






DATA SHEET						
HLL Biotech Limited, Chennai						
nne pharmaplan®		REVIVAL OF DPT VACCINE MANUFACTURING FACILITY, PII, COONOR			 HLL BIOTECH LIMITED <small>(Subsidiary of HLL, formerly unihel) (A Government of India Enterprise)</small>	
		Refrigerator				
		Project #	110831			
		Document #	DS-RFR 01			
1	Process Requirements					
1.1	It is used to store materials at 2-8 °C					
2	Equipment ID, Capacity, and Quantity					
	Equipment ID	Minimum capacity (L) near to standard	Quantity (No.s)	DoorType		
2.1	B1-RFR 01	300	1 (Refer annexure 1)	Vertical single door		
2.2	B1-RFR 02,03,04	300	3			
2.3	B1-RFR 05	160	1			
2.4	B2-RFR 01, 02	300	2			
2.5	F1-RFR 01	300	1			
2.6	M1-RFR 01,02	360	2	Vertical double door		
2.7	A2-RFR 01,02	300	2	Vertical single door		
2.8	A1-RFR 01,02	300	2			
3	Technical Specification					
3.1	Model	cGMP				
3.2	External dimension (W X D X H mm)	vendor to specify (based on the above mentioned capacity)				
3.3	Internal dimension (W X D X H mm)	vendor to specify (As per the capacity)				
3.4	Shelves (W X D mm)	vendor to specify (As per the capacity)				
3.5	Height between the shelves (mm)	vendor to specify				
3.6	No. of Shelves	vendor to specify (SS 304 Perforated shelves shall be adjustable)				
3.7	Temperature Range	2 °C to 8 °C				
3.8	Refrigerant	R 134a				
3.9	Temperature precision	± 0.5 °C				
3.10	Temperature stability	± 1 °C				
3.11	Temperature Resolution	± 1 °C				
3.12	Temperature uniformity	± 2 °C				
3.13	Air circulation	Forced air circulation				
3.14	Quantity	300L- 11no.s				
		160L-1 no.				
		360L-2 no.s				
3.15	Power requirement	To be compatible to standard Indian Power supply socket.				
4	Material of Construction					
4.1		Interior	SS 304			
4.2	Body Construction	Shelves	Adjustable,Perforated, SS304			

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4.3		Exterior	cGMP compliant exterior	
4.4	Gaskets, seals, o-rings	Food Grade/ nontoxic material		
4.5	Insulation	Polyurethane foam(PUF)		
4.6	Door	Stainless steel door		
4.7	All welds shall be ground finish.			
5	Specific Equipment Requirements			
5.1	The design of the equipment should facilitate efficient and easy cleaning			
5.2	The equipment shall be compatible for cleaning with all standards disinfectants			
5.3	Refrigerator shall be fitted with lockable caster wheels for easy transportation.			
5.4	The control shall be microprocessor based with digital display cum controller.			
5.5	Key lock for Parameter change Protection to be provided.			
5.6	Temperature to be recorded, monitored and displayed. Circular chart recorder to be provided.(PT 100)			
5.7	Interface port RS 232 to transfer data to be provided.			
5.8	Positive air circulation by internal fans must be provided to ensure temperature uniformity and recovery			
5.9	Audio visual alarms for parameters like high temperature, low temperature shall be provided and if door is open for > 5min.			
5.10	Light on provision during door opening			
5.11	Door lock should be provided.			
5.12	Spring loaded, self closing door with 90° angle stay open feature should be provided with holder.			
5.13	Validation Ports to be provided for inserting probes for temperature mapping.			
5.14	Temperature mapping during installation is required.			
5.15	Single compressor should be provided.			
5.16	Equipment shall be compatible for cleaning with all standard disinfectant.			
5.17	Design Basis: Refer Annexure 1 for specific design of B1-RFR 01			
6	Other Requirements			
6.1	Training /Demo for the users on operation and cleaning to be provided.			
7	Regulatory Aspects			
7.1	CE certification.			
8	Safety Requirements			
	Following facilities must be provided to protect personnel and equipment:			
8.1	Proper earthing is necessary			
8.2	No sharp edges/Corners in the equipment.			
8.3	Appropriate closure of all parts.			
9	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.			
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 completion.			

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	Refrigerator					
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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					
	NOTE: Accurate size and technical specification need to be mentioned by the vendor					
	AFI Approved for Enquiry			AFO Approved for Ordering		
01	24-09-2015	MNS	PULM	<input type="checkbox"/>	<input type="checkbox"/>	
Rev	Date	Completed By	Checked By	AFI	AFO	Sheet 1 / 3

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	Refrigerator						
	Project #			110831			
	Document #			DS-RFR 01			
TABLE NO: 1							
EQUIPMENT ID	Block Name	Room Name	Quantity(No's)	Capacity(L)	Room No	Room dimension in mm	Room height in mm
B1-RFR 01	Diphtheria Bulk	Seed Preparation	11	300	B1G047	3500 x 6510	3000
B1-RFR 02	Diphtheria Bulk	IPQC			B1G057	2200 x 3310	3000
B1-RFR 03	Diphtheria Bulk	Media and buffer room			B1G069	4900 x 3610 2000 x 2900	4000
B1-RFR 04	Pertussis Bulk	Seed preparation			B1G008	3500 x 6510	3000
B2-RFR 01	Tetanus Bulk	IPQC			B2G026	3200 x 7435	3000
B2-RFR 02	Tetanus Bulk	Seed preparation			B2G028	4600 x 3500 3675 x 2110	3000
F1-RFR 01	Formulation Block	Blending area			F1G057	5515 x 7730	4000
A2-RFR 01	Animal Experiment	Histopathology + Microbiology room			A2G019	6250 x 3250	3000
A2-RFR 02	Animal Experiment	Euthenesia + Post mortem room			A2G021	4400 x 2550	3000
A1-RFR 01	Animal Breeding	Animal health monitor			A1G012	2300 x 6350	2700
A1-RFR 02	Animal Breeding	Animal health monitor			A1F014	2650 x 5215	2700
M1-RFR 01-02	Sterility Media Preparation and Microbiology	Lab	2	360	M1G039	3020 x 5050	3000
B1-RFR 05	Pertussis Bulk	IPQC	1	100	B1G018	2200 x 3310	3000
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Annexure 1 can contain specific equipment details						
Table no.						
EQUIPMENT ID	Door type	Design Basis				
B1-RFR 01	Vertical	To store container having 6L (working volume) of 4 no.s seed flask Glass bottle dimensions: Diameter: 220 mm Height: 360 mm				
	AFI Approved for Enquiry			AFO Approved for Ordering		
01	24-09-2015	MNS	PULM	<input type="checkbox"/>	<input type="checkbox"/>	
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