

DATA SHEET			
HLL BIOTECH LIMITED, CHENNAI			
nne pharmaplan®	REVIVAL OF DPT VACCINE MANUFACTURING FACILITY, PII, COONOOR		 HLL BIOTECH LIMITED <small>(Subsidiary of HLL Lifecare Limited) (A Government of India Enterprise)</small>
	Table Top Lyophiliser		
	Project No :	110831	
	EQUIPMENT ID :	Annexure 1	
	Document No:	DS-TLY-01	
1.0	Process requirements		
1.1	Table Top Lyophiliser shall be used for lyophilisation of samples in vials and Ampule.		
2.0	Technical Specifications		
2.1	Model	Benchtop cGLP model	
2.2	Maximum Condenser Chamber Capacity	TBD	
2.3	Water Removal capacity (in 12hr)	2 L (Vendor to confirm)	
2.4	Maximum Ice holding capacity	6 L (Vendor to confirm)	
2.5	Collector Temperature	-50°C, -58 °F (Vendor to confirm)	
2.6	No of Manifolds	10 ports with vacuum valves (PIIC to confirm)	
2.7	Vaccum	<10 Pa or PIIC to confirm	
2.8	Pump capacity	144 L/Min or larger vacuum pump displacement required (PIIC to confirm)	
2.9	Weight (Kg)	Vendor to specify	
2.10	Overall Dimesions	Vendor to specify	
2.11	Power Consumption	Vendor to specify	
2.12	Total quantity	4 no.s	
3.0	Material of Construction		
3.1	Condensor coil	Stainless steel	
3.2	Internal Body	Stainless steel	
3.3	External Body	Brushed stainless steel, epoxy coated (Vendor to coinfirm)	
3.4	Accessories	Vendor to specify	
4.0	Specific Equipment requirement		
4.1	Design shall be suitable for Flask, vials,Ampule ,Trays and Specimens.		
4.2	-50 °C Horizontal smooth wall all stainless steel ice condenser		
4.3	System shall be design to defrost the hot gases rapidly		
4.4	Vacuum & temperature gauges shall be provided		
4.5	The equipment should be compatible for vials and ampoules with suitable change parts		
4.6	It shall be CFC free refrigeration system		
4.7	LCD with system operating parameters and alarms		
4.8	Moisture sensor must be considered with the system		
4.9	Vacuum break valve for supply of air in system when power to freezer drier is shut off.		
4.10	Side mounted retractable collector drain hose should be considered		
4.11	All type suitable drying accessories shall be provided		
4.12	It should be provided with LED displaying vacuum and temperature wave graphs		
4.13	Automatic start-up switch for collector cool-down and vacuum pull-down with manual override switches should be provided		
4.14	It should be provided choice of selecting temperature in °C & ° F, and vacuum in mBar, Pa & Torr.		
5.0	Other requirements		

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5.1	The equipment should be equipped with RS232 as standard along with USB port also.					
5.2	The control shall be microprocessor based with digital display cum controller.					
5.3	Temperature to be recorded, monitored and displayed. Temperature probe should be installed .					
5.4	Temperature set points should be adjustable and controlling must be based on set point					
5.5	Red alarm light in case of sudden power failure					
6.0	Regulatory aspects					
6.1	cGLP or cGMP					
7.0	Safety requirements					
7.1	Alarms shall be provided for unexpected power shut down.					
8.0	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.					
8.3	Vendor should provide warranty Letter for Minimum 1 years, from the date of supply.					
8.4	Vendor should provide list of standard spare parts with ordering information.					
8.5	Vendor should provide list of change parts (if applicable) with ordering information					
8.6	Vendor should provide list of make with certificate.					
9.0	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	26-10-2015	NRU	MNS	<input type="checkbox"/>	<input type="checkbox"/>	
Rev	Date	Completed By	Checked By	AFI	AFO	Sheet 1/2

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	DOCUMENT NO : DS-TLY-01	

TABLE NO: 1

Equipment ID	Block Name	Quantity	Room Name	Room No	Room dimension in mm	Room height in mm
B1-TLY 01	Diphtheria	1	Seed Preparation	B1G047	3000 x 6510	3000
B1-TLY 01	Pertussis	1	Seed Preparation	B1G008	3500 x 6510	3000
B2-TLY 01	Tetanus	1	Seed Preparation	B2G028	4600 x 5280	3000
M1-TLY 01	Microbiology and QC	1	Lab	M1G039	3020 x 5050	3000



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