

DATA SHEET

HLL BIOTECH LIMITED, CHENNAI

	REVIVAL OF DPT VACCINE MANUFACTURING FACILITY, PII, COONOR		 HLL BIOTECH LIMITED <small>(Subsidiary of HLL Lifecare Limited) (A Government of India Enterprise)</small>
	Inspissator		
	Project #	110831	
	Document #	DS-INP 01	

1) Equipment ID and Process requirements

1.1	Equipment ID	Process requirements
1.2	B1-INP 01	used to produce culture media for process, which coagulate on heating.
1.3	B1-INP 02	

2) Technical Specification

2.1	Model	cGMP model
2.2	Heating capacity(kW)	Vendor to specify
2.4	External dimension(LxWxH)	Vendor to specify
2.5	Temperature controlling mechanism	Microprocessor based PID temperature controller
2.6	Expected operational hours per day	24 hrs
2.7	Display	LED display for temperature
2.8	Working temperature range	Ambient temperature +5 °C to 100°C
2.9	Temperature stability	±0.1 °C
2.10	Temperature Uniformity	±0.2°C
2.11	Resolution	±0.1°C
2.12	Temperature selection	Digital Microprocessor controller (soft touch)
2.13	Quantity	2 No's
2.14	Utility	
2.15	Electrical requirement	Vendor to specify

3) Material of Construction

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

4) Specific Equipment requirement

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.
4.6	All parts in contact with water should be made of SS 304.
4.7	Digital controller for accurate and reproducible time and temperature setting
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	An insect resistant blanket and quilt are placed over the containers to provide thermal insulation and exclude draughts
4.10	Equipment design should facilitate efficient and easy cleaning.
4.11	Constant level device maintains required liquid level for optimal operation
4.12	Water temperature under the tray is controlled by a digital immersion thermostat for accuracy and reproducibility of set temperature
4.13	Clear 4 digit display - easy to read from a distance for instant reassurance

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	RENEWAL OF DPT VACCINE MANUFACTURING FACILITY, PII, COONOOR		
	TOC Analyser		
	Project No :	110831	
	Equipment ID :	TOC 01	
	Document No :	DS/TOC 01	

7 Safety requirements

- 7.1 Following facilities must be provided to protect personnel and equipment:
- 7.2 Emergency stop function on accessible area.
- 7.3 Alarming sensors should be provided.
- 7.4 The heat given off by the unit must be stated.
- 7.5 Arrangement of alternative power supply (UPS) to control and monitoring system.

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

Not Applicable

AFI Approved for Enquiry		AFO Approved for Ordering			
	<i>[Signature]</i>	<i>[Signature]</i>			
01	09-09-2015	NRU	PULM	<input type="checkbox"/>	<input type="checkbox"/>
Rev	Date	Completed By	Checked By	AFI	AFO

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5 Other requirements

5.1 The equipment must be portable

5.2 A training for the users must be provided.

6 Regulatory aspects

6.1 CE

7 Safety requirements

7.1 **Following facilities must be provided to protect personnel and equipment:**

7.2 Appropriate closure of all parts.

7.3 Proper earthing is required

7.4 It should be insulated to avoid dissipation of heat to external surface.

8 Documents

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8.1 IOQ Protocol.

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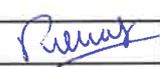
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9 Timelines

Not Applicable

NOTE: Accurate size and technical specification need to be mentioned by the vendor

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TABLE NO: 1

EQUIPMENT ID	Block Name	Room Name	Room No	Room dimension in mm	Room height in mm
B1-INP 01	Diphtheria Bulk	Seed Preparation	B1G047	3500 x 6510	3000
B1-INP 02	Pertussis Bulk	Seed preparation	B1G008	3500 x 6510	3000

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