

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>
	Water bath		
	Project #	110831	
	Document #	DS-WBH 01	
<b>1</b>	<b>Equipment ID, and Process requirements</b>		
	<b>Equipment ID</b>	<b>Process requirements</b>	
1.1	B1-WBH 01	The Water bath shall be used for the incubation of various samples under controlled temperature	
1.2	B1-WBH 02		
1.3	B2-WBH 01		
1.4	M1-WBH 01		
1.5	A1-WBH 01		
<b>2</b>	<b>Technical Specification</b>		
2.1	Model	cGMP model	
2.2	Type	Stationary	
2.3	Heating capacity(kW)	Vendor to specify	
2.4	Inner chamber size(LxWxH)	50 cm x 23 cm x 15 cm (upto platform) and 6 cm from platform to bottom (Near to standard size)	
2.5	Capacity	17.5 L or (Near to standard)	
2.6	View class size(LxH)	45 cm x 13 cm	
2.7	External dimension(LxWxH)	Vendor to specify	
2.8	Temperature controlling mechanism	Microprocessor based PID temperature controller	
2.9	Expected operational hours per day	24 hrs	
2.10	Display	LED display for temperature	
2.11	Working temperature range	Ambient temperature +5 °C to 100°C	
2.12	Temperature stability	±0.2 °C	
2.13	Temperature Uniformity	±0.1°C	
2.14	Resolution	±0.1°C	
2.15	Temperature selection	Digital Microprocessor controller (soft touch)	
2.16	Quantity	5 No's	
2.17	<b>Utility</b>		
2.18	Electrical requirement	Vendor to specify	
<b>3</b>	<b>Material of Construction</b>		
3.1	Inner chamber	SS 304 mirror finish	
3.2	Exterior chamber	cGMP compliant exterior	
3.3	Heating element	Stainless Steel	
3.4	Lid or top cover	cGMP compliant material preferably transparent	
3.5	Perforated tray	Stainless Steel	
3.6	Racks for test tubes	Stainless Steel	
<b>4</b>	<b>Specific Equipment requirement</b>		
4.1	Should be cGMP Compliant		
4.2	Seamless, splash proof key pad with characteristic symbols should be provided for easy operation.		
4.3	Audible and optical alarms are required for protecting from dry-running condition.		
4.4	Warning measures ( audio visual alarm) for deviation of temperature to ±0.5 °C from set point.		

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4.5	Drain should be provided for the ease of emptying the bath.					
4.6	All parts in contact with water should be made of SS 304.					
4.7	Minimum and Maximum Fill level should be clearly indicated by a marking on the inner surface of the bath.					
4.8	The lid should be designed in such a way that the dropping back of the condensate into the test tubes/containers should be avoided.					
4.9	The water bath outer surface should not have any sharp corners.					
4.10	Equipment design should facilitate efficient and easy cleaning.					
<b>5</b>	<b>Other requirements</b>					
5.1	The equipment must be portable					
5.2	A training for the users must be provided.					
<b>6</b>	<b>Regulatory aspects</b>					
6.1	CE					
<b>7</b>	<b>Safety requirements</b>					
7.1	<b>Following facilities must be provided to protect personnel and equipment:</b>					
7.2	Appropriate closure of all parts.					
7.3	Proper earthing is required					
7.4	Water bath should be insulated to avoid dissipation of heat to external surface.					
<b>8</b>	<b>Documents</b>					
	<b>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</b>					
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					
<b>9</b>	<b>Timelines</b>					
	Not Applicable					
	<b>NOTE:</b> Accurate size and technical specification need to be mentioned by the vendor					
	AFI Approved for Enquiry			AFO Approved for Ordering		
01	2015-10-07	NRU	PULM	<input type="checkbox"/>	<input type="checkbox"/>	
Rev	Date	Completed By	Checked By	AFI	AFO	Sheet 1 / 1

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**TABLE NO: 1**

<b>EQUIPMENT ID</b>	<b>Block Name</b>	<b>Room Name</b>	<b>Room No</b>	<b>Room dimension in mm</b>	<b>Room height in mm</b>
B1-WBH 01	Diphtheria Bulk	IPQC	B1G057	2200 x 3310	3000
B1-WBH 02	Pertussis Bulk	IPQC	B1G018	2200 x 3310	3000
B2-WBH 01	Tetanus Bulk	IPQC	B2G026	3200 x 5335	3000
M1-WBH 01	Sterility Media Preparation and Microbiology	Lab	M1G039	3020 x 5050	3000
A1-WBH 01	Animal Breeding	Animal health monitor	A1G012	2300 x 6350	2700

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