

nne pharmaplan®		REVIVAL OF DPT VACCINE MANUFACTURING FACILITY, PII, COONOOR			
		Ultra Low Temperature Deep Freezer			
		PROJECT NO :		110831	
		Equipment ID :		DS-DPF 01	
Document No.		DS-DPF 01		 <small>HBL BIOTECH LIMITED Subsidiary of HBL Life Sciences Limited A Government of India Enterprise</small>	
1	Equipment ID	Capacity (L)	Quantity (no's)		
1.1	M1-DPF 02	300 (TBD)	1	Vertical	It is used to store materials at Ultra low temperature.
2	Technical Specifications				
2.1	Model	cGMP compliant			
2.2	Operating Temperature	- 80°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)			
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			
2.9	Temperature precision (setting resolution)	± 0.5 °C			
2.10	Temperature resolution	± 0.1 °C			
2.11	Control & Display	Touch key pad with LED display mounted in the door			
2.12	Tempertaure Regulation	Microprocessor controlled			
2.13	Temperature uniformity	± 3°C			
2.14	Validation Port	Ports for inserting probes for temperature mapping to be provided			
2.15	Battery back up for panel	To be provided			
2.16	Set point security	To be provided			
2.17	Chart Recorder	To be provided			
2.18	Air circulation	Natural Circulation			
2.19	Total quantity	1 No			
2.20	power requirement	To be compatible to standard Indian power supply sockets			
3	Material of Construction				
3.1	Body Construction	Interior	SS 304		
3.2		Shelves	Adjustable shelf, SS 304		
3.3		Exterior	cGMP compliant		
3.4		Inner Door	SS 304 door for each shelf		
3.5		External Door	cGMP compliant		
3.6	Gaskets, seals, o-rings	Food Grade/ nontoxic material			
3.7	Insulation	CFC Free			
3.8	All welds shall be ground finish				
4	Specific Equipment Requirements				
4.1	The design of the equipment shall facilitate efficiency and easy cleaning				
4.2	Auto defrost to be provided				

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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.(SMS alert at the time of deviation temperature)				
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 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.				
5	Other Requirement				
5.1	Training/Demo for the users on operating and cleaning to be provided.				
6	Regulatory guidelines / Standards				
6.1	CE certification.				
7	Safety Requirements				
	Following facilities must be provided to protect personnel and equipment:				
7.1	Appropriate closure of all parts				
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.				
8	Documents				
	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				
8.1	IOQ Protocol.				
8.2	Operation and maintenance manuals shall be provided along with IQ and OQ documents during installation at site				
8.3	Calibration certificate of critical instruments with respect to the traceable national reference standard instrument and their calibration procedure.				
8.4	All equipment warranty should be valid for one year from the date of completion.				
8.5	Vendor should provide list of standard spare parts with ordering information.				
8.6	Vendor should provide list of change parts (if applicable) with ordering information				
9	Timelines				
9.1	Not Applicable				
	NOTE: Accurate size and technical specification need to be mentioned by the vendor				
	AFI Approved for Enquiry		AFO Approved for Ordering		
01	2015-10-09	MGGP	PULM	<input type="checkbox"/>	<input type="checkbox"/>
Rev	Date	Completed By	Checked by	AFI	AFO

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DATA SHEET

HLL BIOTECH LIMITED, CHENNAI

	REVIVAL OF DPT VACCINE MANUFACTURING FACILITY, PII, COONOOR		 <small>HLL BIOTECH LIMITED (Subsidiary of HLL Lifecare Limited) (A Government of India Enterprise)</small>
	Ultra Low Temperature Deep Freezer		
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	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
M1-DPF 02	Sterility Media Preparation and Microbiology	Lab	M1G039	3020 x 5050	3000



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