

Equipment Specification Data Sheet

HLL Biotech Limited, Chennai

nne pharmaplan®

**REVIVAL OF DPT VACCINE MANUFACTURING FACILITY, PII,
COONOOR**

Low Temperature Deep Freezer

PROJECT NO : 110831

Equipment ID :

Document No. DS-DPF 01



1	Equipment ID	Capacity (L)	Quantity (no's)	Type	Process Requirements
1.1	B1-DPF 01	TBD (It Should store minimum 200Kg of meat)	1	Horizontal (TBD)	It is used to store material at low & ultra low temperature
1.2	M1-DPF 01	300	1	Vertical	
1.3	A2-DPF 01-02	300	2	Vertical	
1.4	A1-DPF 01	100	1	Vertical	
1.5	A1-DPF 02	100	1	Vertical	
2	Technical Specification				
2.1	Model	cGMP compliant			
2.2	Operating Temperature	-20°C			
2.3	External dimension (W X D X H mm)	Vendor to specify based on the above mentioned capacities.			
2.4	Internal dimension (W X D X H mm)	Vendor to specify based on the above mentioned capacities.			
2.5	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			
2.6	Height between the shelves (mm)	Refer Annexure- 1.Vendor to specify based on the above mentioned capacities.			
2.7	Outer Door type	Single door			
2.8	Refrigerant	CFC free(non flammable)			
2.9	Temperature precision (setting resolution)	± 0.5 °C			
2.1	Temperature resolution	± 0.1 °C			
2.11	Temperature range	-10 to -30 °C			
2.12	Control & Display	Touch key pad with LED display mounted in the door			
2.13	Tempertaure Regulation	Microprocessor controlled			
2.14	Temperature uniformity	± 3°C			
2.15	Validation Port	Ports for inserting probes for temperature mapping to be provided			
2.16	Battery back up for panel	To be provided			
2.17	Set point security	To be provided			
2.18	Chart Recorder	To be provided			
2.19	Air circulation	Natural Circulation			
2.2	Total quantity	6 Nos			
2.21	power requied (KW)	To be compatible to standard Indian power supply sockets			
3	Material of Construction				
3.1		Interior			SS 304

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3.2	Body Construction	Shelves	Adjustable shelf, SS 304
3.3		Exterior	cGMP compliant
3.4		Inner Door	SS 304 door for each shelf (not applicable for horizontal deep freezer)
3.5		External Door	cGMP compliant
3.6	Gaskets, seals, o-rings	Food Grade/ nontoxic material	
3.7	Insulation	Polyurethane Foam(PUF)	
3.8	All welds shall be ground finish		
4	Specific Equipment requirement		
4.1	The design of the equipment shall facilitate efficiency and easy cleaning		
4.2	Auto defrost to be provided		
4.3	The equipment shall be compatible for cleaning with all standard disinfectants.		
4.4	Freezer shall be fitted with lockable caster wheels for easy transportation		
4.5	The control shall be microprocessor based with digital display cum controller.		
4.6	Key lock for Parameter change Protection to be provided		
4.7	Temperature to be recorded, monitored and displayed. Temperature probe installed in freezer .		
4.8	Interface port RS 232 to transfer data to be provided .		
4.9	Internal clock to be maintained to retrieve data at setpoint interval i.e.; 24 hrs .		
4.10	Positive air circulation by internal fans must be provided to ensure temperature uniformity and recovery.		
4.11	Audio Visual Alarms for parameters like high temperature, low temperature,door opening shall be provided.		
4.12	Door lock should be provided		
4.13	Spring loaded, self closing door with 90° angle stay open feature should be provided with holder.		
4.14	Temperature mapping during installation is required.		
4.15	Single compressor shall be provided.		
4.16	Temperature sensor(PT 100) should be provided.		
4.17	Equipment shall be compatible for cleaning with all standard disinfectants.		
5	Other requirement		
5.1	Training / demonstration to be provided to users on operation and cleaning to be provided.		
6	Regulatory guidelines / standards		
6.1	CE certification		
7	Safety requirements		
7.1	Following facilities must be provided to protect personnel and equipment:		
7.2	Emergency stop function on accessible area.		
7.3	Noise level Should not be more than 60 decibels.		
7.4	Proper earthing should be provided.		
7.5	No sharp edges/Corners, crevices, in the equipment.		

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7.6	Appropriate closure of all parts
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8	Documents
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	Following documents, but not limited to these, are expected from the vendor as part of the supply package in hard copy as well as editable electronic file
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8.1	IOQ Protocol.
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8.2	Operation and maintenance manuals shall be provided along with IQ and OQ documents during installation at site
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8.3	Calibration certificate of critical instruments with respect to the traceable national reference standard instrument and their calibration procedure.
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8.4	All equipment warranty should be valid for one year from the date of completion.
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8.5	Vendor should provide list of standard spare parts with ordering information.
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8.6	Vendor should provide list of change parts (if applicable) with ordering information
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9	Timelines
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9.1	Not Applicable
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	NOTE: Accurate size and technical specification need to be mentioned by the vendor
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	AFI Approved for Enquiry		AFO Approved for Ordering			
01	2015-10-09	MGGP	PULM	<input type="checkbox"/>	<input type="checkbox"/>	Sheet 1/2
Rev	Date	Completed By	Checked by	AFI	AFO	

DATA SHEET

HLL BIOTECH LIMITED, CHENNAI

nne pharmaplan®	REVIVAL OF DPT VACCINE MANUFACTURING FACILITY, PII, COONOOR		 <small>HLL BIOTECH LIMITED (Subsidiary of HLL Lifecare Limited) (A Government of India Enterprise)</small>
	Low Temperature Deep Freezer		
	PROJECT NO :	110831	
	EQUIPMENT ID :		
	DOCUMENT NO :	DS-DPF-01	

TABLE NO: 1 (Equipment location)

EQUIPMENT ID	Block Name	Room Name	Room No	Room dimension in mm	Room height in mm
B1-DPF 01	Meat Media Preparation	Meat Store	B1G090	3055 x 1575	3000
M1-DPF 01	Sterility Media Preparation and Microbiology	Lab	M1G039	3020 x 5050	3000
A2-DPF 01-02	Animal Experiment	Store	A2G011	5000 x 3230	3000
A1-DPF 01	Animal Breeding	Post mortem room	A1G019	3600 x 3125	2700
A1-DPF 02	Animal Breeding	Post mortem room	A1F018	3700 x 3130	2700

Table-3: (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)
B1-DPF 01	vendor to specify	vendor to specify	vendor to specify	vendor to specify
M1-DPF 01	vendor to specify	vendor to specify	vendor to specify	vendor to specify
M1-DPF 02	vendor to specify	vendor to specify	vendor to specify	vendor to specify
A2-DPF 01-02	vendor to specify	vendor to specify	vendor to specify	vendor to specify
A1-DPF 01	vendor to specify	vendor to specify	vendor to specify	vendor to specify
A1-DPF 02	vendor to specify	vendor to specify	vendor to specify	vendor to specify

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