

Equipment Specification Data Sheet

Equipment Name: Deep Freezer

Document No.: DS-DPF 01

Revision: 04

Project No.: 120310

Project Name: Integrated Vaccines Complex, Chengalpattu

Block Code	Block Name	Identification No.	Capacity (L)	Quantity
Deep Freezer- Low Temperature				
B4	Rabies Vaccine bulk Production	B4-DPF 01	300	1
B4	Rabies Vaccine bulk Production	B4-DPF 02	100	1
G1	Animal House	G1-DPF 02	500	1
Q1	Admin QA & QC	Q1-DPF 04	300	1
Q1	Admin QA & QC	Q1-DPF 05	300	1
Q1	Admin QA & QC	Q1-DPF 11,12	300	2
P1	Secondary packing	P1-DPF 01	300	1
Deep Freezer- Ultra Low Temperature				
B4	Rabies Vaccine bulk Production	B4-DPF 03	500	1
B4	Rabies Vaccine bulk Production	B4-DPF 04	500	1
G1	Animal House	G1-DPF 01	200	1
Q1	Admin QA & QC	Q1-DPF 01-02	300	2
Q1	Admin QA & QC	Q1-DPF 03	300	1
Q1	Admin QA & QC	Q1-DPF 06	300	1
Q1	Admin QA & QC	Q1-DPF 07-08	300	2
Q1	Admin QA & QC	Q1-DPF 9-10	300	2
F1	Viral Vaccine Formulation	F1-DPF 01-02	300	2

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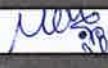
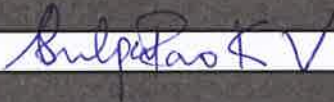

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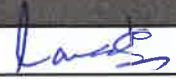
Project No.: 120310


Project Name: Integrated Vaccines Complex, Chengalpattu



NNE Pharmaplan India Limited


Name	Designation	Signature	Date
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HLL Biotech Limited


Name	Designation	Signature	Date
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Equipment Specification Data Sheet			
HLL Biotech Limited, Chennai			
nne pharma plan	INTEGRATED VACCINES COMPLEX, CHENGALPATTU		
	Equipment Name	Deep Freezer- Low Temperature	
	Document No.	DS-DPF 01	
	Revision No.	04	
1	Process Requirements		
1.1	It is used to store material at low temperature		
2	Equipment ID	Capacity (L)	Type
2.1	B4- DPF 01	300	Vertical
2.2	B4- DPF 02	100	Vertical
2.3	G1-DPF 02	500	Horizontal
2.4	Q1-DPF 04	300	Vertical
2.5	Q1-DPF 05	300	Vertical
2.6	Q1-DPF 11,12	300	Vertical
2.7	P1-DPF 01	300	Vertical
3	Technical Specification		
3.1	Model	cGMP compliant	
3.2	Operating Temperature	-20°C	
3.3	External dimension (W X D X H mm)	Vendor to specify based on the above mentioned capacities.	
3.4	Internal dimension (W X D X H mm)	Vendor to specify based on the above mentioned capacities.	
3.5	Shelves (W X D mm)	Removable shelves, no.of shelves vendor to specify based on capacity (minimum 3-5 nos to be provided) Shelves not applicable incase of horizontal deep freezer	
3.6	Height between the shelves (mm)	Refer Annexure- 1.Vendor to specify based on the above mentioned capacities.	
3.7	Outer Door type	Single door	
3.8	Refrigerant	CFC free(nonflammable)	
3.9	Temperature precision (setting resolution)	± 0.5 °C	
3.10	Temperature resolution	± 0.1 °C	
3.11	Temperature range	-10 to -30 °C	
3.12	Control & Display	Touch key pad with LED display mounted in the door	
3.13	Temperature Regulation	Microprocessor controlled	
3.14	Temperature uniformity	± 3°C	
3.15	Validation Port	Ports for inserting probes for temperature mapping to be provided	
3.16	Battery backup for panel	To be provided	
3.17	Set point security	To be provided	
3.18	Chart Recorder	To be provided	
3.19	Air circulation	Natural Circulation	
3.20	Total quantity	8 No's	
3.21	power required (KW)	To be compatible to standard Indian power supply sockets	


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HLL Biotech Limited, Chennai			
	INTEGRATED VACCINES COMPLEX, CHENGALPATTU		
	Equipment Name	Deep Freezer- Low Temperature	
	Document No.	DS-DPF 01	
	Revision No.	04	
4	Material of Construction		
4.1	Body Construction	Interior	SS 304
4.2		Shelves	Adjustable shelf, SS 304
4.3		Exterior	cGMP compliant
4.4		Inner Door	SS 304 door for each shelf (not applicable for horizontal deep freezer)
4.5		External Door	cGMP compliant
4.6	Gaskets, seals, o-rings	Food Grade/ nontoxic material	
4.7	Insulation	Polyurethane Foam(PUF)	
4.8	All welds shall be ground finish		
5	Specific Equipment Requirements		
5.1	The design of the equipment shall facilitate efficient and easy cleaning		
5.2	Auto defrost to be provided		
5.3	The equipment shall be compatible for cleaning with all standard disinfectants.		
5.4	Freezer shall be fitted with lockable caster wheels for easy transportation		
5.5	The control shall be microprocessor based with digital display cum controller.		
5.6	Key lock for Parameter change Protection to be provided		
5.7	Temperature to be recorded, monitored and displayed, Temperature probe installed in freezer.		
5.8	Interface port RS 232 to transfer data to be provided		
5.9	Internal clock to be maintained to retrieve data at set point interval i.e.; 24 hrs.		
5.10	Positive air circulation by internal fans must be provided to ensure temperature uniformity and recovery.		
5.11	Audio Visual Alarms for parameters like high temperature, low temperature, door opening shall be provided.		
5.12	Door lock should be provided		
5.13	Spring loaded, self-closing door with 90° angle stay open feature should be provided with holder.		
5.14	Temperature mapping during installation is required.		
5.15	Single compressor shall be provided.		
5.16	Temperature sensor (PT 100) should be provided.		
5.17	Equipment shall be compatible for cleaning with all standard disinfectants.		
6	Other Requirement		
6.1	Training / demonstration to be provided to users on operation and cleaning to be provided.		
7	Regulatory guidelines / standards		
7.1	CE certification		
8	Safety Requirements		
	Following facilities must be provided to protect personnel and equipment:		
8.1	Emergency stop function on accessible area.		
8.2	Noise level Should not be more than 60 decibels.		
8.3	Proper earthing should be provided.		
8.4	No sharp edges/Corners, crevices, in the equipment.		
8.5	Appropriate closure of all parts		


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HLL Biotech Limited, Chennai		
nne pharmaplan	INTEGRATED VACCINES COMPLEX, CHENGALPATTU	
	Equipment Name	Deep Freezer- Low Temperature
	Document No.	DS-DPF 01
	Revision No.	04
		
9	Documents	
	Following documents, but not limited to these, are expected from the vendor as part of supply package in hard copy as well as editable electronic file.	
9.1	IOQ documents.	
9.2	Operation and maintenance manuals shall be provided along with IOQ documents during installation at site.	
9.3	Warranty letter for 1 year from the date of supply.	
9.4	Calibration certificate of critical instrument with respect to the traceable national reference standard instrument and their calibration procedure.	
9.5	List of standard spare parts with ordering information.	
10	Timelines	
10.1	Not Applicable	
11	List of Preferred make	
11.1	Panasonic, JeioTech, Arctiko, Thermo scientific, Eppendorf	
	NOTE: Accurate size and technical specification need to be mentioned by the vendor	

Equipment Specification Data Sheet					
HLL Biotech Limited, Chennai					
nne pharmaplan®	INTEGRATED VACCINES COMPLEX, CHENGALPATTU				
	Equipment Name	Deep Freezer- Low Temperature			
	Document No.	DS-DPF 01			
	Revision No.	04			
Table-1: Equipment location					
EQUIPMENT ID	Block Name	Room Name	Room No	Room dimension in mm	Room height in mm
B4-DPF 01	Rabies Vaccine bulk Production	Media Preparation	B4G027	6800 x 4150	2700
B4-DPF 02	Rabies Vaccine bulk Production	Virus Inactivation room	B4G059	5700 x 3350	2700
G1-DPF 02	Animal House	Decontamination Autoclave (unloading)	G1G105	7500 x 3450	2700
Q1-DPF 04	Admin QA & QC	Viral sample holding room with deep freezers	Q1S012	3501 x 3550	2400
Q1-DPF 05	Admin QA & QC	Chemical Lab / Bio Chemistry	Q1S022	6250 x 7350	2400
Q1-DPF 11,12	Admin QA & QC	Microbiology Lab	Q1S045	3700 x 4600	2400
P1-DPF 01	Secondary packing	Materials staging for packing - 1	P1S005	4900 x 4080	3000
Table-2: Change Log					
Date	Name	Revision	Section	Change/Comment	
11-07-2014	Manohar	00	-	New document	
04-08-2014	Manohar	01	All	Updated as per comments received from HBL dated 04-08-2014	
27-10-2014	Manohar	02	All	Updated as per comments received from HBL dated 15-10-2014	
06-01-2015	Yogesha M J	03	All	Updated as per comments given by HBL team during meeting dated 06-01-2015 at HBL office	
06-05-2015	Manohar	04	All	Updated as per comments received from HBL dated 27-02-2015	
Table-3: Annexure (specific equipment details)					
EQUIPMENT ID	Shelf Dimension (W X D mm)	Height between the shelves (mm)	Internal Dimension (W X D X H mm)	External Dimension (W X D X H mm)	
B4-DPF 01	vendor to specify	vendor to specify	vendor to specify	vendor to specify	
B4-DPF 02	vendor to specify	vendor to specify	vendor to specify	vendor to specify	
G1-DPF 02	vendor to specify	vendor to specify	vendor to specify	vendor to specify	
Q1-DPF 04	vendor to specify	vendor to specify	vendor to specify	vendor to specify	
Q1-DPF 05	vendor to specify	vendor to specify	vendor to specify	vendor to specify	
Q1-DPF 11	vendor to specify	vendor to specify	vendor to specify	vendor to specify	
P1-DPF 01	vendor to specify	vendor to specify	vendor to specify	vendor to specify	

Equipment Specification Data Sheet		
HLL Biotech Limited, Chennai		
nne pharmaplan®	INTEGRATED VACCINES COMPLEX, CHENGALPATTU	
	Equipment Name	Deep Freezer- Ultra Low Temperature
	Document No.	DS-DPF 01
	Revision No.	04
		
1	Process Requirements	
1.1	It is used to store materials at Ultra low temperature.	
2	Equipment ID	Capacity (L)
2.1	B4- DPF 03	500
2.2	B4- DPF 04	500
2.3	G1-DPF 01	200
2.4	Q1-DPF 01	300
2.5	Q1-DPF 02	300
2.6	Q1-DPF 03	300
2.7	Q1-DPF 06	300
2.8	Q1-DPF 07	300
2.9	Q1-DPF 08	300
2.10	Q1-DPF 09	300
2.11	Q1-DPF 10	300
2.12	F1-DPF 01	300
2.13	F1-DPF 02	300
3	Technical Specifications	
3.1	Model	cGMP compliant
3.2	Operating Temperature	- 80°C
3.3	External dimension (W X D X H mm)	Vendor to specify based on the above mentioned capacities.
3.4	Internal dimension (W X D X H mm)	Vendor to specify based on the above mentioned capacities.
3.5	Shelves (W X D mm)	Removable shelves, no.of shelves vendor to specify based on capacity (minimum 3-5 nos to be provided)
3.6	Height between the shelves (mm)	Refer Annexure- 1.Vendor to specify based on the above mentioned capacities.
3.7	Outer Door type	Single door
3.8	Refrigerant	CFC free
3.9	Temperature precision (setting resolution)	± 0.5 °C
3.10	Temperature resolution	± 0.1 °C
3.11	Control & Display	Touch key pad with LED display mounted in the door
3.12	Temperature Regulation	Microprocessor controlled
3.13	Temperature uniformity	± 3°C
3.14	Validation Port	Ports for inserting probes for temperature mapping to be provided
3.15	Battery backup for panel	To be provided
3.16	Set point security	To be provided
3.17	Chart Recorder	To be provided

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		Revision No.	04	
3.18	Air circulation	Natural Circulation		
3.19	Total quantity	13 No's		
3.20	power requirement	To be compatible to standard Indian power supply sockets		
4	Material of Construction			
4.1	Body Construction	Interior	SS 304	
4.2		Shelves	Adjustable shelf, SS 304	
4.3		Exterior	cGMP compliant	
4.4		Inner Door	SS 304 door for each shelf	
4.5		External Door	cGMP compliant	
4.6	Gaskets, seals, o-rings	Food Grade/ nontoxic material		
4.7	Insulation	CFC Free		
4.8	All welds shall be ground finish			
5	Specific Equipment Requirements			
5.1	The design of the equipment shall facilitate efficient and easy cleaning			
5.2	Auto defrost to be provided			
5.3	The equipment shall be compatible for cleaning with all standard disinfectants.			
5.4	Freezer shall be fitted with lockable caster wheels for easy transportation			
5.5	The control shall be microprocessor based with digital display cum controller (SMS alert at the time of deviation temperature)			
5.6	Key lock for Parameter change Protection to be provided			
5.7	Temperature to be recorded, monitored and displayed. Temperature probe installed in freezer.			
5.8	Interface port RS 232 to transfer data to be provided.			
5.9	Internal clock to be maintained to retrieve data at set point interval i.e.; 24 hrs.			
5.10	Positive air circulation by internal fans must be provided to ensure temperature uniformity and recovery.			
5.11	Audio Visual Alarms for parameters like high temperature, low temperature shall be provided.			
5.12	Door lock should be provided			
5.13	Spring loaded, self-closing door with 90° angle stay open feature should be provided with holder.			
5.14	Temperature mapping during installation is required.			
6	Other Requirement			
6.1	Training/Demo for the users on operating and cleaning to be provided.			
7	Regulatory guidelines / Standards			
7.1	CE certification.			
8	Safety Requirements			
	Following facilities must be provided to protect personnel and equipment:			
8.1	Appropriate closure of all parts			
8.2	Emergency stop function on accessible area.			
8.3	Noise level Should not be more than 60 decibels.			

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8.4	Proper earthing should be provided.	
8.5	No sharp edges/Corners, crevices, in the equipment.	
9	Documents	
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9.1	IQ documents.	
9.2	Operation and maintenance manuals shall be provided along with IQ documents during installation at site.	
9.3	Warranty letter for 1 year from the date of installation.	
9.4	Calibration certificate of critical instrument with respect to the traceable national reference standard instrument and their calibration procedure.	
9.5	List of standard spare parts with ordering information.	
10	Timelines	
10.1	Not Applicable	
11	List of Preferred make	
11.1	Panasonic, JeioTech, Arctiko, Thermo scientific, Eppendorf	
	NOTE: Accurate size and technical specification need to be mentioned by the vendor	

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	Document No.	DS-DPF 01			
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Table-1: Equipment location					
EQUIPMENT ID	Block Name	Room Name	Room No	Room dimension in mm	Room height in mm
B4-DPF 03	Rabies Vaccine bulk Production	Virus Seed Lab	B4G048	4700 x 2950	2700
B4-DPF 04	Rabies Vaccine bulk Production	Spare room	B4G014	2060 x 3900	2700
G1-DPF 01	Animal House	Lab area - Testing	G1G055	4700 x 7300	2700
Q1-DPF 01-02	Admin QA & QC	Control Sample	Q1S007	4750 x 5200	2400
Q1-DPF 03	Admin QA & QC	Viral sample holding room with deep freezers	Q1S012	3500 x 3550	2400
Q1-DPF 06	Admin QA & QC	Chemical Lab / Bio Chemistry	Q1S022	6250 x 7350	2400
Q1-DPF 07-08	Admin QA & QC	Master seed storage (virus)	Q1S030	2500 x 5500	2400
Q1-DPF 09-10	Admin QA & QC	Master seed storage (bacterial)	Q1S031	2900 x 3750	2400
F1-DPF 01-02	Viral Vaccine Formulation	Final Bulk Storage room	F1G052	3800 X 6200	30010
Table-2: Change Log					
Date	Name	Revision	Section	Change/Comment	
11-07-2014	Manohar	00	-	New document	
04-08-2014	Manohar	01	All	Updated as per comments received from HBL dated 04-08-2014	
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06-01-2015	Yogesha M J	03	All	Updated as per comments given by HBL team during meeting dated 06-01-2015 at HBL office	
06-05-2015	Manohar	04	All	Updated as per comments received from HBL dated 27-02-2015	
Table-3: Annexure (specific equipment details)					
EQUIPMENT ID	Model type	Shelf Dimension (W X D mm)	Height between the shelves (mm)	Internal Dimension (W X D X H mm)	External Dimension (W X D X H mm)
B4-DPF 03	Horizontal	vendor to specify	vendor to specify	vendor to specify	vendor to specify
B4-DPF 04	Horizontal	vendor to specify	vendor to specify	vendor to specify	vendor to specify
G1-DPF 01	Vertical	vendor to specify	vendor to specify	vendor to specify	vendor to specify
Q1-DPF 01-02	Vertical	vendor to specify	vendor to specify	vendor to specify	vendor to specify
Q1-DPF 03	Vertical	vendor to specify	vendor to specify	vendor to specify	vendor to specify
Q1-DPF 06	Vertical	vendor to specify	vendor to specify	vendor to specify	vendor to specify
Q1-DPF 07-08	Vertical	vendor to specify	vendor to specify	vendor to specify	vendor to specify
Q1-DPF 09-10	Vertical	vendor to specify	vendor to specify	vendor to specify	vendor to specify
F1-DPF 01-02	Horizontal	vendor to specify	vendor to specify	vendor to specify	vendor to specify