

DATA SHEET		
HLL BIOTECH LIMITED, CHENNAI		
nne pharmaplan®	REVIVAL OF DPT VACCINE MANUFACTURING FACILITY, PII, COONOOR	
	Incubator with Shaker	
	Project No : 110831	
	EQUIPMENT ID : Annexure 1	
	Document No: DS-ICS-01	
		
1.0	Process requirements	
1.1	Incubator with shaker will be used for mixing of samples, Cell cultivation, Extraction and Dissolving of samples in controlled temperature and Relative humidity.	
2.0	Technical Specifications	
2.1	Model	GLP(Table Top Model)
2.2	Quantity	2 No.s
2.3	Temperature Control type	Microprocessor PID control
2.4	Display	LCD
2.5	Temperature Control(°C)	5 to 60
2.6	Temperature Setability(°C)	0.1
2.7	Speed Range(RPM)	10 to 300
2.8	Accuracy(RPM)	± 1
2.9	Platform Size(mm)	Vendor to specify
2.10	Operating Time Range (min)	Vendor to specify
2.11	Operating Temperature(°C)	15 to 60
2.12	Operating Relative Humidity	80% at or below 31°C, decreasing linearity to 50% RH at 40°C
2.13	Motion Type	Orbital or Reciprocating motion selectable
2.14	Exterior Dimensions	User to specify
2.15	Power Consumption	Vendor to specify
3.0	Material of Construction	
3.1	Body Construction	GI Powder coated
3.2	Clamps and platform	SS304
4.0	Specific Equipment requirement	
4.1	High temperature setting limit and open door alarm.	
4.2	High-velocity fan shall be provided for uniform temperature distribution and rapid thermal recovery.	
4.3	Adjustable 3-step fan speed shall be provided for defrosting time and period control.	
4.4	RS-232 interface shall be provided.	
4.5	Microprocessor controller shall be provided.	
4.6	Touch sensitive key pad shall be provided for setting the process parameters.	
4.7	All necessary accessories shall be provide.	
5.0	Other requirements	
5.1	NA	
6.0	Regulatory aspects	
6.1	GLP and cGMP guidelines	
7.0	Safety requirements	
7.1	Heat given out of the equipment should be stated.	
8.0	Documents	
8.1	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	
8.2	IOQ Protocol.	
8.3	Operation and maintenance manuals.	
8.4	Vendor should provide warranty Letter for Minimum 1 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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8.7	Vendor should provide list of make with certificate.
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10.0	Timelines
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10.1	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	09-09-2015	MGGP	PULM	<input type="checkbox"/>	<input type="checkbox"/>	
Rev	Date	Completed By	Checked By	AFI	AFO	Sheet 1/2

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Annexure: 1

Equipment ID	Block Name	Quantity	Room Name	Room No	Room dimension in mm	Room height in mm
B1-ICS-01	Diphtheria Block	1	Seed Preparation	B1G047	3000 x 6510	3000
B1-ICS-01	Pertussis Block	1	Seed Preparation	B1G008	300 x 6510	3000

	AFI Approved for Enquiry		AFO Approved for Ordering			Sheet 2/2
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