
2.9	Temperature Range	+1°C to +8°C
2.10	Refrigrant	R134a (HFC refrigerant) or vendor to specify
2.11	Temperature precision	± 0.5 deg C
2.12	Temperature precision (setting resolution)	± 1 deg C
2.13	Temperature uniformity	± 2 deg C
2.14	Air circulation	Forced air circulation
2.15	Quantity	1 No.




## 3 Material of construction


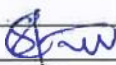




3.1	Body Construction	Interior	SS 304
		Shelves	Perforated, SS304
		Exterior	Powder coated GI sheet or <b>vendor to specify</b>
3.2	Gaskets, seals, o-rings	Food Grade/ nontoxic material Use of Asbestos is prohibited	
3.3	Insulation	Heavy walled CFC Free	
3.4	Door	Double layer Borosilicate glass in upper chamber and Stainless steel door for lower chamber	
3.5	MOC Fan	Aluminium	
3.6	All welds shall be ground finish		

## 4 Specific requirements

- 4.1 Chamber should be rounded corners for easy cleaning.
- 4.2 System shall be designed for 100% coverage of the internal surface areas for manual cleaning.
- 4.3 The vendor shall provide the detail of cleaning agent based on compatibility of material.
- 4.4 The refrigerators shall be provided with adjustable shelves for flexible storage.
- 4.5 Refrigerator shall be fitted with double-roll lockable caster wheels for easy transportation.
- 4.6 The control shall be microprocessor based with digital display cum controller.
- 4.7 Key lock for Parameter change Protection to be provided.
- 4.8 Temperature to be recorded, monitored and displayed. Temperature probe installed in freezer (Two nos).
- 4.9 Temperature controlling must be based on set point.
- 4.10 Interface port RS 232 to transfer data to be provided.
- 4.11 2 Inkless Chart recorder / graphic recorder.



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4.12	A complete batch record indicating the following important parameters, but not limited to these: a) Date, Time b) Infrared port (for optional data transmission) c) All failures and alarms		
4.13	Internal clock to be maintained to retrieve data at setpoint interval i.e.; 24 hrs .		
4.14	Positive air circulation by internal fans must be provided to ensure temperature uniformity and recovery		
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	Light on/ off in case of glass door.		
4.20	Auto switch off of fan when door opens.		
4.21	Automatic defrost cycle and melt water evaporation in heated tray should be provided.		
4.22	Dry contact for remote alarm should be provided.		
4.23	1 no. Door lock should be provided.		
4.24	Spring loaded, self closing door with 90° angle stay open feature should be provided with holder.		
4.25	Both the chambers shall have independent cooling system, controller, and power		
4.26	Ring back function if any alarm condition remains active		
4.27	<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 refrigerator to centralized monitoring device with printer (common) should be minimum of approx. 25m) Placement of centralized monitoring device with printer (common) shall be office room (BF011)		
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5	<b>Other requirements</b>		
5.1	A CE declaration of conformity must be available. The CE Identification must comply with the current EC instructions.		
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5.5	The control circuit has to be 24 Volt		
5.6	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	<b>Regulatory guidelines / standards</b>		
	NA		
7	<b>Safety requirements</b>		
7.1	Emergency stop function on accessible area.		
7.2	Noise level below 75 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.		

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	EQUIPMENT ID :	BF-RFG 05				
	DOCUMENT No :	DS/BF-RFG 05				
8	Documents					
8.1	FDS Document (If applicable)					
8.2	Technical Specifications					
8.3	MOC certificates					
8.4	IOQ protocol					
8.5	CE Certificate					
8.6	List of alarms					
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9	Timelines					
	NA					
	NOTE: Accurate size and technical specification need to be mentioned by the vendor					
	AFI Approved for Enquiry		AFO Approved for Ordering			
						
	2013-12-18	BKSH	VKKA	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
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REVIVAL OF BCG VACCINE LABORATORY, GUINDY, CHENNAI

REFRIGERATOR

PROJECT No:

110729

EQUIPMENT ID :

BF-RFG 05

DOCUMENT No :

DS/BF-RFG 05



ROOM  
LOCATION:

Media preparation, First floor

1

Room no: BF016

2

ROOM DIMENSION:

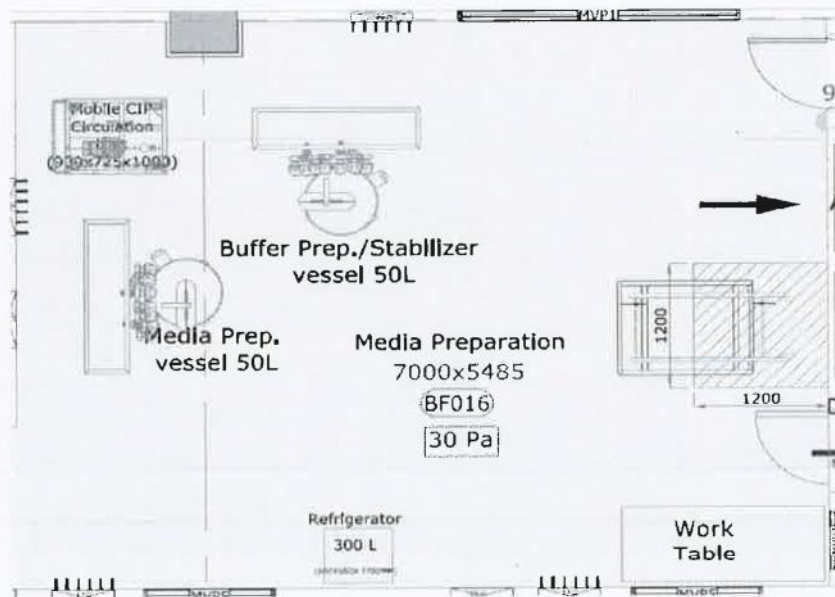
L(7000mm) X W(5485mm)

3

FALSE CEILING: 3000mm

4

ROOM PRESSURE: 30 Pa



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